GLOBAL OFFERING

zai Lab

ZAI LAB LIMITED

(incorporated in the Cayman Islands with limited liability)

Stock Code : 9688

Joint Sponsors, Joint Global Coordinators, Joint Bookrunners and Joint Lead Managers

J.P.Morgan

Goldman Sachs

citi

Joint Global Coordinator, Joint Bookrunner and Joint Lead Manager

Jefferies

Joint Bookrunners and Joint Lead Managers

BofA SECURITIES

CREDIT SUISSE

CICC 中金公司

海通國際 HAITONG

IMPORTANT: If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice.

Zai Lab Limited
再鼎醫藥有限公司*

(Incorporated in the Cayman Islands with limited liability)

Global Offering

Number of Offer Shares under the Global Offering	**:**	**10,564,050 Shares (subject to the Over-allotment Option)**
Number of Hong Kong Offer Shares	**:**	**771,700 Shares (subject to adjustment)**
Number of International Offer Shares	**:**	**9,792,350 Shares (subject to adjustment and the Over-allotment Option)**
Maximum Offer Price	**:**	**HK$648.00, plus brokerage of 1%, SFC transaction levy of 0.0027% and Stock Exchange trading fee of 0.005% (payable in full on application in Hong Kong dollars and subject to refund)**
Nominal value	**:**	**US$0.00006 per Share**
Stock code	**:**	**9688**

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Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited, and Hong Kong Securities Clearing Company Limited take no responsibility for the contents of this prospectus, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this prospectus.

A copy of this prospectus, having attached thereto the documents specified in "Documents Delivered to the Registrar of Companies and Available for Inspection" in Appendix V, has been registered by the Registrar of Companies in Hong Kong as required by Section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong). The Securities and Futures Commission of Hong Kong and the Registrar of Companies in Hong Kong take no responsibility for the contents of this prospectus or any of the other documents referred to above.

We expect to determine the pricing of the Offer Shares by agreement with the Joint Representatives (for themselves and on behalf of the Underwriters) on or about September 22, 2020 and, in any event, not later than September 25, 2020. The Public Offer Price will be not more than HK$648.00 per Offer Share, unless otherwise announced. If, for any reason, we do not agree with the Joint Representatives (for themselves and on behalf of the Underwriters) on the pricing of the Offer Shares by September 25, 2020, the Global Offering will not proceed and will lapse.

We may set the International Offer Price at a level higher than the maximum Public Offer Price if, (a) the Hong Kong dollar equivalent of the closing trading price of the ADSs on Nasdaq on the last trading day on or before the Price Determination Date (on a per-Share converted basis) were to exceed the maximum Public Offer Price as stated in this prospectus; and/or (b) we believe that it is in the best interests of our Company as a listed company to set the International Offer Price at a level higher than the maximum Public Offer Price based on the level of interest expressed by professional and institutional investors during the bookbuilding process. If the International Offer Price is set at or lower than the maximum Public Offer Price, the Public Offer Price must be set at such price that is equal to the International Offer Price. Under no circumstance will we set the Public Offer Price above the maximum Public Offer Price as stated in this prospectus or the International Offer Price.

The Joint Representatives (for themselves and on behalf of the Underwriters) may, with our consent, reduce the number of Offer Shares being offered pursuant to the Global Offering at any time on or prior to the morning of the last day for lodging applications under the Hong Kong Public Offering. Further details are set out in the sections headed "Structure of the Global Offering" and "How to Apply for Hong Kong Offer Shares" in this prospectus.

Prior to making an investment decision, prospective investors should carefully consider all of the information set out in this prospectus, including the risk factors set out in "Risk Factors." The obligations of the Hong Kong Underwriters under the Hong Kong Underwriting Agreement are subject to termination by the Joint Representatives (for themselves and on behalf of the Hong Kong Underwriters) if certain events occur prior to 8:00 a.m. on the Listing Date. See "Underwriting – Underwriting Arrangements and Expenses – Hong Kong Public Offering – Grounds for termination" in this prospectus. It is important that you refer to that section for further details.

Our ADSs, each representing one Share, are listed for trading on Nasdaq under the symbol "ZLAB." The reported sale price of the ADSs on Nasdaq on September 14, 2020 was US$77.42 per ADS. In connection with the Global Offering, we have filed a registration statement on Form F-3 and a preliminary prospectus supplement and plan to file a final prospectus supplement with the SEC to register the sale of Shares under the U.S. Securities Act.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Prospective investors should make the decision to invest in our Company only after due and careful consideration.

* *For identification only*

September 17, 2020

IMPORTANT NOTICE TO INVESTORS
FULLY ELECTRONIC APPLICATION PROCESS

We have adopted a fully electronic application process for the Hong Kong Public Offering. We will not provide printed copies of this prospectus or printed copies of any application forms to the public in relation to the Hong Kong Public Offering.

This prospectus is available at the website of the Hong Kong Stock Exchange at www.hkexnews.hk under the "*HKEXnews > New Listings > New Listing Information*" section, and our website at http://www.zailaboratory.com. If you require a printed copy of this prospectus, you may download and print from the website addresses above.

To apply for the Hong Kong Offer Shares, you may:

(1) apply online through the **White Form eIPO** service at **www.eipo.com.hk**;

(2) apply through the **CCASS EIPO** service to electronically cause HKSCC Nominees to apply on your behalf, including by:

  (i) instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf; or

  (ii) (if you are an existing **CCASS Investor Participant**) giving **electronic application instructions** through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System by calling +852 2979 7888 (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input **electronic application instructions** for CCASS Investor Participants through HKSCC's Customer Service Centre at 1/F, One & Two Exchange Square, 8 Connaught Place, Central, Hong Kong by completing an input request.

If you have any question about the application for the Hong Kong Offer Shares, you may call the enquiry hotline of our Hong Kong Share Registrar and **White Form eIPO** Service Provider, Computershare Hong Kong Investor Services Limited, both at +852 2862 8648 on the following dates:

Thursday, September 17, 2020 – 9:00 a.m. to 9:00 p.m.
Friday, September 18, 2020 – 9:00 a.m. to 9:00 p.m.
Saturday, September 19, 2020 – 9:00 a.m. to 6:00 p.m.
Sunday, September 20, 2020 – 9:00 a.m. to 6:00 p.m.
Monday, September 21, 2020 – 9:00 a.m. to 9:00 p.m.
Tuesday, September 22, 2020 – 9:00 a.m. to 12:00 noon

We will not provide any physical channels to accept any application for the Hong Kong Offer Shares by the public. The contents of the electronic version of this prospectus are identical to the printed document as registered with the Registrar of Companies in Hong Kong pursuant to Section 342C of the Companies (WUMP) Ordinance.

If you are an **intermediary**, **broker** or **agent**, please remind your customers, clients or principals, as applicable, that this prospectus is available online at the website addresses above.

Please refer to "How to Apply for Hong Kong Offer Shares" for further details on the procedures through which you can apply for the Hong Kong Offer Shares electronically.

Your application through the **White Form eIPO** service or the **CCASS EIPO** service must be for a minimum of 50 Hong Kong Offer Shares and in one of the numbers set out in the table. You are required to pay the amount next to the number you select.

No. of Hong Kong Offer Shares applied for	Amount payable on application HK$	No. of Hong Kong Offer Shares applied for	Amount payable on application HK$	No. of Hong Kong Offer Shares applied for	Amount payable on application HK$	No. of Hong Kong Offer Shares applied for	Amount payable on application HK$
50	32,726.49	1,000	654,529.90	8,000	5,236,239.17	200,000	130,905,979.20
100	65,452.99	1,500	981,794.84	8,500	5,563,504.12	300,000	196,358,968.80
150	98,179.48	2,000	1,309,059.79	9,000	5,890,769.06	385,850(1)	252,550,360.37
200	130,905.98	2,500	1,636,324.74	9,500	6,218,034.01		
250	163,632.47	3,000	1,963,589.69	10,000	6,545,298.96		
300	196,358.97	3,500	2,290,854.64	20,000	13,090,597.92		
350	229,085.46	4,000	2,618,119.58	30,000	19,635,896.88		
400	261,811.96	4,500	2,945,384.53	40,000	26,181,195.84		
450	294,538.45	5,000	3,272,649.48	50,000	32,726,494.80		
500	327,264.95	5,500	3,599,914.43	60,000	39,271,793.76		
600	392,717.94	6,000	3,927,179.38	70,000	45,817,092.72		
700	458,170.93	6,500	4,254,444.32	80,000	52,362,391.68		
800	523,623.92	7,000	4,581,709.27	90,000	58,907,690.64		
900	589,076.91	7,500	4,908,974.22	100,000	65,452,989.60		

Note:

(1) Maximum number of Hong Kong Offer Shares you may apply for.

No application for any other number of the Hong Kong Offer Shares will be considered and any such application is liable to be rejected.

Hong Kong Public Offering commences . . . . . 9:00 a.m. on Thursday, September 17, 2020

Latest time for completing electronic applications under **White Form eIPO** service through the designated website **www.eipo.com.hk**[2] . . . . . 11:30 a.m. on Tuesday, September 22, 2020

Application lists open[3] . . . . . 11:45 a.m. on Tuesday, September 22, 2020

Latest time for (a) completing payment for **White Form eIPO** applications by effecting internet banking transfer(s) or PPS payment transfer(s) and (b) giving **electronic application instructions** to HKSCC[4] . . . . . 12:00 noon on Tuesday, September 22, 2020

If you are instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, you are advised to contact your **broker** or **custodian** for the latest time for giving such instructions which may be different from the latest time as stated above.

Application lists close[3] . . . . . 12:00 noon on Tuesday, September 22, 2020

Expected Price Determination Date[5] . . . . . Tuesday, September 22, 2020

Announcement of the Public Offer Price and the International Offer Price on our website at **www.zailaboratory.com**[6] and the website of the Hong Kong Stock Exchange at **www.hkexnews.hk** on or around . . . . . Friday, September 25, 2020

Announcement of the level of indications of interest in the International Offering, the level of applications in the Hong Kong Public Offering and the basis of allocation of the Hong Kong Offer Shares on our website at **www.zailaboratory.com** and the website of the Hong Kong Stock Exchange at **www.hkexnews.hk** on or before . . . . . Friday, September 25, 2020

The results of allocations in the Hong Kong Public Offering (with successful applicants' identification document numbers, where appropriate) to be available through a variety of channels, including:

- in the announcement to be posted on our website and the website of the Hong Kong Stock Exchange at **www.zailaboratory.com** and **www.hkexnews.hk**, respectively . . . . . Friday, September 25, 2020

- from the designated results of allocations website at **www.iporesults.com.hk** (alternatively: English **https://www.eipo.com.hk/en/Allotment**; Chinese **https://www.eipo.com.hk/zh-hk/Allotment**) with a "search by ID" function from . . . . . Friday, September 25, 2020 to Thursday, October 1, 2020

- from the allocation results telephone enquiry by calling +852 2862 8555 between 9:00 a.m. and 6:00 p.m. from . . . . . Friday, September 25, 2020 and from Monday, September 28, 2020 to Wednesday, September 30, 2020

Share certificates in respect of wholly or partially successful applications to be dispatched or deposited into CCASS on or before[7][9] . . . . . Friday, September 25, 2020

White Form e-Refund payment instructions/refund checks in respect of wholly or partially successful applications (if applicable) or wholly or partially unsuccessful applications to be dispatched on or around[8][9] . . . . . Friday, September 25, 2020

Dealings in Shares on the Stock Exchange expected to commence at 9:00 a.m. on . . . . . Monday, September 28, 2020

Notes:

(1) All dates and times refer to Hong Kong local dates and time, except as otherwise stated.

(2) You will not be permitted to submit your application through the designated website at **www.eipo.com.hk** after 11:30 a.m. on the last day for submitting applications. If you have already submitted your application and obtained an application reference number from the designated website at or before 11:30 a.m., you will be permitted to continue the application process (by completing payment of application monies) until 12:00 noon on the last day for submitting applications, when the application lists close.

(3) If there is/are a tropical cyclone warning signal number 8 or above, a "black" rainstorm warning and/or Extreme Conditions in force in Hong Kong at any time between 9:00 a.m. and 12:00 noon on Tuesday, September 22, 2020, the application lists will not open or close on that day. See "How to Apply for Hong Kong Offer Shares – Effect of Bad Weather and Extreme Conditions on the Opening and Closing of the Application Lists."

(4) Applicants who apply for Hong Kong Offer Shares by giving electronic application instructions to HKSCC via CCASS or instructing your broker or custodian to apply on your behalf via CCASS should refer to "How to Apply for Hong Kong Offer Shares – Applications for the Hong Kong Offer Shares – Applying through CCASS EIPO service."

(5) The Price Determination Date is expected to be on or around Tuesday, September 22, 2020 and, in any event, not later than Friday, September 25, 2020. If, for any reason, we do not agree with the Joint Representatives (for themselves and on behalf of the Underwriters) on the pricing of the Offer Shares by Friday, September 25, 2020, the Global Offering will not proceed and will lapse.

(6) None of the websites set out in this section or any of the information contained on the websites forms part of this prospectus.

(7) Share certificates will only become valid at 8:00 a.m. on the Listing Date provided that the Global Offering has become unconditional and the right of termination described in "Underwriting – Underwriting Arrangements and Expenses – Hong Kong Public Offering – Grounds for Termination" has not been exercised. Investors who trade Shares on the basis of publicly available allocation details or prior to the receipt of Share certificates or the Share certificates becoming valid do so entirely at their own risk.

(8) e-Refund payment instructions/refund checks will be issued in respect of wholly or partially unsuccessful applications pursuant to the Hong Kong Public Offering and also in respect of wholly or partially successful applications in the event that the final Public Offer Price is less than the price payable per Offer Share on application. Part of the applicant's Hong Kong identity card number or passport number, or, if the application is made by joint applicants, part of the Hong Kong identity card number or passport number of the first-named applicant, provided by the applicant(s) may be printed on the refund check, if any. Such data would also be transferred to a third party for refund purposes. Banks may require verification of an applicant's Hong Kong identity card number or passport number before encashment of the refund check. Inaccurate completion of an applicant's Hong Kong identity card number or passport number may invalidate or delay encashment of the refund check.

(9) Applicants who have applied on White Form eIPO for 300,000 or more Hong Kong Offer Shares may collect any refund checks (where applicable) and/or Share certificates in person from our Hong Kong Share Registrar, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong from 9:00 a.m. to 1:00 p.m. on Friday, September 25, 2020 or such other date as notified by us as the date of dispatch/collection of Share certificates/e-Refund payment instructions/refund checks. Applicants being individuals who are eligible for personal collection may not authorize any other person to collect on their behalf. Individuals must produce evidence of identity acceptable to our Hong Kong Share Registrar at the time of collection.

Applicants who have applied for Hong Kong Offer Shares through CCASS EIPO service should refer to "How to Apply for Hong Kong Offer Shares – Despatch/collection of share certificates/e-refund payment instructions/refund checks – Personal Collection – If you apply through CCASS EIPO service" for details.

Applicants who have applied through the White Form eIPO service and paid their applications monies through single bank accounts may have refund monies (if any) dispatched to the bank account in the form of e-Refund payment instructions. Applicants who have applied through the White Form eIPO service and paid their application monies through multiple bank accounts may have refund monies (if any) dispatched to the address as specified in their application instructions in the form of refund checks by ordinary post at their own risk.

Share certificates and/or refund checks for applicants who have applied for less than 300,000 Hong Kong Offer Shares and any uncollected Share certificates and/or refund checks will be dispatched by ordinary post, at the applicants' risk, to the addresses specified in the relevant applications.

Further information is set out in "How to Apply for Hong Kong Offer Shares – Refund of application monies" and "How to Apply for Hong Kong Offer Shares – Despatch/collection of share certificates/e-refund payment instructions/refund checks."

The above expected timetable is a summary only. For details of the structure of the Global Offering, including its conditions, and the procedures for applications for Hong Kong Offer Shares, please refer to "Structure of the Global Offering" and "How to Apply for Hong Kong Offer Shares," respectively.

If the Global Offering does not become unconditional or is terminated in accordance with its terms, the Global Offering will not proceed. In such a case, we will publish an announcement as soon as practicable thereafter.

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IMPORTANT NOTICE TO INVESTORS

This prospectus is issued by us solely in connection with the Hong Kong Public Offering and the Hong Kong Offer Shares and does not constitute an offer to sell or a solicitation of an offer to buy any security other than the Hong Kong Offer Shares offered by this prospectus pursuant to the Hong Kong Public Offering. This prospectus may not be used for the purpose of making, and does not constitute, an offer or invitation in any other jurisdiction or in any other circumstances. No action has been taken to permit the distribution of this prospectus in any jurisdiction other than Hong Kong. The distribution of this prospectus and the offering of the Offer Shares in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdictions pursuant to registration with or authorization by the relevant securities regulatory authorities or an exemption therefrom.

You should rely only on the information contained in this prospectus to make your investment decision. We have not authorized anyone to provide you with information that is different from what is contained in this prospectus. Any information or representation not made in this prospectus must not be relied on by you as having been authorized by us, the Joint Sponsors, Joint Representatives, Joint Global Coordinators and Joint Bookrunners, the Underwriters, any of our or their respective directors or any other person or party involved in the Global Offering.

CONTENTS

This summary aims to give you an overview of the information contained in this prospectus. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to invest in the Offer Shares. In particular, we are a biotechnology company seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours. In addition, we have incurred significant operating losses since our inception, and we expect to remain loss making in the near term. We had negative net cash flow from operating activities for certain periods during the Track Record Period. We did not declare or pay any dividends during the Track Record Period and do not intend to pay any dividends in the near future. Your investment decision should be made in light of these considerations.

There are risks associated with any investment. Some of the particular risks in investing in the Offer Shares are set out in the section headed "Risk Factors" in this prospectus. You should read that section carefully before you decide to invest in the Offer Shares.

OVERVIEW

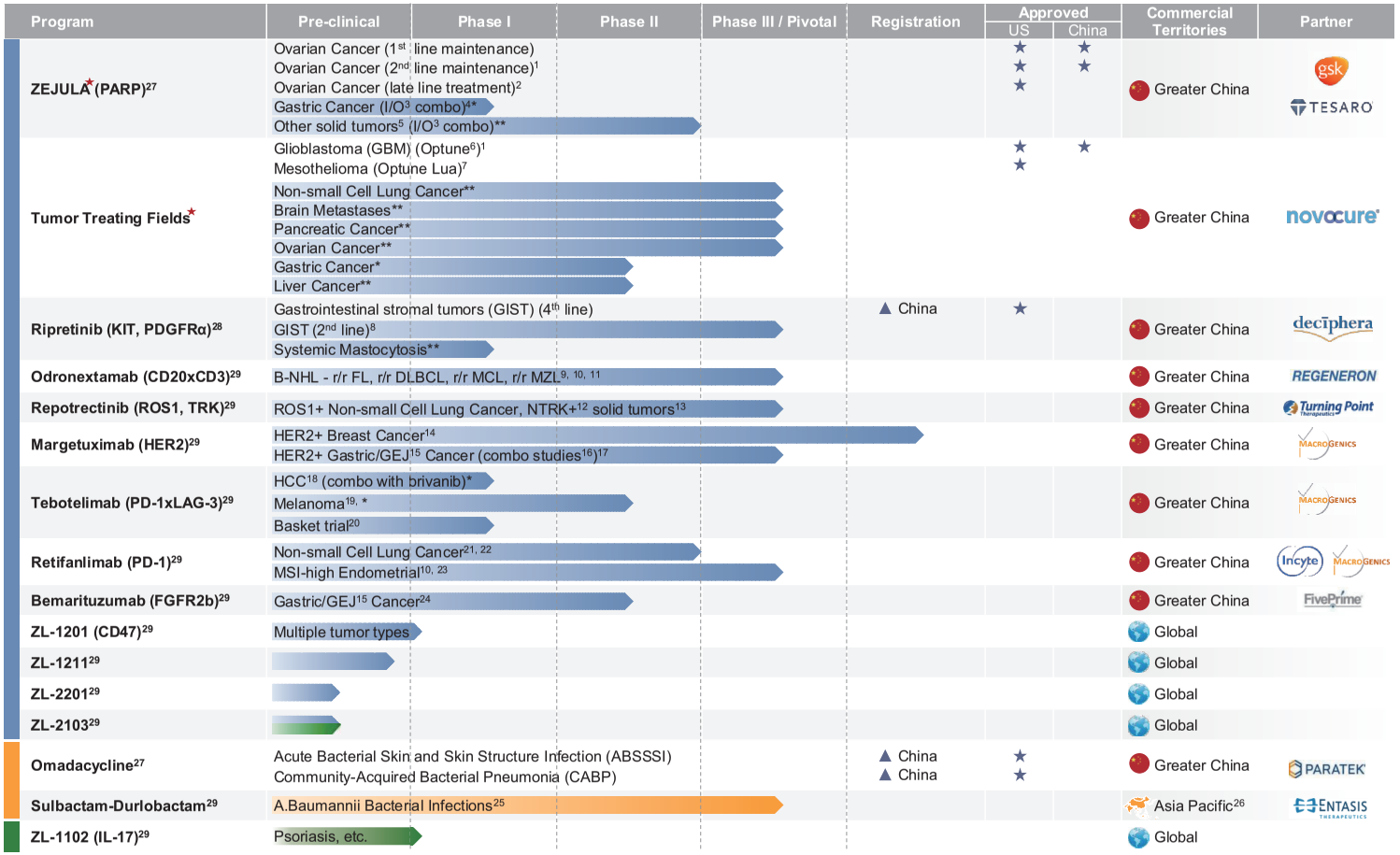
We are an innovative, research-based, commercial-stage biopharmaceutical company with a focus on discovering, licensing, developing and commercializing therapies that address areas of large unmet medical need in the China and global markets, including the fields of oncology, infectious and autoimmune diseases. By effectively executing our plan and closely following our strategy, we have built an integrated platform to bring both in-licensed and internally-discovered novel therapeutics to patients globally. We believe we are one of the first biopharmaceutical companies in China to scale, allowing us to further capitalize on the latest innovation and business opportunities globally.

Since our inception, we have executed our strategic approach of in-licensing promising biopharmaceutical products via global collaboration and investing in internal discovery and development efforts. Our robust portfolio consists of 16 products and drug candidates, including two commercialized products in China, Hong Kong and Macau and seven assets in pivotal or potentially registration-enabling trials in oncology and infectious diseases, which are therapeutic areas with large unmet needs and lack of innovative treatment options in Greater China. Although we have limited experience in manufacturing and commercializing our products and drug candidates, we are nevertheless at the inflection point of commercialization with recent launches of ZEJULA and Optune (Tumor Treating Fields) in multiple regions, empowered by our commercialization team with heritage from top-selling MNCs and innovative oncology brands. We believe that we remain the trusted partner in our areas of focus

for the biopharmaceutical industry as we provide a differentiated approach for our collaborators to achieve success while also conducting timely trials and achieving eventual commercialization of promising therapies, accelerating access to the large patient population.

We founded Zai Lab with the intent to build a highly differentiated biopharmaceutical company delivering transformative therapies to patients. We have assembled a leadership team of industry veterans with global experience in the biopharmaceutical sector who have been at the frontier of framing the Chinese biopharma industry for more than two decades. Led by our experienced management team, we have developed into a leading biopharmaceutical company with products approved in Greater China, broad pipeline with differentiated innovative assets from collaboration and in-house development and state-of-art capabilities across research and development, clinical development and commercialization.

We have assembled a deep, clinically-validated and innovative portfolio through collaborations and partnerships with global biopharmaceutical companies as well as in-house discovery and development, targeting large markets and characterized by high unmet medical need. We believe our product portfolio is one of the most robust and differentiated portfolios in the biopharmaceutical sector in China with therapeutics that aim to treat serious diseases such as gynecologic cancer, gastric cancer, brain cancer, lung cancer and multidrug-resistant bacterial infections. The following table summarizes the global development status of our portfolio of commercialized products and drug candidates and programs.



Note:★denotes our core product; * denotes China-only trials; ** Greater China trial in preparation or under planning
(1) Also launched in Hong Kong and Macau; (2) Bridging study initiated in China; (3) Immuno-oncology; (4) Phase Ib proof-of-concept combo trial with tebotelimab; (5) Including non-small cell lung cancer; (6) Class III medical device by NMPA; (7) Under preparation for MAA submission in China; (8) Bridging trial application approved in China; (9) B-NHL, B-cell non-Hodgkin lymphoma; r/r, relapsed or refractory; FL, follicular lymphoma; DLBCL, diffuse large B-cell lymphoma; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; (10) Global potentially registration-enabling trial; (11) Phase II pivotal trial application submitted in China; (12) Neurotrophic tropomyosin receptor kinase; (13) Phase II registrational trial application submitted in China; (14) Bridging study initiated in Greater China; (15) Gastroesophageal junction cancer; (16) Global Phase II/III study and registration path in first-line gastric & GEJ cancer; combo with retifanlimab and tebotelimab, respectively; (17) Phase II/III trial application approved in Greater China; (18) Hepatocellular Carcinoma; Phase I proof-of-concept trial; (19) Phase II proof-of-concept trial; (20) Phase I trial application approved in Greater China; (21) Global Phase III study in preparation; (22) Phase III trial application approved in China; (23) Phase II trial application accepted in China; (24) Phase II trial initiated in Greater China; (25) Phase III trial initiated in Greater China; (26) Including China, Hong Kong, Macau, Taiwan, South Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan; (27) Class 1 drug by NMPA; (28) Class 5.1 drug by NMPA; (29) The drug class will be designated upon the NDA submission.

For detailed discussion of our commercial products and drug candidates, please see "Business."

Our team has successfully advanced each of the programs above on timelines that have met or exceeded our expectations. For example, it took us less than three years from ZEJULA's FDA approval to commercial launch in China. It took us less than three months from obtaining the exclusive license for Optune to commercial launch in Hong Kong, and an additional 20 months further to commercial launch in China, without the need of a clinical trial. In less than six years since our founding, we have successfully transformed into a fully-integrated commercial enterprise. Beyond ZEJULA and Optune, we have submitted two NDAs with respect to omadacycline and ripretinib, respectively, which are under priority review. See "Business – Research and Development – Highlights of Our Research Efforts" for detailed discussion. On September 8, 2020, the NMPA also approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

To implement on our commercialization strategy, we have built our own commercial team to execute the successful launches of ZEJULA and Optune in China, Hong Kong and Macau. We launched ZEJULA in China in January 2020, and as of August 31, 2020, ZEJULA has been successfully enrolled into the regional reimbursement program that complements China's basic medical insurance scheme in one province and six cities. As of August 31, 2020, ZEJULA has also been listed in 17 commercial health insurances and 12 supplemental insurances guided by municipal governments (城市定制險); in addition, since we launched Optune in China in June 2020, Optune has been listed in four supplemental insurances guided by provincial or municipal governments, as of August 31, 2020, both of which underscores our execution capability in bringing important therapies to patients.

In addition to our development stage products, we have seen similar success in building comprehensive in-house research and development capabilities in China and the U.S. We have assembled an integrated drug discovery and development team with nearly 400 dedicated personnel who have extensive experience from discovery, translational medicine to late stage development and have been directly involved in the discovery and development of several innovative drug candidates. Through these efforts over the past few years, we have advanced two of our in-house discovery candidates, namely ZL-1102 and ZL-1201, with global intellectual property into global clinical development and we plan to have multiple innovative and differentiated assets move into the clinical development over the next few years. We believe our discovery initiatives along with our collaborations with leading academic institutions will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new products and drug candidates for patients around the world.

To supplement our discovery, research and development and commercialization efforts, we have also efficiently established both large and small molecule drug manufacturing capabilities, capable of supporting clinical and commercial production of our drug candidates. These facilities would allow us to produce both large and small molecule therapeutics under global standards, such as current good manufacturing practices, or cGMP. Our small molecule manufacturing facility supports the commercial production of ZEJULA. The production capacity of our small molecule manufacturing facility is up to 50 million units per year for both commercial oral tablets and capsules. During the Track Record Period, less than 10 percent of the total production capacity of our small molecule manufacturing facility was utilized. Our large molecule manufacturing facility supports the clinical production of ZL-1201. The annual production capacity of our large molecule manufacturing capacity is up to 12 to 18 200L or 1000L clinical batches, respectively. During the Track Record Period, approximately 40% of the production capacity of our large molecule manufacturing facility was utilized. We intend to expand our manufacturing capacity in a manner that will provide us with tangible and intangible benefits, including cost advantages, better control over quality and enhanced compliance capabilities and better ability to plan logistics for commercialization of drug candidates.

We aim to stay at the forefront of innovation in our industry by quickly and efficiently adopting technologies to further enhance our capabilities across research and development, manufacturing and commercialization. Together with our unique and strengthening platform and commitment to global standards, we believe we will contribute significantly to the improvement of the well-being of the patients globally.

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors:

- Proprietary platform committed to bring innovative therapies to patients
- Highly differentiated and validated portfolio of assets with significant commercial opportunities
- Established disease area strongholds within oncology driving scale and operational synergies
- Distinguished world-class leadership team and deep talent pool
- Proven institutionalized execution capabilities and track record of success
- Fully-integrated global biopharmaceutical platform with end-to-end capabilities

OUR STRATEGIES

Since our inception in 2013, our mission has been to leverage our expertise and insight to address the increasing needs of patients in China and to utilize our China-based competencies to improve the lives of patients worldwide. To achieve our mission, we intend to capitalize on our strengths to pursue the following strategies:

- Rapidly ramp up the sales of our commercialized products and establish a strong commercial presence in Greater China
- Further expand our drug pipeline through our proprietary platform
- Seek expedited approval on our late-stage clinical assets and advance other clinical or IND stage candidates through development stages
- Enhance our internal research platform and discovery efforts
- Efficiently grow our world-class organization and invest in our capabilities to support our global aspirations

OUR PLATFORM

We pursue a strategy that consists of both in-licensing and in-house research development. We primarily adopt an in-licensing business model for our products and late-stage drug candidates where we in-license promising biopharmaceutical products via global collaboration. While we intend to expand our pipeline through both in-licensing and internal research and discovery efforts, we expect to primarily rely on in-licensing to seek drug candidates with demonstrated promising data in clinical studies in the short-to-medium term. As part of the global collaboration with our business partners, we participate in our business partners' global clinical studies by joining in the clinical studies in China, with us taking the operational lead by conducting the screening, enrollment and treatment of patients and coordinating development, registration and commercialization in the specified territories. We are generally responsible for financial costs associated with the clinical studies conducted by us in the territories we have the rights for. We believe that the execution capabilities of our management team, our scale of operation and unique resources, our commitment to excellence as well as our accumulated knowledge base and insights into the pharmaceutical industry, clinical development pathway and regulatory system in China have enabled us to institutionalize strong execution capabilities across our organization. We, however, have limited experience in manufacturing and commercializing our products and drug candidates. See "Risk Factors – We have limited experience manufacturing our products and drug candidates on a large clinical or commercial scale. We are or will be dependent on third party manufacturers for the manufacture of certain of our products and drug candidates as well as on third parties for our supply chain, and if any of these third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices, our business could be harmed." For details of our products and late stage product candidates, including our business partners where we in-licensed relevant patents from and our clinical development plan, please see "Business – Research and Development – Highlights of Our Research Efforts."

OUR INNOVATIVENESS

We believe our success is attributable to strong innovations in our broad and validated pipeline with treatment options as well as our R&D capability in innovative drugs treating oncology, infectious and autoimmune diseases. Our highly differentiated innovative portfolio consists of 16 products and drug candidates, including two commercialized products in China, Hong Kong and Macau and seven assets in pivotal or potentially registration-enabling trials. In particular, the commercial launch of ZEJULA, one of our Core Products, in Greater China has demonstrated our commitment to bringing global innovative therapies to patients and differentiated us from existing players in the market.

ZEJULA is a potentially global best-in-class PARP inhibitor for ovarian cancer based on its clinical data to date, once-daily dosing and PK properties, and is currently the only PARP inhibitor to have received a broad approval by FDA to treat all advanced ovarian cancer patients regardless of biomarker status as a monotherapy in both first-line and recurrent maintenance treatment settings. ZEJULA was also recommended in the NCCN Clinical Practice Guidelines in Oncology as monotherapy for first-line maintenance treatment for women with ovarian cancer. We licensed ZEJULA from Tesaro (now GSK) in September 2016

and have since successfully commercialized ZEJULA in Hong Kong, Macau and China. Upon obtaining the exclusive license to develop and commercialize ZEJULA in Greater China, we conducted the NORA trial in Chinese patients with platinum-sensitive recurrent ovarian cancer. The NORA trial was the first fully powered, randomized, controlled (RCT) Phase III trial ever done in ovarian cancer in China. In December 2019, ZEJULA was approved by the NMPA as a Category 1 maintenance therapy for adult patients with platinum-sensitive recurrent ovarian cancer, which made ZEJULA the first and so far only Category 1 PARP inhibitor approved in China. In 2019, ZEJULA was designated as a "National Science and Technology Major Project" by the Chinese government as part of a key initiative to strengthen local innovation. In addition, ZEJULA was recommended as a monotherapy first-line maintenance treatment for women with platinum-responsive advanced ovarian cancer in the Ovarian Cancer PARP Inhibitor Clinical Guidelines (卵巢癌PARP抑制劑臨床應用指南) published by Gynecological Oncology, Chinese Medical Association (中華醫學會婦科腫瘤學分會) in May 2020. On September 8, 2020, the NMPA also approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

OVERVIEW OF OUR BUSINESS COLLABORATION

As of the Latest Practicable Date, we had 12 active in-licensed clinical drug candidates for development in China, Hong Kong, Macau and, in certain instances, Taiwan, Australia, New Zealand and other countries throughout the Asia Pacific region, through partnerships with GSK, BMS, Paratek, Five Prime, Entasis, Novocure, MacroGenics, Deciphera, Incyte, Regeneron and Turning Point. As of the Latest Practicable Date, all of our business partners are independent from us and our affiliates. We discuss and negotiate each license and/or collaboration arrangement on a case-by-case basis; therefore, the terms under each arrangement are customized. However, based on our understanding on the industry, and according to Frost & Sullivan, we also believe the overall arrangement under our collaboration agreements is consistent with general industry norms for similar kinds of products. Please see "Business" for detailed discussion on our products and late-stage clinical drug candidates and collaboration with our business partners. For the risks associated with the protection of intellectual property rights under the license and sub-license arrangements, please also refer to "Risk Factors – We depend on our licensors or patent owners of our in-licensed patent rights to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations."

Set forth below is a summary of the commercial arrangements between our business partners and us. For further details, please refer to the section headed "Business – Overview of Our License and Strategic Collaboration Agreements" in this prospectus.

GSK

In September 2016, we entered into a collaboration, development and license agreement with Tesaro (now GSK) to develop, manufacture, use, sell, import and commercialize ZEJULA in China, Hong Kong and Macau for treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). Janssen Biotech, Inc. entered a worldwide collaboration and license agreement with Tesaro (GSK) for exclusive rights to the investigational compound niraparib (ZEJULA) in prostate cancer in April 2016 before we entered the license agreement with Tesaro (GSK). We have the right of first negotiation to obtain a license to develop and commercialize certain follow-on compounds of ZEJULA and have agreed not to research, develop or commercialize certain competing products. Under this agreement, we are required to pay milestone payments and tiered royalties on net sales of the licensed product to GSK. This agreement will remain in effect until the expiration of our applicable royalty payment obligations. Either party may terminate the agreement for the other party's uncured material breach bankruptcy or insolvency or by mutual agreement of the parties.

Novocure

In September 2018, we entered into a license and collaboration agreement with Novocure to perform clinical studies, sublicensable to affiliates and third parties, sell, offer for sale and import Tumor Treating Fields products in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay milestone payments and tiered royalties on the net sales of Tumor Treating Fields products. This agreement will be in effect until the expiration of and payment by us of all of our applicable royalty payment obligations. Each party may terminate the agreement upon the material breach of the agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Deciphera

In June 2019, we entered into a license agreement with Deciphera to obtain the rights to perform clinical studies, sublicenseable to affiliates, sell, offer for sale and import ripretinib for the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay upfront license fee, milestone payments and tiered royalties on the net sales of ripretinib. This agreement will be in effect until the expiration of and payment by us of all of our applicable royalty payment obligations. Each party may terminate the agreement upon the material breach of a material term of the agreement by the other party. We may terminate the agreement for convenience upon prior notice.

Regeneron

In April 2020, we entered into a strategic collaboration with Regeneron, a company independent from us and our affiliates, for the development and exclusive commercialization of odronextamab in oncology in mainland China, Hong Kong, Taiwan and Macau, or the territory. Under this agreement, we agreed to pay upfront fee, milestone payments and royalties based on a percentage of net sales of odronextamab. This agreement will be in effect, unless terminated earlier, until we have ceased development and commercialization activities on odronextamab for six consecutive months.

Turning Point

In July 2020, we entered into an exclusive license agreement with Turning Point to obtain the rights to develop and commercialize products containing repotrectinib in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay Turning Point an upfront license fee, milestone payments and royalties based on net sales of repotrectinib. This agreement will be in effect until the expiration of and payment by us of our applicable royalty payment obligations and certain expiration conditions. Either party may terminate the agreement for the other party's uncured material breach of the agreement. We may terminate the agreement for convenience upon advance notice.

MacroGenics

In November 2018, we entered into a collaboration agreement with MacroGenics to obtain regional development and commercialization rights to margetuximab, tebotelimab and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay upfront license fee, milestone payments and royalties based on net sales of margetuximab, tebotelimab and TRIDENT molecule. This agreement will be in effect until the expiration of and payment by us of all of our applicable royalty payment obligations. Either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Incyte

In July 2019, we entered into a collaboration and license agreement with Incyte to obtain the exclusive rights to perform clinical studies, sublicenseable to affiliates, sell, offer for sale and import retifanlimab (PD-1) in humans in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay upfront license fee, milestone payments and royalties based on the net sales of retifanlimab (PD-1). This agreement will be in effect until the expiration of and payment by us of all our applicable royalty payment obligations. Either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Five Prime

In December 2017, we entered into a license and collaboration agreement with Five Prime, a company independent from us and our affiliates, under which we obtained exclusive rights to develop and commercialize bemarituzumab (FPA144) in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay upfront license fee, milestone payments and royalties based on net sales of bemarituzumab (FPA144). This agreement will be in effect until the expiration of and payment by us of all of our applicable royalty payment obligations. Either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Paratek

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda Ltd., a company independent from us and our affiliates, under which we obtained exclusive rights to develop, manufacture, use, sell, import and commercialize omadacycline (ZL-2401) in China, Hong Kong, Macau and Taiwan. Under this agreement, we agreed to pay upfront license fee, milestone payments and royalties based on net sales of omadacycline (ZL-2401). This agreement will be in effect until the expiration of and payment by us of all of our applicable royalty payment obligations. Either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Entasis

In April 2018, we entered into a collaboration and license agreement with Entasis, a company independent from us and our affiliates, under which we obtained exclusive rights to develop and commercialize durlobactam with the possibility of developing and commercializing a combination of such compounds with Imipenem, in China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan. Under this agreement, we agreed to pay upfront payment, milestone payments and royalties based on the net sales of durlobactam. This agreement will be in effect until the expiration of and payment by us of all of our applicable royalty payment obligations. Either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Bristol-Myers Squibb

In March 2015, we entered into a license agreement with Bristol-Myers Squibb under which we obtained exclusive rights to develop, manufacture, use, sell, import and commercialize brivanib, in China, Hong Kong and Macau with the exclusive right to expand our licensed territory to include Taiwan and Korea under certain conditions. Under this agreement, we agreed to pay Bristol-Myers Squibb milestone payments and royalties based on the net sales of brivanib. This agreement will be in effect until the expiration of all payment obligations. Either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party. We may terminate the agreement for convenience upon advance notice.

Our Manufacturing

We currently operate two manufacturing facilities in Suzhou, China, which support clinical and commercialized production of certain of our products and drug candidates, including ZEJULA, one of our Core Products. We do not manufacture Optune, one of our Core Products; instead, we source Optune from our licensor, Novocure. In early 2017, we built a cGMP-compliant small molecule facility in Suzhou capable of supporting clinical and commercialized production. In 2018, we completed construction of a large molecule facility in Suzhou using GE Healthcare FlexFactory platform technology capable of supporting the clinical production of our drug candidates. We are investing in the expansion of the manufacturing site to anticipate the increased sales of our current commercialized products and the launch of our clinical drug candidates. We believe that possessing manufacturing and commercialization capabilities presents benefits, which include maintaining better control over the quality and compliance of our operations with increasingly stringent industry regulations. As of the Latest Practicable Date, our manufacturing team consisted of 60 employees. For detailed discussion, please see "Business – Manufacturing."

Our Commericialization

As we believe the scale and sophistication of our commercial operation are crucial to our business, we have invested, and will continue to invest, substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of the sales of our commercialized products. We successfully launched ZEJULA in Hong Kong in the fourth quarter of 2018 and achieved over majority market share in the PARP inhibitor category with in terms of sales in 2019. Leveraging the valuable marketing experience and strong physician endorsement we accumulated from the successful commercial launch of ZEJULA, we launched Optune in Hong Kong in December 2018. As of the Latest Practicable Date, we have commercialized ZEJULA in Hong Kong, Macau and China, and Optune in Hong Kong and China. We believe our initial commercial success in Hong Kong allows us to establish our commercial presence in Greater China.

As of the Latest Practicable Date, our commercialization team consisted of 401 sales and marketing staff, covering major medical centers across Greater China. Our commercialization team has a proven track record and experience from top-selling oncology multinational pharmaceutical companies including AstraZeneca, Roche, Novartis and BMS in China. In anticipation of the increased market demand for ZEJULA and Optune in China, and more late-stage drug candidates becoming available for sale, if approved, we plan to further expand our sales and marketing force in the next few years to scale up the precedence of our ZEJULA and Optune in China and ramp up the sales of our commercialized products in the target markets. For detailed discussion, please see "Business – Sales and Marketing – Commercialization."

OUR MAJOR SHAREHOLDERS

QM11 Limited beneficially owned approximately 12.0% of our issued share capital as of the Latest Practicable Date, and is our single largest shareholder. Immediately following the completion of the Global Offering, QM11 Limited will continue to be our single largest shareholder.

As of the Latest Practicable Date, Samantha Du, our founder, Chairwoman and Chief Executive Officer, beneficially owned approximately 7.8% of our Shares, and our directors and executive officers beneficially owned approximately 9.6% of our Shares in aggregate.

SUMMARY OF FINANCIAL INFORMATION

The following tables set forth a summary our financial information for the two years ended December 31, 2018 and 2019 and six months ended June 30, 2020 and should be read in conjunction with our financial information included in the Accountants' Report set out in Appendix I to this prospectus, including the notes thereto. Our consolidated financial statements are prepared and presented in accordance with US GAAP. The basis of preparation is set forth in Note 2(a) included in the Accountants' Report set out in Appendix I to this prospectus.

Selected Consolidated Statements of Operations

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
			(Unaudited)	
	(US dollars in thousands, except share and per share data)			
Comprehensive Loss Data:				
Revenue	129	12,985	3,420	19,213
Expenses:				
Cost of sales	(43)	(3,749)	(882)	(4,980)
Research and development	(120,278)	(142,221)	(58,928)	(102,049)
Selling, general and administrative	(21,576)	(70,211)	(29,489)	(42,472)
Loss from operations	(141,768)	(203,196)	(85,879)	(130,288)
Interest income	3,261	8,232	3,365	2,882
Interest expense	(40)	(293)	(137)	(114)
Other income (expense), net	59	938	(307)	(691)
Loss before income tax and share of loss from equity method investment	(138,488)	(194,319)	(82,958)	(128,211)
Income tax expenses	–	–	–	–
Share of loss from equity method investment	(587)	(752)	(316)	(406)
Net loss attributable to ordinary shareholders	(139,075)	(195,071)	(83,274)	(128,617)
Weighted-average shares used in calculating net loss	52,609,810	64,369,490	60,919,842	73,847,551
Net loss per share, basic and diluted	(2.64)	(3.03)	(1.37)	(1.74)

We started to generate revenue from sales of our commercialized products since 2018. In 2018, our revenue was primarily generated from the sales of ZEJULA in Hong Kong. In 2019, our revenue was primarily generated from the sales of ZEJULA and Optune in Hong Kong. In the six months ended June 30, 2020, we generated revenue primarily from the sales of both ZEJULA and Optune in Hong Kong and China.

We have incurred losses since our inception in 2013. For the years ended December 31, 2018 and 2019 and for the six months ended June 30, 2020, we reported a net loss of US$139.1 million, US$195.1 million and US$128.6 million, respectively. Our net losses mainly resulted from research and development expenses, selling, general and administrative expenses and cost of sales. For further information, please see detailed discussion in "Financial Information."

Consolidated balance sheets

	As of		
	December 31, 2018	**December 31, 2019**	**June 30, 2020**
	(US dollars in thousands, except share data)		
Assets			
Current assets:			
Cash and cash equivalents	62,952	75,932	258,604
Short-term investments	200,350	200,000	205,000
Accounts receivable (net of allowance of nil, nil and $2 as of Dec 31, 2018 and 2019 and June 30, 2020)	90	3,791	7,024
Inventories	4	6,005	6,569
Prepayments and other current assets	5,749	6,736	7,684
Total current assets	269,145	292,464	484,881
Restricted cash, non-current	—	510	510
Investments in equity investees	3,150	2,398	1,991
Prepayments for equipment	276	440	383
Property and equipment, net	20,494	21,353	21,017
Operating lease right-of-use assets	—	15,071	13,929
Land use rights	—	7,655	7,416
Intangible assets, net	321	1,148	1,216
Long term deposits	557	377	712
Value added tax recoverable	8,044	13,737	16,159
Total assets	**301,987**	**355,153**	**548,214**
Liabilities and shareholders' equity			
Current liabilities:			
Short-term borrowings	3,643	6,450	4,238
Accounts payable	37,432	22,660	32,392
Current operating lease liabilities	—	4,351	4,175
Other current liabilities	7,767	13,174	15,750
Total current liabilities	48,842	46,635	56,555
Deferred income	2,064	2,881	15,736
Non-current operating lease liabilities	—	10,977	10,457
Total liabilities	**50,906**	**60,493**	**82,748**
Shareholders' equity			
Ordinary shares (par value of US$0.00006 per share; 83,333,333 shares authorized, 58,006,967, 68,237,247 and 74,882,338 shares issued and outstanding as of December 31, 2018, December 31, 2019 and June 30, 2020, respectively)	3	4	4
Additional paid-in capital	498,043	734,734	1,031,791
Accumulated deficit	(249,627)	(444,698)	(573,315)
Accumulated other comprehensive income	2,662	4,620	6,986
Total shareholders' equity	**251,081**	**294,660**	**465,466**
Total liabilities and shareholders' equity	**301,987**	**355,153**	**548,214**

We had net cash outflows in operating activities during the Track Record Period. Our primary uses of cash are to fund the development of both our in-licensed and internally developed drug candidates, our clinical trials, our payment for the construction of research and manufacturing facilities and for the purchase of equipment, selling and administrative expenses and other recurring expenses. Our net cash used in operating activities was US$97.5 million, US$191.0 million, US$83.2 million and US$92.3 million in 2018 and 2019, and in the six months ended June 30, 2019 and 2020, respectively, primarily due to the significant research and development expenses and selling, general and administrative expenses we incurred during the Track Record Period without generating substantial revenue from sales of our commercialized products. Our operating cash flow will continue to be affected by our research and development expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements from proceeds from our initial public offering and subsequent follow-on offerings. As our business develops and expands, we expect to generate cash flow from operations including but not limited to the selling of our commercial products. We shall continue to advance our late-stage clinical assets into NDA stage and commercialization which will bring incremental cash flow to fund our operation in the foreseeable future. Our management also closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Our Directors are of the opinion that, taking into account the financial resources available to us, including cash and cash equivalents, available credit facilities, the estimated net proceeds from the Global Offering and government grants, we have sufficient working capital to cover at least 125% of our costs, including research and development costs, business development and marketing expenses, and administrative and operating costs for at least the next 12 months from the date of this prospectus.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, which includes research and development expenses and (ii) capital expenditures. Assuming an average cash burn rate going forward of 1.3 times level for the six-month period ended June 30, 2020, we estimate that our cash and cash equivalents and short-term investments (primarily comprise of the time deposits with original maturities between three months and one year that were deposited with licensed commercial banks or financial institutions) in total of US$463.6 million as of June 30, 2020 will be able to maintain our financial viability for 23.2 months or, if we also take into account 10% of the estimated net proceeds from the Listing, 26.9 months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12.0 months.

Selected Consolidated Statements of Cash Flows

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
			(Unaudited)	
	(US dollars in thousands)			
Operating cash flows before changes in operating assets and liabilities	(124,920)	(167,728)	(71,210)	(110,709)
Changes in operating assets and liabilities	27,382	(23,283)	(11,974)	18,390
Net cash (used in) operating activities	(97,538)	(191,011)	(83,184)	(92,319)
Net cash (used in) investing activities	(212,554)	(14,892)	(106,017)	(6,521)
Net cash provided by financing activities	144,147	219,302	217,880	281,500
Effect of foreign exchange rate changes	(763)	91	(28)	12
Net (decrease) increases in cash and cash equivalents	(166,708)	13,490	28,651	182,672

Key Financial Ratios

The following table sets forth our key financial ratios for the periods indicated:

	As of December 31,		As of June 30,
	2018	2019	2020
Gross margin[(1)]	66.7%	71.1%	74.1%
Current ratio[(2)]	5.5	6.3	8.6
Gearing ratio[(3)]	1.5%	2.2%	0.9%

Notes:

(1) Gross margin equals gross profit divided by revenue for the period.

(2) Current ratio equals current assets divided by current liabilities as of the end of the period.

(3) Gearing ratio equals total interest-bearing loans divided by total equity as of the end of the period.

Our gross margin increased from 66.7% as of December 31, 2018 to 77.1% as of December 31, 2019, primarily because we started generating revenue only from the last quarter of 2018. Gross margin increased further to 74.1% as of June 30, 2020, mainly due to the launch of ZEJULA in China and the decrease in cost of sales resulting from the local manufacturing.

Our current ratio increased from 5.5 as of December 31, 2018 to 6.3 as of December 31, 2019, mainly due to (i) the increase in cash and cash equivalents as a result of our public offering of ADSs in May 2019 and (ii) a higher level of accounts receivable and inventories. Current ratio increased further to 8.6 as of June 30, 2020, mainly due to the increase of cash and cash equivalents resulting from the issuance of ADSs in our subsequent follow-on offering in January 2020.

Our gearing ratio increased from 1.5% as of December 31, 2018 to 2.2% as of December 31, 2019, mainly due to the increase of short-term borrowings from commercial banks and partially offset by the increase in additional paid-in capital as a result of our public offering of ADSs in May 2019. Gearing ratio decreased from 2.2% as of December 31, 2019 to 0.9% as of June 30, 2020, mainly due to the increase in additional paid-in capital as a result of our follow-on offering of ADSs in January 2020.

GLOBAL OFFER STATISTICS

All statistics in the following table are based on the assumptions that (i) the Global Offering has been completed and 10,564,050 new Shares are issued pursuant to the Global Offering; and (ii) 85,446,388 Shares are issued and outstanding following the completion of the Global Offering.

	Based on the indicative offer price per Offer Share of HK$648.00 for both Hong Kong Public Offering and International Offering
Market capitalization of our Shares[(1)]	HK$55,369.3 million
Unaudited pro forma adjusted net tangible asset value per Share[(2)]	HK$119.51

Notes:

(1) The calculation of the market capitalization is based on the assumption that 85,446,388 Shares in issue assuming that the Global Offering had been completed on June 30, 2020 without taking into account any allotment and issuance of any Shares upon the exercise of the Over-allotment Option, the Shares to be issued pursuant to the Equity Plans and other compensation programs, including pursuant to the exercise of options or the vesting of restricted shares or other awards that have been or may be granted from time to time and any issuance or repurchase of Shares by the Company.

(2) The unaudited pro forma adjusted consolidated net tangible assets attributable to the equity holders of our Company per Share in the above table is calculated as at June 30, 2020 after the adjustments referred to in the section entitled "Appendix II – Unaudited Pro Forma Adjusted Net Tangible Assets" in this prospectus and on the basis of 85,446,388 Shares in issue assuming that the Global Offering had been completed on June 30, 2020 without taking into account any allotment and issuance of any Shares upon the exercise of the Over-allotment Option, the Shares to be issued pursuant to the Share Incentive Plans and other compensation programs, including pursuant to the exercise of options or the vesting of restricted shares or other awards that have been or may be granted from time to time and any issuance or repurchase of Shares by the Company.

RISK FACTORS

Our operations and the Global Offering involve certain risks and uncertainties, some of which are beyond our control and may affect your decision to invest in us and/or the value of your investment. See the section headed "Risk Factors" for details of our risk factors, which we strongly urge you to read in full before making an investment in our Shares. Some of the major risks we face include:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.

- We will continue to require substantial additional funding for our drug development programs and for our commercialization efforts for ZEJULA, Optune and other products for which we may obtain regulatory approval, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.

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

- Even though we have launched ZEJULA and Optune in China, Hong Kong and Macau, we may never obtain approval of ZEJULA and Tumor Treating Fields for other indications or jurisdictions outside of the regulatory approvals we have already obtained, which would limit our ability to realize their full market potential.

- We are invested in the commercial success of ZEJULA and Optune and our ability to generate product revenues in the near future is highly dependent on the commercial success of ZEJULA in China, Hong Kong and Macau and Optune in China and Hong Kong.

- Many of our drug candidates are still in clinical development. If we are unable to obtain regulatory approval and ultimately commercialize these drug candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects may be materially adversely harmed.

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

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

- We may incur additional costs or experience delays in completing pre-clinical or clinical trials, or ultimately be unable to complete the development and commercialization of our products and drug candidates. You may lose all or part of your investment if we are unable to successfully complete clinical development, obtain regulatory approval and successfully commercialize our products and drug candidates.

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

DIVIDEND POLICY

We have never declared or paid regular cash dividends on our Shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Companies Law a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this prospectus, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year. If we pay dividends in the future, in order for us to distribute dividends to our shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries.

Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See "Risk Factors – Risks Relating to Doing Business in China" in this prospectus.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the Global Offering of approximately HK$6,613.8 million after deducting estimated underwriting fees and the estimated offering expenses payable by us, assuming the Over-allotment Option is not exercised and based upon an indicative maximum offer price of HK$648.00 per Offer Share.

The International Offer Price in the International Offering may be higher than, or the same as, the Public Offer Price in the Hong Kong Public Offering. See "Structure of the Global Offering – Pricing and Allocation."

We plan to use the net proceeds we will receive from the Global Offering for the following purposes:

- approximately HK$3,055.6 million, or 46.2%, is expected to be allocated to our Core Products.
    - approximately HK$1,468.3 million, or 22.2% is expected to be allocated to R&D efforts with respect to our Core Products:
        - approximately HK$1,058.2 million, or 16.0% is expected to be allocated to one of our Core Products, ZEJULA, among which approximately HK$813.5 million or 12.3% is expected to be used to seek indication expansion and hire high-caliber R&D staff dedicated to the development of ZEJULA, and approximately HK$244.7 million, or 3.7%, is expected to be used to develop and improve our manufacturing facilities to bring ZEJULA, to commercialization, as further described in the "Business" section of this prospectus; and
        - approximately HK$410.1 million, or 6.2% is expected to be used to fund our ongoing and planned clinical trials and preparation for registration filings of Tumor Treating Fields in multiple solid tumor cancer indications.
    - approximately HK$1,587.3 million, or 24.0%, is expected to enhance our commercialization capabilities for our Core Products, among which
        - approximately HK$1,058.2 million, or 16.0%, is expected to be used for ZEJULA to enhance our commercialization capabilities through increasing our sales and marketing headcounts, among other efforts, see "Business – Our Strategies – Efficiently grow our world-class organization and invest in our capabilities to support our global aspirations" for detailed discussion on the commercialization plan; and

  - approximately HK$529.1 million, or 8.0%, is expected to be used to strengthen commercialization efforts for Tumor Treating Fields through recruiting key talents in relevant indications to drive sales and future potential product launch;

- approximately HK$780.4 million, or 11.8%, is expected to fund our ongoing and planned clinical trials and preparation for registration filings of other drug candidates in our pipeline, especially our late-stage drug candidates:

  - approximately HK$231.5 million, or 3.5%, is expected to be allocated to ripretinib;

  - approximately HK$324.1 million, or 4.9%, is expected to be allocated to margetuximab;

  - approximately HK$224.9 million, or 3.4%, is expected to be allocated to other late-stage drug candidates;

- approximately HK$1,653.4 million, or 25.0%, is expected to be used to explore new global licensing and collaboration opportunities and bring in potentially global best-in-class/first-in-class assets with clinical validation, synergistic with our our current pipeline and aligned to our expertise, especially around our disease strongholds within oncology, infectious and autoimmune diseases. During the Track Record Period, we have entered into six license agreements and/or collaboration agreements with global biopharmaceutical companies. Please refer to the section headed "Business – Overview of Our License and Strategic Collaboration Agreements" in this prospectus for detailed discussion on the material collaboration agreements we have entered into as of the Latest Practicable Date. We continuously seek potential global licensing and collaboration opportunities to further expand its drug pipeline by leveraging our relationship with the existing partners and expertise in our focused therapeutic areas. We also expect to seek such opportunities through our well-established industry network and dedicated business development team;

- approximately HK$463.0 million, or 7.0%, is expected to be used to continue investing in and expanding our internal discovery pipeline and recruit and train high-caliber talent globally, in particular talent with expertise and experience in R&D, with a goal to enhance our internal research platform and discovery efforts;

  - approximately HK$172.0 million, or 2.6%, is expected to be allocated to ZL-1201 and ZL-1102;

  - approximately HK$291.0 million, or 4.4%, is expected to be allocated to other internal discovered drug candidates; and

- approximately HK$661.4 million, or 10.0%, is expected to fund working capital and other general corporate purposes.

To the extent that the net proceeds are not immediately applied to the above purposes and to the extent permitted by the relevant law and regulations, we plan to use the proceeds which are not immediately applied for the intended purposes for interest-bearing deposits with licensed commercial banks or financial institutions.

THE LISTING

Our ADSs have been listed and traded on Nasdaq since September 2017. Dealings in our ADSs on Nasdaq have been conducted in U.S. dollars. We have applied for a listing of our Shares on the Main Board under Chapter 19C (Secondary Listings of Qualifying Issuers) and Chapter 18A (Biotech Companies) of the Listing Rules. Dealings in our Shares on the Hong Kong Stock Exchange will be conducted in Hong Kong dollars. Our Shares will be traded on the Hong Kong Stock Exchange in board lots of 50 Shares. For additional information, see "Information about This Prospectus and the Global Offering."

WAIVERS AND EXEMPTIONS

As we are applying for listing under Chapter 19C and Chapter 18A of the Listing Rules, we will not be subject to certain provisions of the Listing Rules, including, among others, rules on notifiable transactions, connected transactions, share option schemes, content of financial statements as well as certain other continuing obligations. In addition, in connection with the Listing, we have applied for a number of waivers and/or exemptions from strict compliance with the Listing Rules, the Companies (WUMP) Ordinance and the SFO in relation to printed corporate communications, disclosure requirements relating to the Accountants' Report, disclosure of financial results for two financial years in the Accountants' Report, dealing in Shares prior to Listing, subscription for Shares by existing shareholders, printed prospectuses, monthly returns, shareholder protection requirements, disclosure requirements of options, timing requirement of liquidity disclosure, disclosure requirement of the remuneration of directors and five individuals whose emoluments were highest, disclosure of interests, disclosure of offer price, clawback mechanism and publication of the interim report. We have also applied for a ruling under the Takeovers Codes in relation to whether we are a "public company" in Hong Kong. For additional information, see "Waivers and Exemptions."

ARTICLES OF ASSOCIATION

We are an exempted company incorporated in the Cayman Islands with limited liability and our affairs are governed by our Articles of Association, the Cayman Companies Law, as well as the common law of the Cayman Islands. The laws of Hong Kong differ in certain respects from the Cayman Companies Law, and our Articles of Association are specific to us and include certain provisions that may be different from common practices in Hong Kong. For example:

(a) Rule 19C.07(1) of the Listing Rules requires that a super-majority vote of the Qualifying Issuer's members in general meeting is required to approve changes to the rights attached to any class of shares of the Qualifying Issuer. However, Article 23 of our Articles of Association provides that the rights attaching to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may be varied or abrogated with the written consent of the holders of a majority of the issued shares of that class or series, or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class or series. Accordingly, under our Articles of Association, a super majority vote of our Company's members in general meeting is not required to approve changes to the rights attached to any class of shares of the Company.

Therefore, we have applied for, and the Stock Exchange has granted, a waiver from strict compliance with Rule 19C.07(1) of the Listing Rules, subject to the conditions that (i) as of the date of this prospectus, we only have one class of shares and we will adopt transitional arrangements such that, after the Global Offering and until the following proposed amendment to our Articles of Association is passed, we will not seek to vary or abrogate any class right, and any request by shareholders to vary or abrogate any class right will require the written consent 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 general meeting of the holders of the shares of that class or series; (ii) we will convene our next annual general meeting in the second quarter of 2021 and put forth a resolution at such annual general meeting, to revise our Articles of Association, so that the rights attaching to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may be varied or abrogated with the written consent 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 general meeting of the holders of the shares of that class or series. In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed; (iii) we have been advised by our legal advisers as to Cayman Islands law that there is no legal impediment on the adoption of the above-mentioned transitional arrangements, and that the adoption of such transitional arrangements is not in breach of our Articles of Association or any rules and regulations in the Cayman Islands.

(b) Rule 19C.07(3) of the Listing Rules requires a change to the auditors or their remuneration to be approved by the shareholders or another body independent of the board of directors of the issuer; however, our Articles of Association does not contain an equivalent provision. Therefore, we have applied for, and the Stock Exchange has granted, a waiver from strict compliance with Rule 19C.07(3) of the Listing Rules.

(c) Rule 19C.07(4) of the Listing Rules requires that the Qualifying Issuer must hold a general meeting each year as its annual general meeting and that generally not more than 15 months should elapse between the date of one annual general meeting of the Qualifying Issuer and the next, while there is no such requirement to hold annual general meeting in our Articles of Association.

We have applied for, and the Stock Exchange has granted us, a waiver from strict compliance with Rule 19C.07(4) of the Listing Rules on the condition that we undertake to convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend our Articles of Association in accordance with the requirement under Rule 19C.07(4) of the Listing Rules such that our Articles of Association will require our Company to hold an annual general meeting each year and not more than 15 months should elapse between the date of one annual general meeting of our Company and the next. Following the Listing, we will continue to hold our annual general meeting each year. In the event that the proposed amendment of our Articles of Association as described above is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed; and

(d) Rule 19C.07(7) of the Listing Rules requires that members holding a minority shareholding in an issuer's total number of issued shares must be able to requisition an extraordinary general meeting and add resolutions to a meeting agenda. The minimum stake required to do so must not be higher than 10% of the voting rights, on a one vote per share basis, in the share capital of the issuer, while the minimum stake as currently set out in our Articles of Association is not less than one-third of the share capital of the Company.

We have applied for, and the Stock Exchange has granted us, a waiver from strict compliance with Rule 19C.07(7) of the Listing Rules on the conditions that (i) we will undertake to convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend the Articles of Association in accordance with the requirement under Rule 19C.07(7) of the Listing Rules, such that (A) members holding not less than 10% of the total number of issued shares of our Company shall be able to convene an extraordinary general meeting and add resolutions to a meeting agenda, and (B) the quorum for holding general meetings shall be members holding not less than 10% of our Company's total number of issued shares. In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed; and (ii) we will adopt transitional arrangements to ensure that (A) where after the Global Offering and before the above-mentioned proposed amendment to our Articles of Association is passed, if one or more members holding not less than 10% of the total number of issued shares of our Company raise requisition for an extraordinary general meeting or requests

to add resolutions to a meeting agenda, such members will be permitted to do so, and (B) one or more members holding not less than 10% of our Company's total number of issued shares will also be able to form a quorum at any general meeting which is held after the Global Offering and before the above-mentioned proposed amendment to our Articles of Association is passed. We have been advised by our legal advisers as to Cayman Islands law that there is no legal impediment on the adoption of such transitional arrangements, and that the adoption of such transactional arrangements is not in breach of our Articles of Association or any rules and regulations in the Cayman Islands.

We will seek irrevocable undertakings from our existing shareholders holding in aggregate over 50% of the total issued shares of the Company as of the Latest Practicable Date to vote in favor of the resolutions in relation to compliance with Rules 19C.07(1), 19C.07(4) and 19C.07(7) as mentioned above and Rule 19C.07(5) as mentioned in the section headed "Appendix III – General Meetings of Shareholders" and will continue to seek such irrevocable undertakings until our Articles of Association has been amended accordingly, with a view to ensuring that there will be adequate votes in favor of such resolutions.

In the event that the proposed amendments to the Articles of Association are not approved by our shareholders at the next annual general meeting, we will continue to put forth resolutions for the proposed amendments at each of the following annual general meetings until such resolutions are passed.

See "Risk Factors – Risks related to our Shares, the ADSs, the Listing and the Global Offering – Holders of our Shares and/or ADSs may have difficulty enforcing judgments obtained against us," "Information about This Prospectus and the Global Offering" and "Waivers and Exemptions – Shareholder Protection Requirements."

DETERMINATION OF OFFER PRICE

We will determine the pricing of the Offer Shares on the Price Determination Date, which is expected to be on or about September 22, 2020 and, in any event, not later than September 25, 2020, by agreement with the Joint Representatives (for themselves and on behalf of the Underwriters).

The Public Offer Price will be determined by reference to, among other factors, the closing price of the ADSs on Nasdaq on the last trading day on or before the Price Determination Date (which is accessible to the Shareholders and potential investors at **www.nasdaq.com/market-activity/stocks/zlab**), and the Public Offer Price will not be more than HK$648.00 per Offer Share.

We may set the International Offer Price at a level higher than the maximum Public Offer Price if (a) the Hong Kong dollar equivalent of the closing trading price of the ADSs on Nasdaq on the last trading day on or before the Price Determination Date (on a per-Class A ordinary share converted basis) were to exceed the maximum Public Offer Price as stated in this prospectus and/or (b) we believe that it is in the best interests of our Company as a listed company to set the International Offer Price at a level higher than the maximum Public Offer Price based on the level of interest expressed by professional and institutional investors during the bookbuilding process.

If the International Offer Price is set at or lower than the maximum Public Offer Price, the Public Offer Price must be set at such price that is equal to the International Offer Price. Under no circumstance will we set the Public Offer Price above the maximum Public Offer Price as stated in this prospectus or the International Offer Price.

LISTING EXPENSES

Based on the maximum Offer Price of HK$648.00, the total estimated listing related expenses payable by us in relation to the Global Offering is approximately US$29.9 million (assuming the Over-allotment Option is not exercised), representing approximately 3.5% of the estimate net proceeds from the Listing. We estimate that most of the listing expenses will be recorded as a deduction in equity directly. These listing expenses mainly comprise professional fees paid and payable to the Joint Sponsors, the Joint Bookrunners, the Underwriters, legal advisors and the reporting accountants for their services rendered in relation to the Listing and the Global Offering.

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

Outbreak of COVID-19

In December 2019 a respiratory illness known as COVID-19 caused by a novel strain of coronavirus, SARS-CoV-2 emerged. As of the Latest Practicable Date, we believe we have experienced only minimal disruption to our commercialization of ZEJULA and Optune and our planned clinical trials since the outbreak. For example, due to business interruptions to hospitals and treatment centers in China arising in connection with the outbreak of COVID-19, some patients have experienced difficulties in accessing hospital care and, as a result, our commercialization team has had fewer opportunities to reach patients who could benefit from

ZEJULA or Optune. In addition, we have experienced delays in the enrollment of patients in our clinical trials due to the outbreak of COVID-19. Our commercial partners and licensors also have similarly experienced delays in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. However, none of our NDA submission and acceptance or CTA approvals are delayed. In addition, there is no impact on most of our clinical studies and execution because we either completed enrollment before COVID-19 outbreak or we were in preparation of study start-up at that time. Further, as of the Latest Practicable Date, we have not experienced material supply disruptions or backlog due to the outbreak of COVID-19. We cannot guarantee, however, that the COVID-19 pandemic will not further escalate or have any material adverse effect on our results of operations. Please refer to "Risk Factors – We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations" for further details.

U.S. – China Trade Deal

In December 2019, the U.S. and China reached a partial trade deal, under which the U.S. agreed to cancel some new tariffs and reduce rates for other duties in exchange for China to purchase more U.S. agricultural products and to make changes regarding intellectual property and technology. In light of the current situations and the peculiarities of the biopharmaceutical industry, we are of the view that the U.S. – China tension has not had any material impact on our business operations, including our collaborations with business partners, our clinical trial designs and execution, patient enrollment, data transfer, and related regulatory approval process, and prospects. In addition, we have suppliers across the world and do not rely exclusively on the imports from the suppliers in the U.S. We plan to source domestically manufactured drug substances if the supply from overseas are not available. We cannot guarantee, however, that the U.S. – China tension will not escalate which may have a material adverse effect on our results of operations. Please refer to "Risk Factors – Changes in U.S. and international trade policies and relations, particularly with regard to China, may adversely impact our business and operating results."

No Material Adverse Change

Our Directors confirm, as of the date of this prospectus, that there has been no material adverse change in our financial or trading position, indebtedness, mortgage, contingent liabilities, guarantees or prospects of our Group since June 30, 2020, the end of the period reported on in the Accountants' Report set out in Appendix I to this prospectus. As of the Latest Practicable Date, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals for our Core Products. We believe that as of the date of the Latest Practicable Date, we had not received any material comments or concerns raised by the relevant regulatory authorities with respect to our Core Products that we are not able to address in a timely manner, and we believe we are on track to file for approval related to our drug candidates as described in "Business – Our Products and Drug Candidate Pipeline."

In this prospectus, unless the context otherwise requires, the following expressions have the following meanings. Certain other terms are defined in "Glossary of Technical Terms" in this prospectus.

"2015 Equity Plan"	the 2015 Equity Incentive Plan adopted by our Company, a brief summary of which are set out in the section headed "Appendix IV – Statutory and General Information – D. Share Incentive Plans and Other Compensation Programs – 2015 Equity Plan"
"2017 Equity Plan"	the 2017 Equity Incentive Plan adopted by our Company, in the principal terms of which are set out in the section headed "Appendix IV – Statutory and General Information – D. Share Incentive Plans and Other Compensation Programs – 2017 Equity Plan"
"ADS(s)"	American Depositary Shares (each representing one Share of our Company)
"Articles" or "Articles or Association"	the fourth amended and restated articles of association of our Company adopted by special resolution of the shareholders passed on August 30, 2017 and effective on September 20, 2017, as amended from time to time, a summary of which is set out in the section headed "Appendix III – Summary of the Constitution of the Company and Cayman Companies Law"
"associate"	has the meaning ascribed to it under the Listing Rules
"board" or "board of directors"	our board of directors
"business day"	any day (other than a Saturday or Sunday) on which banks in Hong Kong are open generally for normal banking business
"BVI"	the British Virgin Islands
"Cayman Companies Law"	the Companies Law, Cap. 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands
"CCASS"	the Central Clearing and Settlement System established and operated by HKSCC

"CCASS Clearing Participant"	a person admitted to participate in CCASS as a direct clearing participant or a general clearing participant
"CCASS Custodian Participant"	a person admitted to participate in CCASS as a custodian participant
"CCASS EIPO"	the application for the Hong Kong Offer Shares to be issued in the name of HKSCC Nominees and deposited directly into CCASS to be credited to your or a designated CCASS Participant's stock account through causing HKSCC Nominees to apply on your behalf, including by (i) instructing your broker or custodian who is a CCASS Clearing Participant or a CCASS Custodian Participant to give electronic application instructions via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, or (ii) if you are an existing CCASS Investor Participant, giving electronic application instructions through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input electronic application instructions for CCASS Investor Participants through HKSCC's Customer Service Centre by completing an input request
"CCASS Investor Participant"	a person admitted to participate in CCASS as an investor participant, who may be an individual or joint individuals or a corporation
"CCASS Participant"	a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant
"China" or "PRC"	the People's Republic of China, which for the purpose of this prospectus and for geographical reference only, excludes Hong Kong, Macau and Taiwan
"close associate(s)"	has the meaning ascribed to it under the Listing Rules
"Companies Ordinance"	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time

"Companies (WUMP) Ordinance"	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Company," "our Company," "we" or "us"	Zai Lab Limited, a company incorporated in the Cayman Islands with limited liability on March 28, 2013
"core connected person(s)"	has the meaning ascribed to it under the Listing Rules
"director(s)" or "our director(s)"	the director(s) of our Company or any one of them
"Dr. Du" or "Samantha Du"	Dr. Ying Du, our founder, Chairwoman and Chief Executive Officer
"DTC"	The Depository Trust Company, the central book-entry clearing and settlement system for equity securities in the United States and the clearance system for our ADSs
"Equity Plans"	2015 Equity Plan and 2017 Equity Plan
"Extreme Conditions"	any extreme conditions or events, the occurrence of which causes interruption to the ordinary course business operations in Hong Kong and/or that may affect the Price Determination Date or the Listing Date
"FDA"	U.S. Food and Drug Administration
"foreign private issuer"	as such term is defined in Rule 3b-4 under the U.S. Exchange Act
"Global Offering"	the Hong Kong Public Offering and the International Offering
"Greater China"	China, Hong Kong, Macau and Taiwan
"Green Application Form(s)"	the application form(s) to be completed by the White Form eIPO Service Provider, Computershare Hong Kong Investor Services Limited
"Group," "our Group," "we," "us" or "our"	our Company and its subsidiaries

"GSK"	GlaxoSmithKline plc, a science-led global healthcare company that acquired Tesaro in January 2019
"HK$" or "Hong Kong dollars" or "HK dollars" and "HK cents"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"HKSCC"	Hong Kong Securities Clearing Company Limited
"HKSCC Nominees"	HKSCC Nominees Limited, a wholly-owned subsidiary of HKSCC
"Hong Kong" or "HK"	the Hong Kong Special Administrative Region of the PRC
"Hong Kong Offer Shares"	771,700 Shares (subject to adjustment as described in the section headed "Structure of the Global Offering" in this prospectus) being offered by our Company for subscription pursuant to the Hong Kong Public Offering
"Hong Kong Public Offering"	the offer of the Hong Kong Offer Shares for subscription by the public in Hong Kong, on the terms and subject to the conditions described in this prospectus, as further described in the section headed "Structure of the Global Offering – The Hong Kong Public Offering" in this prospectus
"Hong Kong Share Registrar"	Computershare Hong Kong Investor Services Limited
"Hong Kong Stock Exchange" or "Stock Exchange"	The Stock Exchange of Hong Kong Limited
"Hong Kong Underwriters"	the underwriters of the Hong Kong Public Offering listed in the section headed "Underwriting – Hong Kong Underwriters"

"Hong Kong Underwriting Agreement"	the Hong Kong underwriting agreement dated September 16, 2020 relating to the Hong Kong Public Offering entered into among our Company, J.P. Morgan Securities (Far East) Limited, J.P. Morgan Securities (Asia Pacific) Limited, Goldman Sachs (Asia) L.L.C., Citigroup Global Markets Asia Limited and the Hong Kong Underwriters, as further described in the section headed "Underwriting – Underwriting Arrangements and Expenses – Hong Kong Public Offering – Hong Kong Underwriting Agreement" in this prospectus
"independent director(s)"	our directors who are "independent" under applicable U.S. regulations and considered "independent non-executive directors" for the purpose of Rule 3.10 of the Listing Rules
"independent third party(ies)"	party or parties which, to our best knowledge, is/are not connected persons (as defined in the Listing Rules) or any of their respective associates
"International Offer Price"	the final offer price per International Offer Share in Hong Kong dollars (exclusive of brokerage of 1%, SFC transaction levy of 0.0027% and Hong Kong Stock Exchange trading fee of 0.005%)
"International Offer Shares"	the 9,792,350 Shares (subject to adjustment and the exercise of the Over-allotment Option as described in the section headed "Structure of the Global Offering" in this prospectus), which are the subject of the International Offering
"International Offering"	the offer of the International Offer Shares at the International Offer Price pursuant to the shelf registration statement on Form F-3ASR that was filed with the SEC and became effective on March 29, 2020, and the preliminary prospectus supplement filed with the SEC on September 16, 2020 and the final prospectus supplement to be filed with the SEC on or about September 22, 2020
"International Underwriters"	the underwriters of the International Offering

"International Underwriting Agreement"	the international underwriting agreement relating to the International Offering to be entered into among our Company, the Joint Representatives (for themselves and on behalf of the International Underwriters) and the Joint Sponsors on or about September 22, 2020, as further described in the section headed "Underwriting" in this prospectus
"Joint Bookrunners"	J.P. Morgan Securities (Asia Pacific) Limited (in relation to the Hong Kong Public Offering), J.P. Morgan Securities plc and J.P. Morgan Securities LLC (in relation to the International Offering), Goldman Sachs (Asia) L.L.C., Citigroup Global Markets Asia Limited (in relation to the Hong Kong Public Offering), Citigroup Global Markets Limited (in relation to the International Offering), Jefferies Hong Kong Limited, Merrill Lynch (Asia Pacific) Limited, Credit Suisse (Hong Kong) Limited, China International Capital Corporation Hong Kong Securities Limited and Haitong International Securities Company Limited
"Joint Global Coordinators"	J.P. Morgan Securities (Asia Pacific) Limited, Goldman Sachs (Asia) L.L.C., Citigroup Global Markets Asia Limited and Jefferies Hong Kong Limited
"Joint Lead Managers"	J.P. Morgan Securities (Asia Pacific) Limited (in relation to Hong Kong Public Offer), J.P. Morgan Securities plc and J.P. Morgan Securities LLC (in relation to International Offering), Goldman Sachs (Asia) L.L.C., Citigroup Global Markets Asia Limited (in relation to the Hong Kong Public Offering), Citigroup Global Markets Limited (in relation to the International Offering) , Jefferies Hong Kong Limited, Merrill Lynch (Asia Pacific) Limited, Credit Suisse (Hong Kong) Limited, China International Capital Corporation Hong Kong Securities Limited and Haitong International Securities Company Limited
"Joint Policy Statement"	the Joint Policy Statement Regarding the Listing of Overseas Companies jointly issued by the Hong Kong Stock Exchange and the SFC on September 27, 2013

"Joint Representatives"	J.P. Morgan Securities (Asia Pacific) Limited, Goldman Sachs (Asia) L.L.C. and Citigroup Global Markets Asia Limited
"Joint Sponsors"	J.P. Morgan Securities (Far East) Limited, Goldman Sachs (Asia) L.L.C. and Citigroup Global Markets Asia Limited
"Latest Practicable Date"	September 7, 2020, being the latest practicable date prior to the printing of this prospectus for the purpose of ascertaining certain information contained in this prospectus
"Listing"	the listing of the Shares on the Main Board of the Stock Exchange pursuant to Chapter 19C and 18A of the Listing Rules
"Listing Date"	the date expected to be on or about September 28, 2020 on which the Shares are listed and from which dealings therein are permitted to take place on the Stock Exchange
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended or supplemented from time to time)
"Main Board"	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange. For the avoidance of doubt, the Main Board excludes the Growth Enterprise Market
"Memorandum" or "Memorandum of Association"	the memorandum of association of our Company as amended from time to time
"MOFCOM"	the Ministry of Commerce of the PRC (中華人民共和國商務部)
"Nasdaq"	Nasdaq Global Market
"Nasdaq rules"	The Nasdaq Stock Market LLC Rules, or the rules applicable to issuers listed on the Nasdaq, and as amended from time to time

"NCCN Guidelines"	The NCCN Clinical Practice Guidelines in Oncology, a comprehensive set of guidelines detailing the sequential management decisions and interventions on cancer treatment compiled by The National Comprehensive Cancer Network
"NMPA"	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局) of the PRC, or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or SDA
"Offer Share(s)"	the Hong Kong Offer Shares and the International Offer Shares, where relevant, with any Shares being issued pursuant to the exercise of the Over-allotment Option
"Over-allotment Option"	the option to be granted by our Company to the Joint Representatives (on behalf of the International Underwriters) under the International Underwriting Agreement pursuant to which our Company may be required by the Joint Representatives to allot and issue up to 1,584,600 additional Shares, representing approximately 15% of the Offer Shares initially available under the Global Offering, at the International Offer Price to cover over-allocations in the International Offering, details of which are described in the section headed "Structure of the Global Offering" in this prospectus
"Price Determination Agreement"	the agreement to be entered into among our Company and the Joint Representatives (for themselves and on behalf of the Underwriters) on or before the Price Determination Date to record and fix the price of the Offer Shares
"Price Determination Date"	the date on which the International Offer Price and Public Offering Price will be fixed
"prospectus"	this prospectus being issued in connection with the Hong Kong Public Offering
"Public Offer Price"	the final offer price per Hong Kong Offer Share in Hong Kong dollars (exclusive of brokerage of 1%, SFC transaction levy of 0.0027% and Hong Kong Stock Exchange trading fee of 0.005%)
"Qualifying Issuer"	has the meaning given to it under Chapter 19C of the Listing Rules

"Regulation S"	Regulation S under the U.S. Securities Act
"Relevant Persons"	the Joint Sponsors, the Joint Representatives, the Joint Global Coordinators, Underwriters, any of their or the Company's respective directors, officers, employees, partners, agents, advisers and any other parties involved in the Global Offering
"SEC"	the U.S. Securities and Exchange Commission
"SFC"	the Securities and Futures Commission of Hong Kong
"SFO"	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Share(s)"	ordinary share(s) of par value US$0.00006 per share, in the capital of the Company
"Shareholder(s)"	holder(s) of Shares and, where the context requires, ADSs
"Significant Subsidiaries"	our subsidiaries as identified in "History and Corporate Structure – Significant Subsidiaries"
"Stabilization Manager"	Goldman Sachs (Asia) L.L.C.
"Stock Borrowing Agreement"	the stock borrowing agreement expected to be entered into on or around the Price Determination Date between the Stabilization Manager and QM11 Limited pursuant to which the Stabilization Manager may borrow up to 1,584,600 Shares from QM11 Limited to facilitate the settlement of over-allocations
"subsidiary(ies)"	has the meaning ascribed to it under the Listing Rules
"substantial shareholder(s)"	has the meaning ascribed to it under the Listing Rules
"Takeovers Code"	the Hong Kong Code on Takeovers and Mergers
"Tesaro"	acquired by GSK in January 2019, Tesaro was a fully-integrated Boston based oncology-focused biopharmaceutical company with operations in North America and Europe; we obtained an exclusive license from Tesaro for the development and commercialization of ZEJULA in China, Hong Kong and Macau in 2016

"Track Record Period"	the periods comprising the two years ended December 31, 2018 and 2019 and the six months ended June 30, 2020
"US$" or "U.S. dollars"	United States dollars, the lawful currency of the United States
"U.S. Exchange Act"	the United States Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder
"U.S. Securities Act"	the United States Securities Act of 1933 (as amended)
"Underwriters"	the International Underwriters and the Hong Kong Underwriters
"Underwriting Agreements"	the International Underwriting Agreement and the Hong Kong Underwriting Agreement
"United States" or "U.S."	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US GAAP," "U.S. GAAP" or "GAAP"	United States generally accepted accounting principles
"White Form eIPO"	the application for Hong Kong Offer Shares to be issued in the applicant's own name by submitting applications online through the designated website of the **White Form eIPO** Service Provider, **www.eipo.com.hk**
"White Form eIPO Service Provider"	Computershare Hong Kong Investor Services Limited
"Zai Lab HK"	Zai Lab (Hong Kong) Limited (再鼎醫藥(香港)有限公司), a company incorporated under the laws of Hong Kong on September 18, 2017 and an indirectly wholly owned subsidiary of our Company
"Zai Lab Suzhou"	Zai Lab (Suzhou) Co., Ltd.* (再鼎醫藥(蘇州)有限公司), a company incorporated under the laws of PRC on October 20, 2015 and an indirectly wholly owned subsidiary of our Company
"Zai Lab Shanghai"	Zai Lab (Shanghai) Co., Ltd.* (再鼎醫藥(上海)有限公司), a company incorporated under the laws of PRC on January 6, 2014 and an indirectly wholly owned subsidiary of our Company

"%"	percent

In this prospectus:

- *Unless otherwise expressly stated or the context otherwise requires, all data in this prospectus is as of the date of this prospectus.*

- *Unless otherwise specified, all references to any shareholdings in our Company assume that the Over-allotment Option has not been exercised.*

* *The English names of the PRC entities, PRC laws or regulations, and the PRC governmental authorities referred to in this prospectus are translations from their Chinese names and are for identification purposes only. If there is any inconsistency, the Chinese names shall prevail.*

This glossary contains definitions of certain terms used in this prospectus in connection with our business. These terms and their definitions may not correspond to industry standard definitions or usage, and may not be directly comparable to similarly titled terms adopted by other companies operating in the same industries as our Company.

"AEs"	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
"All-comer"	in the context of cancer treatment, refers to a treatment which can be used for all patients, regardless of a particular biomarker status
"ALT"	alanine aminotransferase
"API"	Active Pharmaceutical Ingredient, a substance used in a finished pharmaceutical product, which is intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings
"assay"	an analysis done to determine (1) the presence of a substance and the amount of that substance and (2) the biological or pharmacological potency of a drug
"AST"	aspartate aminotransferase
"astrocytes"	star-shaped glial cells in the brian and spinal cord that that have a number of functions, including support of the blood-brain barrier, provision of nutrients to neurons, repair to nervous tissue following injury, and facilitation of neurotransmission
"astrocytoma"	a glioma that develops from star-shaped glial cells (astrocytes) that support nerve cells
"AUC"	area under curve, a parameter of systemic exposure

"B-cell"	a type of white blood cell that differs from other lymphocytes like T-cells by the presence of the BCR on the B-cell's outer surface. Also known as B-lymphocytes
"basket trial"	a type of clinical trial that tests how well a new drug or other substance works in patients who have different types of cancer that all have the same mutation or biomarker
"Bemarituzumab"	also known as FPA144, internal identification number ZL-1303, a humanized monoclonal antibody (IgG1 isotype) specific to the human fibroblast growth factor receptor 2b, or FGFR2b, in clinical development as a targeted therapy for tumors that overexpress FGFR2b, including gastric and gastroesophageal cancer
"bioavailability"	the fraction of an administered dose of drug that reaches the systemic circulation, which is one of the principal pharmacokinetic properties of drugs
"BRAF"	a human gene that makes the B-raf protein involved in sending internal cell signals that direct cell growth
"BRCA"	breast cancer susceptibility gene, of which there are two (BRCA1 and BRCA2). BRCA proteins are key components of homologous recombination DNA repair pathway. BRCA deleterious mutations are associated with breast and ovarian cancers
"bridging study"	a supplemental trial or study performed in the new region to provide pharmacodynamic or clinical data on efficacy, safety, dosage, and dose regimen in the new region that will allow extrapolation of the foreign clinical data to the new region
"Brivanib"	internal identification number ZL-2301, an investigational, oral, anti-tumorigenic that inhibits vascular endothelial growth factor receptor (VEGFR) and fibroblast growth factor receptors (FGFR)
"carcinoma"	a cancer that begins in the lining layer (epithelial cells) of organs

"CD20"	B-lymphocyte antigen CD20, a B-cell specific cell-surface molecule that is encoded by the MS4A1 gene
"CD47"	a broadly expressed protein that costimulates T cells, facilitates leukocyte migration, and inhibits macrophage scavenger function
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"cholangiocarcinoma"	bile duct cancer, a type of cancer that forms in the bile ducts
"CHOP"	cyclophosphamide, doxorubicin hydrochloride (hydroxydaunomycin), vincristine sulfate (oncovin) and prednisone
"Class III Hospitals"	the largest regional hospitals with the highest standard in China designated as Class III hospitals by the National Health Commission hospital classification system, typically having more than 500 beds in operation, providing high-quality professional healthcare services covering a wide geographic area and undertaking higher academic and scientific research initiatives
"Cmax"	maximum concentration, a parameter of systemic exposure
"CMO(s)"	contract manufacturing organization(s), a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
"cohort"	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
"complete response (CR)"	the disappearance of all signs of cancer in response to treatment

"CRO(s)"	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
"CT"	computerized tomography
"CTCAE"	the Common Terminology Criteria for Adverse Events, a set of criteria for the standardized classification of adverse effects of drugs used in cancer therapy
"cytokine"	a broad and loose category of small proteins that are important in cell signalling. Their release has an effect on the behaviour of cells around them
"DART"	dual affinity re-targeting, a diabody-like entity that have the variable heavy chain domain of the first variable region linked to the variable light chain domain of the second binder, and the variable heavy chain domain of the second variable region linked to the variable light chain domain of the first
"DLBCL"	diffuse large B-cell lymphoma
"DLT"	dose-limiting toxicity
"DNA"	deoxyribonucleic acid
"DOR"	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
"Durlobactam"	internal identification number ZL-2402, a novel beta-lactamase inhibitor
"EMA"	European Medicines Agency
"Fc region"	the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system. This property allows antibodies to activate the immune system

"first-in-human"	a key step in medicines development, where a medicine already tested in vitro, in animals or in other pre-clinical studies is administered to people for the first time
"first-line"	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment of a given type and stage of cancer
"First-Patient-In"	the date and time the first subject meeting the trial's inclusion or exclusion criteria is enrolled and randomized into a study
"FISH"	fluorescence in situ hybridization, an in situ hybridization procedures use fluorescent probes to detect DNA sequences
"FL"	follicular lymphoma
"Front-line"	in the context of cancer treatment, front-line setting or front-line treatment generally refers to the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment of a given type of cancers, which are not defined by lines of treatment
"GC"	gastric cancer
"GEJ"	gastroesophageal junction, where the esophagus joins the stomach
"GGT"	gamma-glutamyl transferase
"GIST"	gastrointestinal stromal tumor
"Hanhui"	Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd. (輝正(上海)醫藥科技有限公司), a local pharmaceutical company in China with a strong commercial presence in antibiotics

"HER2"	human epidermal growth factor receptor 2, also known as receptor tyrosine-protein kinase erbB-2. HER2 is a member of the human epidermal growth factor receptor (HER/EGFR/ERBB) family. Amplification or overexpression of this oncogene is associated with certain aggressive types of breast cancer
"HercepTest"	a semi-quantitative immunohistochemical assay to determine HER2 protein overexpression in breast cancer tissues routinely processed for histological evaluation and formalin-fixed, paraffin-embedded cancer tissue from patients with adenocarcinoma of the stomach, including the gastroesophageal junction
"IgG1"	one type of the most common class of antibody, Immunoglobulin G, which includes IgG1, IgG2, IgG3 and IgG4
"IL-17"	a key cytokine that links T cell activation to neutrophil mobilization and activation
"immuno-oncology"	a type of immunotherapy that is specifically targeted to fight cancer
"immunoglobulin"	glycoprotein molecules produced by plasma cells (white blood cells), which are also known as antibodies. They act as a critical part of the immune response by specifically recognizing and binding to particular antigens, such as bacteria or viruses, and aiding in their destruction
"immunotherapy"	use of the immune system to treat disease
"kinase"	a type of enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates. The protein kinases make up the majority of all kinases. Protein kinases act on proteins, phosphorylating them on their serine, threonine, tyrosine, or histidine residues. These kinases play a major role in protein and enzyme regulation as well as signaling in the cell

"KIT"	a tyrosine receptor kinase that is normally expressed in hematopoietic stem cells, MCs, melanocytes, and the interstitial cells of Cajal in the digestive tract
"late-line"	for this Prospectus only, in the context of ZEJULA registrational bridging trial for late-line ovarian cancer treatment, treatment beyond second or further lines of therapy
"Level 1 evidence"	based on data from well-structured and rigorously controlled meta-analysis, and/or large-scale, randomized controlled clinical trials, and experts' consensus reached with support level over 60%
"Level 2 evidence"	based on data from meta-analysis, small-scale, randomized controlled trials, well-designed large-scale retrospective studies, and/or case-control studies, and experts' consensus reached with support level over 60%
"Level 1 recommendation"	therapies have good accessibility (including clearly specified indication); clinical value of tumor treatment is relatively stable; basically, the drugs involved are included in the NRDL
"Level 2 recommendation"	supported by the high-level clinical evidence from international or domestic randomized controlled clinical trials, but the therapies have low cost-potency ratio and accessibility; some therapies with expensive pricing may be recommended as Level 2 considering the significant clinical benefit of the oncology treatment as well
"Level 3 recommendation"	therapies which are under exploratory study and lack corroborative clinical evidence while experts reached consensus can be recommended as Level 3
"lymphocytes"	a sub-type of white blood cells, such as T cells, B-cells and NK cells
"Margetuximab"	internal identification number ZL-1302, an immune-optimized anti-HER2 monoclonal antibody developed by MacroGenics

"Marketing Authorization Application" or "MAA"	an application made to the regulatory authorities in a given jurisdiction for approval to market a device within such jurisdiction
"MCL"	mantle cell lymphoma
"MoA"	mechanism of action, the specific biochemical interaction through which a drug substance produces its pharmacological effect
"metastatic"	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
"MNC"	multinational corporation
"monotherapy"	therapy that uses a single drug to treat a disease or condition
"MSI-high"	microsatellite instability high
"MTD"	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
"MZL"	marginal zone lymphoma
"NDA"	new drug application
"NHL"	non-Hodgkin's lymphoma
"NSCLC"	non-small cell lung cancer
"Odronextamab"	formerly known as REGN1979, an investigational bispecific monoclonal antibody that is designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20)
"Omadacycline"	internal identification number ZL-2401, a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines

"only-in-class"	for this Prospectus only, in the context of describing Optune, a category of drugs with unique mechanism of actions that is distinct from other therapies for treating the same medical condition
"Optune"	internal identification number ZL-8301, a portable battery or power supply operated device which act by delivering low intensity (1-3 V/cm), intermediate frequency (100-300 kHz), alternating Tumor Treating Fields to a patient's shaved head by means of electrically insulated surface transducer arrays; Optune is the complete delivery system that delivers Tumor Treating Fields for the treatment of GBM. It is a noninvasive, antimitotic cancer treatment
"Optune Lua™"	formerly known as NovoTTF-100L, Tumor Treating Fields delivery system for the treatment of malignant pleural mesothelioma (MPM). It is a noninvasive antimitotic cancer treatment
"ORR"	the overall response rate
"OS"	overall survival
"PARP"	poly ADP ribose polymerase, a family of proteins involved in numerous cellular processes, mostly involving DNA replication and transcriptional regulation, which plays an essential role in cell survival in response to DNA damage
"PCT"	Patent Cooperation Treaty
"PCV"	Procarbazine, CCNU and Vincristine, a chemotherapy regimen
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on T-cells and pro-B-cells that binds two ligands, PD-L1 and PD-L2. PD-1 is a cell surface receptor that plays an important role in down-regulating the immune system by preventing the activation of T-cells

"PD-L1"	programmed death-ligand 1, a protein in humans encoded by the CD274 gene. PD-L1 binds the PD-1 receptor and sends an inhibitory signal inside the T-cell, stopping it from making more poisonous proteins and killing the cells that send the signal via PD-L1 and in the neighborhood
"PDGFRα"	PDGF receptor, cell surface tyrosine kinase receptors for members of the PDGF family
"pharmacodynamics" or "PD"	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
"pharmacokinetics" or "PK"	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
"Phase Ib study"	Phase Ib is the study that tests the safety, side effects, and best dose of a new treatment. It is conducted in target patient popular with selected dose levels. Phase Ib study also investigates how well a certain type of disease responds to a treatment. In the phase IIa part of the study, patients usually receive multiple dose levels and often include the highest dose of treatment that did not cause harmful side effects in the phase Ia part of the study. Positive results will be further confirmed in a Phase IIb or Phase III study
"pilot trial"	a small study conducted to help design and assess the feasibility of doing a larger, full-scale trial; a pilot trial also investigates whether the methods and procedures are able to obtain the data that is needed to answer the question that will be addressed in the larger study
"pivotal trial"	the final controlled trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
"PR"	partial response

"pre-clinical studies"	pre-clinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
"progression-free survival" or "PFS"	the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse
"proof of concept"	a demonstration, the purpose of which is to verify that certain concepts or theories have the potential for real-world application; proof of concept is therefore a prototype that is designed to determine feasibility, but does not represent deliverables; proof of concept is not a regulatory status, but a term-of-art in the biopharmaceutical industry that often links between Phase I and Phase II trials
"registrational trial"	large confirmatory studies meant to establish an acceptable benefit/safety profile in order to gain regulatory approval for a precisely defined indication
"Relapsed/refractory (R/R)"	relapsed means patients initially respond to treatment but then cancer returns after a period of remission; refractory means cancer/tumor did not respond to treatment
"Repotrectinib"	an investigational next-generation TKI designed to effectively target ROS1 and TRK A/B/C with potential to treat TKI-naïve or -pretreated patients
"Retifanlimab"	formerly known as INCMGA0012, internal identification number ZL-1306, an investigational monoclonal antibody that inhibits PD-1
"R-CHOP"	rituximab, cyclophosphamide, doxorubicin hydrochloride (hydroxydaunomycin), vincristine sulfate (oncovin) and prednisone
"Ripretinib"	internal identification number ZL-2307, an investigational KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including GIST, systemic mastocytosis, or SM, and other cancers

"SAE"	serious AE, any medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage
"second-line"	therapies that are tried when the first-line treatments do not work adequately or stop working
"sNDA"	supplemental new drug application, a supplement based on a new drug application filed and approved by the relevant government authorities with respect to an existing or approved drug
"solid tumors"	an abnormal mass of tissue that usually does not contain cysts or liquid areas
"stable disease (SD)"	cancer that is neither decreasing nor increasing in extent or severity
"standard of care"	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
" Sulbactam-Durlobactam" or "SUL-DUR"	a novel beta-lactamase inhibitor for the treatment of carbapenem-resistant Acinetobacter baumannii infections including penem-resistant A
"$T_{½}$"	terminal half-life, the time required for the concentration to fall to 50% of its peak value
"T-cell"	T-cell immunoglobulin and mucin-domain containing-3, a Th1-specific cell surface protein that functions as an immune checkpoint, regulating macrophage activation and enhancing the severity of experimental autoimmune encephalomyelitis in mice
"TCR"	T-cell receptor

"Tebotelimab"	formerly known as MGD013, internal identification number ZL-1301, a bispecific monoclonal antibody designed to block the interaction of PD-1 or LAG-3 with their respective ligands, thereby contributing to sustain or restore the function of exhausted T-cells
"toxicity"	the degree to which a substance or a mixture of substances can harm humans or animals
"TRAE"	treatment-related adverse event, undesirable events not present prior to medical treatment or an already present event that worsens in intensity or frequency following the treatment
"treatment emergent adverse events" or "TEAE"	adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
"Tumor Treating Fields"	a proprietary platform technology that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and potentially causing cancer cell death; Tumor Treating Fields is approved in certain countries for the treatment of adults with GBM (Optune) and in the U.S. for MPM (Optune Lua™)
"TMZ"	temozolomide, an oral alkylating agent for the treatment of newly diagnosed glioblastoma multiforme and refractory anaplastic astrocytoma
"ZEJULA"	also known as niraparib, internal identification number ZL-2306, a small molecule poly (ADP-ribose) PARP 1/2 inhibitor

This prospectus contains forward-looking statements that relate to our current expectations and views of future events. These forward-looking statements are contained principally in the sections entitled "Summary," "Risk Factors," "Use of Proceeds," "Financial Information," "Industry Overview" and "Business." These statements relate to events that involve known and unknown risks, uncertainties and other factors, including those listed under "Risk Factors," which 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, these forward-looking statements can be identified by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. These forward-looking statements include, among other things, statements relating to:

- our ability to successfully commercialize ZEJULA, Optune and any other products and drug candidates that we may obtain regulatory approval for;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals;
- our ability to continue to develop our commercialization team and our sales and marketing capabilities;
- our ability to contract on commercially reasonable terms with contract research organizations, or CROs, third-party suppliers and manufacturers;
- the pricing and reimbursement of our drug candidates, if approved;
- our ability to contract on commercially reasonable terms with CROs;
- the disruption of our business relationships with our licensors;
- our ability to operate our business without breaching our licenses or other intellectual property-related agreements;
- cost associated with defending against intellectual property infringement, product liability and other claims;
- regulatory developments in China, the United States and other jurisdictions;
- the ability to obtain additional funding for our operations;
- the rate and degree of market acceptance of our products and drug candidates;

- developments relating to our competitors and our industry;
- our ability to effectively manage our growth; and
- our ability to retain key executives and to attract, retain and motivate personnel.

These forward-looking statements are subject to risks, uncertainties and assumptions, some of which are beyond our control. In addition, these forward-looking statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual outcomes may differ materially from the information contained in the forward-looking statements as a result of a number of factors, including, without limitation, the risk factors set forth in the section entitled "Risk Factors."

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this prospectus completely and with the understanding that our actual future results or performance may be materially different from what we expect.

In this prospectus, statements of, or references to, our intentions or those of any of our Directors are made as of the date of this prospectus. Any of these intentions may change in light of future developments.

An investment in our Shares and/or ADSs involves significant risks. You should carefully consider all of the information in this prospectus, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the "Financial Information" section, before deciding to invest in our Shares and/or ADSs. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the market price of our Shares and/or ADSs could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed "Forward-looking Statements" in this prospectus.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks related to our financial position and need for additional capital; (ii) risks related to our dependence of third parties; (iii) risks related to doing business in China; (iv) risks related to intellectual property; (v) risks related to our Shares, the ADSs, the listing and the Global Offering.

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.

The Hong Kong Department of Health approved ZEJULA in October 2018 and we launched ZEJULA in Hong Kong in December 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. The China National Medical Products Administration, or NMPA, approved ZEJULA in December 2019 as a maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy and we launched ZEJULA in the People's Republic of China, or PRC or China, in January 2020. In December 2018, we announced the launch of Optune for the

treatment of glioblastoma multiforme, or GBM, in Hong Kong. In May 2020, we obtained the NMPA MAA approvals for Optune in combination with TMZ for the treatment of patients with newly diagnosed GBM, and also as a monotherapy for the treatment of patients with recurrent GBM. Although we launched ZEJULA in China in January 2020 for recurrent ovarian cancer, in Macau in June 2019 for recurrent ovarian cancer, and in Hong Kong in December 2018 for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy and we launched Optune in Hong Kong in December 2018 and in China in May 2020, it will take some time to attain profitability and we may never do so. We have also obtained the rights to commercialize many clinical-stage drug candidates. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017 and multiple follow-on offerings. For the year ended December 31, 2018 and 2019 and for the six months ended June 30, 2020, we generated revenue of US$0.1 million, US$13.0 million and US$19.2 million from product sales, respectively, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2013. For the years ended December 31, 2018 and 2019 and for the six months ended June 30, 2020, we reported a net loss of US$139.1 million, US$195.1 million and US$128.6 million, respectively.

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

- continue to commercialize ZEJULA, Optune and any other products for which we may obtain regulatory approval;
- maintain and expand sales, marketing and commercialization infrastructure for ZEJULA, Optune and any other products for which we may obtain regulatory approval;
- maintain and expand regulatory approvals for our products and drug candidates that successfully complete clinical trials;
- continue our development and commence clinical trials of our drug candidates;
- maintain our manufacturing facilities;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- seek to identify additional drug candidates;
- obtain, maintain, expand and protect our intellectual property portfolio;

- enforce and defend intellectual property-related claims; and
- acquire or in-license other intellectual property, drug candidates and technologies.

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

We had net operating cash outflow during the Track Record Period.

Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was US$97.5 million, US$191.0 million and US$92.3 million for the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue to commercialize ZEJULA and Optune, research and develop our pre-clinical-stage drug candidates and initiate additional clinical trials of, and seek and/or expand regulatory approval for, ZEJULA, Tumor Treating Fields and our other drug assets. In addition, if we obtain regulatory approval for any additional drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, if more of our drug candidates are approved, additional costs may be substantial as we may have to modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers. We have, and may continue to, incur expenses as we create additional infrastructure to support our operations. Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations.

We will continue to require substantial additional funding for our drug development programs and for our commercialization efforts for ZEJULA, Optune and other products for which we may obtain regulatory approval, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.

To date, we have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017 and multiple follow-on offerings. As of June 30, 2020, through these offerings, we have raised US$958.6 million. We will likely need to obtain substantial additional funding in connection with our continuing operations through public orprivate equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts.

We believe our cash and cash equivalents and short-term investments as of June 30, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for ZEJULA, Optune and any other products for which we receive regulatory approval;

- the cash received, if any, from future commercial sales of ZEJULA, Optune and any other products for which we receive regulatory approval;

- the number and development requirements of the drug candidates we pursue;

- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;

- the number and characteristics of other drug candidates that we may pursue;

- the cost, timing and outcome of seeking, obtaining, maintaining and expanding regulatory approval of our products and drug candidates;

- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangement and the financial terms of such arrangements;

- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property related claims;

- the extent to which we acquire or in-license other drug candidates and technologies;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations;
- our headcount growth and associated costs; and
- the costs of operating as a public company in both the United States and Hong Kong.

Raising additional capital or entering into certain other arrangements may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Identifying and acquiring rights to develop potential drug candidates, conducting pre-clinical testing and clinical trials and commercializing products for which we receive regulatory approval is a time-consuming, expensive and uncertain process that may take years to complete. During the Track Record Period, we have generated our revenue mainly from the sales of ZEJULA and Optune, after we have received respective regulatory approval in relevant jurisdictions. Our near-term commercial revenue, will continue to be derived from sales of ZEJULA and Optune. Any additional commercial revenue, if any, will be derived from sales of drug candidates that we do not expect to be commercially available until we receive regulatory approval, if at all. We may never generate the necessary data or results required to obtain regulatory approval and achieve product sales of some of our drug candidates, and even if we obtain regulatory approval, our products may not achieve commercial success. 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.

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

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

We commenced our operations in 2013. Our operations to date have been limited to organizing and staffing our company, identifying potential partnerships and drug candidates, acquiring product and technology rights, conducting research and development activities for our drug candidates and, more recently, commercializing products for which we have obtained regulatory approval. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials. Additionally, we have limited experience in the sale, marketing or distribution of pharmaceutical and medical device products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

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

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

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

We have licensed and sublicensed patent rights from third parties for some of our development programs, including but not limited to ZEJULA from GSK, Tumor Treating Fields from Novocure, ripretinib from Deciphera, repotrectinib from Turning Point, margetuximab, tebotelimab and a pre-clinical multi-specific TRIDENT molecule from MacroGenics, retifanlimab from Incyte, bemarituzumab from Five Prime, omadacycline from Paratek and durlobactam from Entasis. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. We cannot be certain that the patents and patent applications for our products and drug candidates have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our drug candidates. If our

licensors or such third parties fail to prepare, prosecute, or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drug candidates that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. For example, under our agreement with Novocure for Tumor Treating Fields, Novocure owns and has the right to control all patent application and patent prosecution activities related to Tumor Treating Fields in China, Hong Kong, Macau and Taiwan. Similarly, the first right to enforce such patent portfolio within China, Hong Kong and Macau. However, GSK maintains the right to enforce such patent portfolio in all other territories or, if we fail to bring an action within 90 days within China, Hong Kong or Macau, GSK can control such enforcement actions in those areas as well. In the case where GSK controls such enforcement actions, although we have rights to consult with GSK on such actions within China, Hong Kong and Macau, rights granted by GSK under ZEJULA to another licensee, such as Janssen Biotech, Inc. to whom GSK has granted an exclusive right to develop ZEJULA for the treatment of prostate cancer, could potentially influence GSK's interests in the exercise of its prosecution, maintenance and enforcement rights in a manner that may favor the interests of such other licensee as compared with us, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

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

Our business relies, in large part, on our ability to develop and commercialize products and drug candidates from third parties including but not limited to ZEJULA from GSK; Tumor Treating Fields from Novocure Limited, or Novocure. If we have not obtained a license to all intellectual property rights that are relevant to our products and drug candidates and that are owned or controlled by our licensors and collaboration partners or owned or controlled by affiliates of such licensors and collaboration partners, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis,

on commercially reasonable terms or at all. In addition, if our licensors and collaboration partners breach such agreements, we may not be able to enforce such agreements against our licensors' parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable drug candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such drug candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and other intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such drug candidates and/or maintaining the confidentiality of information we receive from our licensors. For example, we are obligated to use commercially reasonable efforts to develop and commercialize Tumor Treating Fields in the territories specified under its agreement.

If we fail to meet any of our obligations under our license and other intellectual property-related agreements, our licensors have the right to terminate our licenses and sublicenses and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses or sublicenses, we will lose the right to develop and commercialize our applicable products and drug candidates and other third parties may be able to market products or drug candidates similar or identical to ours. In such case, we may be required to provide a grant back license or expand an existing license to the licensors under our own intellectual property with respect to the terminated products. For example, if our agreements with GSK for ZEJULA terminate for any reason, we are required to grant GSK an exclusive license to certain of our intellectual property rights that relate to ZEJULA, as applicable.

While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our drug candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such drug candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable drug candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, disputes may further arise regarding intellectual property subject to a license and/or collaboration agreement.

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party, and have granted us a sub-license. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements.

For example, our licenses from GSK, Paratek, MacroGenics and Incyte comprise sublicenses to us of certain intellectual property rights owned by third parties that are not our direct licensors. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our rights to the applicable licensed intellectual property may be terminated or narrowed, our exclusive licenses may be converted to non-exclusive licenses, and our ability to produce and sell our products and drug candidates may be materially harmed. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or drug candidates and our business could be substantially harmed. If we lose our relationships with our third parties, especially our CROs, our product or drug development efforts could be delayed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for some of our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our pre-clinical studies in accordance with Good Laboratory Practices, or GLP, and the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) or the Animal Welfare Act requirements. We and our CROs are required to comply with GCP regulations and guidelines enforced by the NMPA, and comparable foreign regulatory authorities for all of our products or drug candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable foreign

regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with products or drugs produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

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

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

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter 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 have limited experience manufacturing our products and drug candidates on a large clinical or commercial scale. We are or will be dependent on third party manufacturers for the manufacture of certain of our products and drug candidates as well as on third parties for our supply chain, and if any of these third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices, our business could be harmed.

If our two manufacturing facilities are unable to meet our intended production capacity in a timely fashion, we may have to engage a contract manufacturing organization, or CMO, for the production of clinical supplies of our products or drug candidates.

Additionally, in order to successfully commercialize our products and drug candidates, we will need to identify qualified CMOs for the scaled production of a commercial supply of certain of our products and drug candidates. The CMOs should be drug manufacturers holding manufacturing permits with a scope that can cover our drug registration candidates. We have not yet identified suppliers to support scaled production. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our products or drug candidates, or market or distribute them.

We rely on third-party manufacturers to manufacture at least some of our products and drug candidates. For example, we rely on MacroGenics to manufacture and supply margetuximab, tebotelimab, and a pre-clinical multi-specific TRIDENT molecule, Entasis to manufacture and supply durlobactam, Novocure to manufacture and supply Optune, Deciphera to manufacture and supply ripretinib, Incyte to manufacture and supply retifanlimab and, as of April 2020, Regeneron to manufacture and supply odronextamab.

Such reliance entails risks to which we would not be subject to if we manufactured drug candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing or supply agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our drug candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the NMPA and other regulatory authorities require that our drug candidates and any products that we may eventually commercialize be manufactured according to cGMP standards. Any failure by our third-party manufacturers to comply with cGMP standards or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of drug candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our drug candidates. In addition, such failure could be the basis for the NMPA to issue a warning or untitled letter, withdraw approvals for drug candidates previously granted to us, or take other regulatory or legal action,

including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Furthermore, because of the complex nature of our compounds, we or our manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to make commercially successful products and drugs. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have limited experience manufacturing pharmaceutical products or drugs on a commercial scale and some of our current suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met.

We rely on supplies from our licensors, which may severely harm our business and results of operations.

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

During the Track Record Period, we relied on a limited number of customers for a substantial portion of our revenue.

During the Track Record Period, a substantial amount of our revenue was derived from sales to a limited number of customers, which are distributors as consistent with industry norm. In 2018, 2019 and the first half of 2020, the aggregate amount of revenue generated from our five largest customers accounted for approximately 89.6%, 85.0% and 44.5% of our total revenue, respectively. Revenue generated from our largest customer for the same periods accounted for approximately 39.6%, 41.6% and 16.8% of our total revenue, respectively. Please refer to the section headed "Business – Customers" for more details. While we are

rapidly expanding our customer base upon our successful launch of ZEJULA and Optune in China, we may continue to rely on such major customers in ramping up the sales of our commercialized products. There is no assurance that our five largest customers will continue to purchase from us at the current levels or at all in the future. If any of our five largest customers significantly reduces its purchase volume or ceases to purchase from us, and we are not able to identify new customers in a timely manner, our business, financial condition and results of operation may be materially and adversely affected. In addition, there is no assurance that our major customers will not negotiate for more favorable terms for them in the future. Under such circumstances, we may have to agree to less favorable terms so as to maintain the ongoing cooperative relationships with our major customers. If we are unable to reduce our production cost accordingly, our profitability, results of operations and financial condition may be materially and adversely affected. Therefore, any risks which could have a negative impact on our major customers could in turn have a negative impact on our business.

If we fail to maintain an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected.

We rely on third-party distributors to distribute our commercialized products. We also expect to rely on third-party distributors to distribute our other products and internally discovered products, if approved. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributors, who may fail to distribute our products in the manner we contemplate. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our products to hospitals, medical institutions and sub-distributors, they may terminate their relationship with us. While we believe alternative distributors are readily available, there is a risk that, if the distribution of our products is interrupted, our sales volumes and business prospects could be adversely affected.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

Even though we have launched ZEJULA and Optune in China, Hong Kong and Macau, we may never obtain approval of ZEJULA and Tumor Treating Fields for other indications or jurisdictions outside of the regulatory approvals we have already obtained, which would limit our ability to realize their full market potential.

In order to market products in any given jurisdiction, we must comply with numerous and varying regulatory requirements of such jurisdiction regarding safety, efficacy and quality. The Hong Kong Department of Health approved ZEJULA in October 2018 and we launched ZEJULA in Hong Kong in December 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. The NMPA approved ZEJULA in December 2019 as a maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy and we launched ZEJULA in China in

January 2020. In December 2018, we announced the launch of Optune for the treatment of GBM in Hong Kong. In May 2020, we obtained the NMPA MAA approvals for Optune in combination with TMZ for the treatment of patients with newly diagnosed GBM, and also as a monotherapy for the treatment of patients with recurrent GBM. The approval of ZEJULA and Optune for certain indications does not mean that the NMPA will approve ZEJULA and Tumor Treating Fields for other indications. Approval procedures vary among jurisdictions and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other jurisdiction.

We are invested in the commercial success of ZEJULA and Optune and our ability to generate product revenues in the near future is highly dependent on the commercial success of ZEJULA in China, Hong Kong and Macau and Optune in China and Hong Kong.

A substantial portion of our time, resources and effort are focused on the commercialization of our commercialized product ZEJULA in China, Hong Kong, and Macau, and our commercialized product Optune in China and Hong Kong. Our ability to generate product revenues will depend heavily on the successful commercialization of ZEJULA in China, Hong Kong and Macau and Optune in China and Hong Kong. Our ability to successfully commercialize ZEJULA and Optune will depend on, among other things, our ability to:

- maintain commercial manufacturing or supply arrangements with third-party manufacturers for ZEJULA and Optune;
- produce, through a validated process or procure, from third-party manufacturers sufficient quantities and inventory of ZEJULA and Optune to meet demand;
- build and maintain internal sales, distribution and marketing capabilities sufficient to generate commercial sales of ZEJULA and Optune;
- secure widespread acceptance of our product from physicians, healthcare payors, patients and the medical community;
- properly price and obtain coverage and adequate reimbursement of ZEJULA and of Optune by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing regulatory labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements;
- manage our growth and spending as costs and expenses increase due to commercialization; and

- manage business interruptions resulting from the occurrence of any pandemic, epidemic, including from the outbreak of the novel coronavirus, COVID-19, or any other public health crises, natural catastrophe or other disasters.

There are no guarantee that we will be successful in completing these tasks. In addition, we have invested, and will continue to invest, substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of our sales of ZEJULA and Optune.

Sales of ZEJULA and Optune may be slow or limited for a variety of reasons including competing therapies or safety issues. If ZEJULA or Optune is not successful in gaining broad commercial acceptance, our business would be harmed.

Any sales of ZEJULA and Optune will be dependent on several factors, including our and our partners' ability to educate and increase physician awareness of the benefits, safety and cost-effectiveness of ZEJULA and Optune relative to competing therapies. The degree of market acceptance of ZEJULA and Optune among physicians, patients, healthcare payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing, cost effectiveness and value propositions;
- effectiveness of our sales and marketing capabilities and strategies;
- ability to obtain sufficient third-party coverage and reimbursement;
- the clinical indications for which ZEJULA and Optune are approved, as well as changes in the standard of care for their targeted indications;
- the continuing effectiveness of manufacturing and supply chain;
- warnings and limitations contained in the approved labeling for ZEJULA and for Optune;
- safety concerns with similar products marketed by others;
- the prevalence and severity of any side effects as a result of treatment with ZEJULA or Optune;

- our ability to comply with regulatory post-marketing requirements associated with the approval of ZEJULA or Optune;

- the actual market-size for ZEJULA and Optune, which may be larger or smaller than expected; and

- our ability to manage complications or barriers that inhibit our commercialization team from reaching the appropriate audience to promote our product(s) because of the outbreak of COVID-19 or any other public health crises, natural catastrophe or other disasters.

We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The continued COVID-19 pandemic could adversely impact our operations, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of us and our business partners, and the ability to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on our business and our financial results.

For example, due to business interruptions to hospitals and treatment centers in China arising in connection with the outbreak of COVID-19, some patients have experienced difficulties in accessing hospital care and, as a result, our commercialization team has had fewer opportunities to reach patients who could benefit from ZEJULA or Optune. In addition, we have experienced delays in the enrollment of patients in our clinical trials due to the outbreak of COVID-19. Our commercial partners and licensors also have similarly experienced delays in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. None of our NDA submission and acceptance nor CTA approvals are delayed, however.

However, as the outbreak of COVID-19 has largely been contained in China, we believe we have experienced only minimal disruption to our commercialization of ZEJULA and Optune and our planned clinical trials since the outbreak. Nevertheless, outbreaks may occur again and may result in similar business interruptions in the future. Additionally, although we

have not experienced material supply disruptions due to the outbreak of COVID-19, we cannot guarantee that we will not experience supply disruptions in the future due to COVID-19 or any other pandemic, epidemic or other public health crises, natural catastrophe or other disasters.

There are no comparable recent events that provide guidance as to the effect the COVID-19 outbreak as a global pandemic may have, and, as a result, the ultimate impact of the pandemic is highly uncertain and subject to change. To the extent the outbreak of COVID-19 results in delay and interruptions to our or our commercial partners' and licensors' clinical trials in the future, such delays may result in increased development costs for our products and drug candidates, which could cause the value of our company to decline and limit our ability to obtain additional financing.

Many of our drug candidates are still in clinical development. If we are unable to obtain regulatory approval and ultimately commercialize these drug candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects may be materially adversely harmed.

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

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;

- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;

- successful completion of all safety studies required to obtain regulatory approval in China, the United States and other jurisdictions for our drug candidates;

- adapting our commercial manufacturing capabilities to the specifications for our drug candidates for clinical supply and commercial manufacturing;

- making and maintain arrangements with third-party manufacturers;

- obtaining and maintaining patent, trade secret and other intellectual property protection and/or regulatory exclusivity for our drug candidates;

- launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and alternative drugs;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the drug candidates following regulatory approval.

The success of our business is substantially dependent on our ability to successfully commercialize ZEJULA and Optune as well as complete the development of, maintain, expand or obtain regulatory approval for, and successfully commercialize our drug candidates in a timely manner.

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

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

Because we have limited financial and managerial resources, we must limit our licensing, research, development and commercialization programs to specific products and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other products or drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

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

Our products and drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the NMPA, FDA and European Medicines Agency, or EMA, and other regulatory agencies in China and the United States and by comparable authorities in other countries. We are not permitted to market any of our products or drug candidates in China, the United States and other jurisdictions unless and until we receive regulatory approval from the NMPA, FDA and EMA and other comparable authorities, respectively. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product's or drug candidate's safety and efficacy. Securing regulatory approval may also require the submission of information about the product or drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our products and drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. In addition, we cannot provide any assurance that we will ever obtain regulatory approval for any of our drug candidates in any jurisdiction or that any of our drug candidates will be successfully commercialized even if we receive regulatory approval.

The process of obtaining regulatory approvals in China, the United States and other countries is expensive, may take many years of additional clinical trials and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product or drug candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or

changes in regulatory review for each submitted New Drug Application, or NDA, pre-market approval or equivalent application type, may cause delays in the approval or rejection of an application. The NMPA, FDA and EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies. Our products and drug candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the NMPA, FDA and EMA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the NMPA, FDA and EMA or comparable regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- failure of CROs, clinical study sites or investigators to comply with the ICH-good clinical practice, or GCP, requirements imposed by the NMPA, FDA and EMA or comparable regulatory authorities;
- failure of the clinical trial results to meet the level of statistical significance required by the NMPA, FDA and EMA or comparable regulatory authorities for approval;
- failure to demonstrate that a product's or drug candidate's clinical and other benefits outweigh its safety risks;
- the NMPA, FDA and EMA or comparable regulatory authorities disagreeing with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA or other submission or to obtain regulatory approval in China, the United States or elsewhere;
- the NMPA, FDA and EMA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the NMPA, FDA or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the NMPA, FDA or comparable regulatory authorities restricting the use of our products to a narrow population; and
- our CROs or licensors taking actions that materially and adversely impact the clinical trials.

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

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

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, manufacturing, distribution, and marketing of new drugs. In recent years, the pharmaceutical laws and regulations in China has undergone significant changes including but not limited to the adoption of some exploratory programs in pilot regions, and we expect that the transformation will continue. Any changes or amendments with respect to government regulation and supervision of the pharmaceutical industry in China may result in uncertainties with respect to the interpretation and implementation of the relevant laws and regulations or adversely impact the development or commercialization of our drugs and drug candidates in China. For instance, in March 2020, Medical Products Administration of Hainan Province promulgated the Interim Measures for the Administration of Taking Away the Imported Urgently Needed Drug from the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《海南博鰲樂城國際醫療旅遊先行區臨床急需進口藥品帶離先行區使用管理暫行辦法》), which allows that a patient may apply for taking away a small amount of the legally imported drugs that is not yet registered domestically but is on urgent medical need from the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province following his therapeutic schedule, which is also known as the special Named Patient Program (NPP). However, as NPP is newly adopted, any change in future policies or implementing measures, which we may not be able to predict or control, could create uncertainties affecting our development and commercialization of our drugs candidates. For further information regarding government regulation in China, see "Regulatory Environment – PRC Regulation of Pharmaceutical Product Development and Approval."

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

We plan to develop certain of our products and drug candidates for use as a combination therapy. However, we did not develop or obtain regulatory approval for, and we do not manufacture or sell any therapeutic we use in combination with our products or drug candidates. If the NMPA, FDA or another regulatory agency revokes its approval of any therapeutic we use in combination with our products and drug candidates, we will not be able

to market our products and drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with the therapeutics that we seek to combine with our products and drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any combination therapeutic, we may not be able to successfully commercialize our products or drug candidates on our current timeline or at all.

Even after obtaining regulatory approval for use in combination with any therapeutic, we would continue to be subject to the risk that the NMPA, FDA or another regulatory agency could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with any of our combination therapeutic. This could result in our products being removed from the market or being less successful commercially.

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

The development and commercialization of new medical device products and drugs is highly competitive. We face competition with respect to our current products and drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies and medical device companies worldwide. For example, there are a number of large pharmaceutical and biotechnology companies that currently market drugs or are pursuing the development of therapies in the field of poly ADP ribose polymerase, or PARP, inhibition to treat cancer. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to that of our drug candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Specifically, there are a large number of companies developing or marketing treatments for oncology, autoimmune and infectious diseases including many major pharmaceutical and biotechnology companies.

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

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products or drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products or drugs that we may develop. Our competitors also may obtain NMPA, FDA or other regulatory approval for their products or drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our products or potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our products or drug candidates against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

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

There is a risk of failure for each of our drug candidates. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any drug candidate, our drug candidates must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete.

The outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Future clinical trials of our drug candidates may not be successful. For example, brivanib (ZL-2301) failed to meet its primary endpoint of overall survival, or OS, noninferiority for brivanib (ZL-2301) versus sorafenib in Phase III trials in patients with HCC conducted by Bristol-Myers Squibb Company, or BMS, before we licensed the development rights from them. In addition, brivanib (ZL-2301) showed no difference when compared to placebo in the primary efficacy endpoint. We believe that brivanib (ZL-2301) has the potential to be an effective treatment for Chinese patients and merits further clinical trials patients. We are currently developing ZL-2301 as a combination therapy where ZL-2301 is currently at Phase I dose escalation for the Phase I/II combination trial. We, however, cannot guarantee that our future clinical trials of brivanib (ZL-2301) in Chinese patients will be successful. In early 2018, we terminated ZL-1204, an in-house early-stage candidate, after evaluating the relevant competitive landscape and potential market opportunity.

Commencement of clinical trials is subject to finalizing the trial design based on ongoing discussions with the NMPA, FDA and/or other regulatory authorities. The NMPA, FDA and other regulatory authorities could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not currently expect. Successful completion of our clinical trials is a prerequisite to submitting an NDA (or equivalent filing) to the NMPA, FDA and/or other regulatory authorities for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. There are inherent uncertainties associated with development of our drug candidates. We do not know whether the clinical trials for our drug candidates will begin or be completed on schedule, if at all. Our future clinical trial results may not be favorable.

We may incur additional costs or experience delays in completing pre-clinical or clinical trials, or ultimately be unable to complete the development and commercialization of our products and drug candidates. You may lose all or part of your investment if we are unable to successfully complete clinical development, obtain regulatory approval and successfully commercialize our products and drug candidates.

We may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, future clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us or them, to conduct additional clinical trials or we may decide to abandon drug development programs;

- the number of patients required for clinical trials of our products and drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- the ability to conduct a companion diagnostic test to identify patients who are likely to benefit from our products and drug candidates;

- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our products and drug candidates may be greater than we anticipate;

- the supply or quality of our products and drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and

- our products and drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our products and drug candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or the ethics committee of the institutions in which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA, FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, a failure to obtain the regulatory approval and/or complete record filings with respect to the collection, preservation, use and export of China's human genetic resources, inspection of the clinical trial operations or trial site by the NMPA, FDA or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the NMPA, FDA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. You may lose all or part of your investment if we are unable to successfully complete clinical development, obtain regulatory approval and successfully commercialize our products and drug candidates.

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

- be delayed in obtaining regulatory approval for our products and drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements;
- encounter difficulties obtaining or be unable to obtain reimbursement for use of our products and drug candidates;
- be subject to restrictions on the distribution and/or commercialization of our products and drug candidates; or
- have our products and drug candidates removed from the market after obtaining regulatory approval.

Our product and drug development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products and drug candidates and may harm our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and prospects significantly.

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

We may not be able to initiate or continue clinical trials for our products and drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, FDA or similar regulatory authorities. In particular, we have designed many of our clinical trials, and expect to design future trials, to include some patients with the applicable genomic mutation with a view to assessing possible early evidence of potential therapeutic effect. Genomically defined diseases, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable

genomic mutation. The inability to enroll a sufficient number of patients with the applicable genomic alteration or that meet other applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

In addition, some of our competitors have ongoing clinical trials for products or drug candidates that treat the same indications as our products or drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' products or drug candidates.

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product or drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability of competing therapies also undergoing clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the occurrence of any pandemic, epidemic, including from the outbreak of COVID-19, or any other public health crises, natural catastrophe or other disasters may cause a delay in enrollment of patients in clinical trials.

Our products and drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects caused by our products or drug candidates could cause us to interrupt, delay or halt clinical trials or could cause regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA or other regulatory authorities. In particular, as is the case with all oncology products and drugs, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology products or drug candidates. For example, the known adverse events for ZEJULA include thrombocytopenia, anemia and neutropenia and for brivanib (ZL-2301), the known adverse events include hyponatremia, AST elevation, fatigue, hand-foot skin reaction and hypertension. The results of our products' or drug candidates' trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, trials of our products or drug candidates could be suspended or terminated and the NMPA, FDA or comparable regulatory authorities could order us to cease further development of or deny approval of our products or drug candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, our products and drug candidates could cause undesirable side effects related to off-target toxicity. For example, many of the currently approved PARP inhibitors have been associated with off-target toxicities. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

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

- the NMPA, FDA or other comparable regulatory authorities may withdraw or limit their approval of such products or drug candidates;

- the NMPA, FDA or other comparable regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication;

- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

- we may be required to change the way such products or drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of our products or drug candidates;

- the NMPA, FDA or other comparable regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS (or analogous requirement), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;

- we may be subject to regulatory investigations and government enforcement actions;

- we may decide to remove such products or drug candidates from the marketplace;

- we could be sued and held liable for injury caused to individuals exposed to or taking our products or drug candidates; and

- our reputation may suffer.

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

If we are unable to obtain NMPA approval for our products and drug candidates to be eligible for an expedited registration pathway, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive Category 1 drug designation, it may not lead to a faster development, review or approval process.

The NMPA categorizes innovative drug applications as Category 1, provided such drug has a new and clearly defined structure, pharmacological property and apparent clinical value and has not been marketed anywhere in the world. Such innovative drugs will be attributed to Category 1 for their clinical trial application, or CTA, and NDA applications. Our CTAs for ZEJULA and omadacycline (ZL-2401) were approved as Category 1 drugs by the NMPA. A Category 1 designation by the NMPA may not be granted for any of our other drug candidates that will not be first approved in China or, if granted, such designation may not lead to faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our product or drug candidates will receive regulatory approval. Optune is a medical device and does not follow the NMPA drug categorization.

Furthermore, despite positive regulatory changes introduced since 2015 which significantly accelerated time to market for innovative drugs, the regulatory process in China is still relatively ambiguous and unpredictable. The NMPA might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

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

Even after obtaining regulatory approval, our products and drug candidates will be subject to, among other things, ongoing regulatory requirements governing the labeling, packaging, promotion, recordkeeping, data management and submission of safety, efficacy and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and GCPs. For example, ZEJULA and Optune will continue to be subject to post-approval development and regulatory requirements, which may limit how they are manufactured and marketed, and could materially impair our ability to generate revenue. As such, we and our partners and any of our and their respective contract manufacturers will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. Additionally, to the extent we want to make certain changes to the approved products, product labeling, or manufacturing processes, we will need to submit new applications or supplements to the Hong Kong Department of Health and the NMPA and obtain the agencies' approval.

Additionally, any additional regulatory approvals that we receive for our products or drug candidates may also be subject to limitations on the approved indicated uses for which the products or drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV studies for the surveillance and monitoring the safety and efficacy of the products or drug.

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

- restrictions on the marketing or manufacturing of the product or drug, withdrawal of the product or drug from the market, or voluntary or mandatory product or drug recalls;

- fines, warning letters or holds on clinical trials;

- refusal by the NMPA, FDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product or drug license approvals;

- drug seizure or detention, or refusal to permit the import or export of the product or drug; and

- injunctions or the imposition of civil, administrative or criminal penalties.

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

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

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our product and drug development strategy, including acquiring or in-licensing products or drug candidates and determining indications on which to focus in pre-clinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, their acceptance by the medical community and patient access, product and drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

The recent restructure of the drug regulatory authorities may delay approval of our products or drug candidates.

On March 17, 2018, China's highest legislative body, the National People's Congress, approved a sweeping government restructuring plan. This is generally considered to be the most comprehensive government restructuring that China has undertaken since its "Open Door" policy in the late 1970s. As part of the new plan, China has established a State Administration for Market Regulation, or SAMR, which merges and undertakes the responsibilities previously held by the China State Food and Drug Administration, or SFDA, the State Administration for Industry and Commerce, or SAIC, General Administration of Quality Supervision, Inspection and Quarantine, or AQSIQ, price supervision and antitrust enforcement responsibilities previously held by the National Development and Reform Commission, or NDRC, the antitrust enforcement responsibilities previously held by the Ministry of Commerce, or MOFCOM, and the Antimonopoly and Anti-Unfair Competition Bureau of State Council, as well as the responsibilities previously held by the Certification and Accreditation Administration, or CAC, and the Standardization Administration of China, or SAC.

The new NMPA reports to the SAMR, is responsible for the review and approval of drugs, medical devices and cosmetics, and maintains its own branches at the provincial level and leave the post-approval enforcement authorities at the local level to the consolidated SAMR branches.

Although the NMPA is fully functional as of 2019 and the restructuring at the state, municipal and county level authorities has been mostly completed as of July 2019, there could still be delays in the NMPA's implementation of the new reform initiatives and disruption in the NMPA's routine operations due to personnel reshuffling post-restructuring.

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

We are highly dependent on the expertise of the members of our research and development team, as well as the other principal members of our management, including Samantha Du, our founder, Chairwoman and Chief Executive Officer. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time with one months' prior written notice. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of certain of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing certain of our executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our management will be required to devote significant time to new compliance initiatives from our status as both a U.S. public company and a Hong Kong public company, which may require us to recruit more management personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

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

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of drug development, drug commercialization, regulatory affairs and business development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified

personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and have a materially adverse effect on our business.

In addition to in-licensing or acquiring drug candidates, we may engage in future business acquisitions that could disrupt our business, cause dilution to the holders of our Shares and/or ADSs and harm our financial condition and operating results.

We have, from time to time, evaluated partnership opportunities or investments and may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current drug candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute the percentage of ownership of the holders of our Shares and/or ADSs;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete partnership opportunities or investments on favorable terms, if at all. If we do enter into partnership opportunities or investments, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future partnership opportunities or investments could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more partnership opportunities or investments or effectively integrate the operations, products or personnel gained through any such partnership opportunities or investments without a material adverse effect on our business, financial condition and results of operations.

We may need to significantly concede on prices for ZEJULA, Optune or our other drug candidates and devices for which we may receive regulatory approval in China and face uncertainty of reimbursement, which could diminish our sales or affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceutical drugs and devices vary widely from country to country. In China, the newly created National Healthcare Security Administration, or NHSA, an agency responsible for administering China's social security system, organized a price negotiation with drug companies for 119 new drugs that had not been included in the National Reimbursable Drug List, or the NRDL, at the time of the negotiation in November 2019, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation. NHSA, together with other government authorities, review the inclusion or removal of drugs from the NRDL regularly, and the tier under which a drug or device will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. In November 2019, the NRDL was expanded to include 70 new drugs.

We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in China, but we will likely need to significantly reduce our prices, and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. If we were to successfully launch commercial sales of our oncology-based product and drug candidates, our revenue from such sales is largely expected to be self-paid by patients, which may make our drug candidates and devices less desirable. On the other hand, if the NHSA or any of its local counterpart includes our drugs and devices in the NRDL, which may increase the demand for our drug candidates and devices, our potential revenue from the sales of our drug candidates, if and when approved, and devices may still decrease as a result of lower prices. Eligibility for reimbursement in China does not imply that any drug or device will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution.

Moreover, the centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products, and we cannot assure you that our drug price would not be adversely affected. Also, the two-invoice system might lead to a decrease in the price of our products. For details, please refer to "Regulatory Environment – Coverage and Reimbursement – PRC Coverage and Reimbursement – Price Control and Two-invoice System."

Companies in China that manufacture or sell drugs and medical devices are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our drug candidates.

The life sciences industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including approval, registration, production, distribution, packaging, labelling, storage and shipment, advertising, licensing and certification requirements and procedures, periodic renewal and reassessment processes, registration of new products and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. In order to manufacture and distribute drug and medical device products in China, we are required to:

- obtain a manufacturing permit for each production facility from the NMPA and its relevant branches for the manufacture of drug and device products;

- obtain a marketing authorization, which includes an approval number, from the NMPA for each drug or device manufactured by us;

- obtain a pharmaceutical operation permit (or record filing) from the NMPA and its relevant branches; and

- renew the manufacturing permits, the distribution permits (or record-filing) and marketing authorizations every five years, among other requirements.

If we are unable to obtain or renew such permits or any other permits or licenses required for our operations, will not be able to engage in the commercialization, manufacture and distribution of our products and drug candidates and our business may be adversely affected.

The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. China government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services without incurring significant fiscal burden. The specific regulatory changes under the reform still remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the level we expect, if at all. Moreover, the reform could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

For further information regarding government regulation in China and other jurisdictions, see "Regulatory Environment – PRC Regulation of Pharmaceutical Product Development and Approval," "Regulatory Environment – Coverage and Reimbursement" and "Regulatory Environment – Other Healthcare Laws."

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

We face an inherent risk of product liability exposure related to the use of our products and drug candidates in clinical trials or any products or drug candidates we may decide to commercialize and manufacture. If we cannot successfully defend against claims that the use of such products or drug candidates in our clinical trials or any products that we procure from third-party manufacturers, or that we may choose to manufacture at our production facilities in the future, including any of our products or drug candidates which receive regulatory approval, caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Any litigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), product liability insurance to cover our product liability claims and general liability insurance to cover other commercial liability claims, these insurances may not fully cover our potential liabilities. Additionally, inability to obtain sufficient insurance coverage at an acceptable cost could prevent or inhibit the successful commercialization of products or drugs we develop, alone or with our collaborators.

The research and development projects under our internal discovery programs are at an early stage of development. As a result, we are unable to predict if or when we will successfully develop or commercialize any drug candidates under such programs.

Our internal discovery programs are at an early stage of development and will require significant investment and regulatory approvals prior to commercialization. Each of our drug candidates will require additional clinical and pre-clinical development, management of clinical, pre-clinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before they generate any revenue from product sales. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the NMPA, the FDA or comparable regulatory authorities, and we may never receive such regulatory approval for any such drug candidates.

We cannot be certain that clinical development of any drug candidates from our internal discovery programs will be successful or that we will obtain regulatory approval or be able to successfully commercialize any of our drug candidates and generate revenue. Success in pre-clinical testing does not ensure that clinical trials will be successful, and the clinical trial process may fail to demonstrate that our drug candidates are safe and effective for their proposed uses. Any such failure could cause us to abandon further development of any one or more of our drug candidates and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any NDAs with the NMPA, the FDA or comparable regulatory authorities and, ultimately, our ability to commercialize our drug candidates and generate product revenue.

If our manufacturing facilities are not approved by regulators, are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

In 2017, we built a small molecule facility capable of supporting clinical and commercial production, and in 2018, we built a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. We intend to rely on these facilities for the manufacture of clinical and commercial supply of some of our products or drug candidates. Prior to being permitted to sell any products or drugs produced at these facilities, the facilities will need to be inspected and approved by regulatory authorities. If either facility is not approved by regulators or is damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our manufacturing capabilities. In such event, we would be forced to identify and rely partially or entirely on third-party contract manufacturers for an indefinite period of time. Any new facility needed to replace an existing production facility would need to comply with the necessary regulatory requirements and be tailored to our production requirements and processes. We also would need regulatory approvals before using any products or drugs manufactured at a new facility in clinical trials or selling any products or drugs that are

ultimately approved. Any disruptions or delays at our facility or its failure to meet regulatory compliance would impair our ability to develop and commercialize our products or drug candidates, which would adversely affect our business and results of operations.

We may become involved in lawsuits to protect or enforce our intellectual property.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. If we are unable to protect our intellectual property, our competitors could use our intellectual property to market offerings similar to ours and we may not be able to compete effectively. Moreover, others may independently develop technologies that are competitive to ours or infringe on our intellectual property. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. We may not be able to prevent third parties from infringing upon or misappropriating our intellectual property, particularly in countries where the laws may not protect intellectual property rights as fully as in the United States. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. 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.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

The data privacy regime in China and in the United States are evolving and there may be more stringent compliance requirements for the collection, processing, use, and transfer of personal information and important data. In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or

service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues, and invite regulator's scrutiny. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We are subject to laws and government regulations relating to privacy and data protection that have required us to modify certain of our policies and procedures with respect to the collection and processing of personal data, and future laws and regulations may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

We may be subject to data privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the United States, there are numerous federal and state laws and regulations related to the privacy and security of personal information. For example, at the federal level, our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, collectively, HIPAA, which impose obligations on certain "covered entities" and their "business associates" with respect to the privacy and security and transmission of individually identifiable health information. Although we believe that we are not currently directly subject to HIPAA, HIPAA affects the ability of health care providers and other entities with which we may interact to disclose patient health information to us. As another example, at the state level, we are subject to the California Consumer Privacy Act, or CCPA, that became effective on January 1, 2020 and has been enforced by the California Attorney General since July 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose details about the personal information they collect, as well as other rights such as the right to ask companies to delete a consumer's personal information and opt out of the sale of personal information.

Numerous other jurisdictions regulate the privacy and security of personally identifiable data. For example, the General Data Protection Regulation, or GDPR, imposes obligations on companies that operate in our industry with respect to the processing of personal data collected in relation to an establishment located in the European Economic Area (EEA) or in connection with the offering goods and services to individuals located in the EEA or monitoring the behavior of individuals located in the EEA. GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If we or our service providers fail to comply with any applicable GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. GDPR additionally places restrictions on the cross-border transfer of personal data from the EEA to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the People's Republic of China and the United States. In July 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms

used to legitimize the transfer of personal data from the EEA to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S. This CJEU decision may lead to increased scrutiny on data transfers from the EEA to the U.S. generally and increase our costs of compliance with data privacy legislation. For further information regarding data privacy regulations in China, see "Regulatory Environment – PRC Regulation of Pharmaceutical Product Development and Approval – Data Privacy and Data Protection" of this prospectus.

We could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims under the laws described, as well as for alleged unfair or deceptive practices. If our operations are found to be in violation of any of the privacy laws, rules or regulations that apply to us, we could be subject to penalties, including civil penalties, damages, injunctive relief, and other penalties, which could adversely affect our ability to operate our business and our financial results. We will continue to review these and all future privacy and other laws and regulations to assess whether additional procedural safeguards are warranted, which may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

RISKS RELATED TO DOING BUSINESS IN CHINA

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce hazardous waste products. We are therefore subject to PRC laws and regulations concerning the discharge of waste water, gaseous waste and solid waste during our processes of research and development of drugs. We engage competent third party contractors for the transfer and disposal of these materials and wastes. We may not at all times comply fully with environmental regulations. Any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligation to take corrective measures. We cannot completely eliminate the risk of contamination or injury from these materials and wastes. In the event of contamination or injury resulting from the use or discharge of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil, administrative or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees, such insurance may not provide adequate coverage against potential liabilities. Furthermore, China government may take steps towards

the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our manufacturing facility and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations.

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

Substantially all of our operations are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China as well as China's economic, political, legal and social conditions in relation to the rest of the world. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. China's government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall economy in China, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, China's government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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

We conduct our business primarily through our subsidiaries in China. PRC laws and regulations govern our operations in China. Our subsidiaries are generally subject to laws and regulations applicable to foreign investments in China, which may not sufficiently cover all of the aspects of our economic activities in China. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not always be aware of any potential violation of these policies and rules. Such unpredictability regarding our contractual, property and procedural rights could adversely affect our business and impede our ability to continue our operations. Furthermore, since 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 could materially and adversely affect our business and results of operations.

In January 2015, the Ministry of Commerce of China, or the MOFCOM, published a discussion draft of the proposed Foreign Investment Law. The Foreign Investment Law passed the legislative review in March 2019, and came into effect on January 1, 2020. Foreign-invested entities will enjoy national treatment in industry sectors that are not prohibited or restricted from foreign investment. The Foreign Investment Law imposes information reporting requirements on foreign investors and the applicable foreign invested entities. Non-compliance with the reporting requirements will result in corrective orders and fines between RMB100,000 to 500,000. The Foreign Investment Law reinforces the duties of government authorities to protect intellectual property rights and trade secrets of foreign-investment entities. Government authorities cannot compel technology transfer by administrative means, reveal or provide trade secrets of foreign-invested entities to third parties. Last but not least, the Foreign Investment Law calls for the establishment of a foreign investment security review mechanism, details of which will be further developed by the Chinese government.

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

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

We are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery laws of other jurisdictions, particularly China. As our business continues to expand, the applicability of the FCPA and other anti-bribery laws to our operations will continue to increase. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

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

Our PRC subsidiaries' ability to obtain foreign exchange is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and/or registration with PRC government authorities, including the state administration of foreign exchange, or SAFE. In particular, if we finance our PRC subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local counterpart of the SAFE. If we finance our PRC subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the PRC Ministry of Commerce, or registration with other governmental authorities in China.

In the light of the various requirements imposed by PRC regulations on loans to, and direct investment in, PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government formalities or obtain the necessary government approvals on timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries. If we fail to complete such registrations or obtain such approval, our ability 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.

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

In 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or SAFE Circular 37. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by the PRC residents in the offshore special purpose vehicles or PRC companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle. If the shareholders of the offshore holding company who are PRC residents do not complete their

registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with SAFE registration and amendment requirements described above could result in liability under PRC law for evasion of applicable foreign exchange restrictions.

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

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

PRC regulations and rules concerning mergers and acquisitions including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, and other regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a 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. Moreover, according to the Anti-Monopoly Law of PRC promulgated on August 30, 2007 and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《國務院關於經營者集中申報標準的規定》) issued by the State Council in August 2008 and amended in September 2018, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the threshold is crossed

and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《商務部實施外國投資者併購境內企業安全審查制度的規定》) issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise "national defense and security" concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise "national security" concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises "national defense and security" or "national security" concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

It may be difficult for overseas regulators to conduct investigations or collect evidence within China.

Shareholder claims or regulatory investigation that are common in the United States generally are difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of mutual and practical cooperation mechanisms. Furthermore, according to Article 177 of the PRC Securities Law, or Article 177, 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. While detailed interpretations of or implementation rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase difficulties you may face in protecting your interests.

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

The Enterprise Income Tax Law (《中華人民共和國企業所得税法》), or the EIT Law, which was promulgated in March 2007, became effective in January 2008 and was amended in February 2017 and December 2018, and the Regulation on the Implementation of the EIT Law (《中華人民共和國企業所得税法實施條例》), effective as of January 1, 2008 and amended in April 2019, define the term "de facto management bodies" as "bodies that substantially carry out comprehensive management and control on the business operation, employees, accounts and assets of enterprises." Under the EIT Law, an enterprise incorporated outside of PRC whose "de facto management bodies" are located in PRC may be considered a "resident enterprise" and will be subject to a uniform 25% enterprise income tax, or EIT, rate on its global income. On April 22, 2009, PRC's State Administration of Taxation, or the SAT, in the Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》), or SAT Circular 82, further specified certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise may be regarded to have its "de facto management bodies" located in China and therefore be considered a PRC resident enterprise. These criteria include: (i) the enterprise's day-to-day operational management is primarily exercised in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in China; and (iv) 50% or more of voting board members or senior executives of the enterprise habitually reside in China. Although SAT Circular 82 only applies to foreign enterprises that are majority-owned and controlled by PRC enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in SAT Circular 82 may be adopted by the PRC tax authorities as the test for determining whether the enterprises are PRC tax residents, regardless of whether they are majority-owned and controlled by PRC enterprises.

We believe that neither Zai Lab Limited nor any of our subsidiaries outside of China 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." If the PRC tax authorities determine that Zai Lab Limited or any of its subsidiaries outside of China is a PRC resident enterprise for EIT purposes that entity would be subject to a 25% EIT on its global income. If such entity derives income other than dividends from its wholly-owned subsidiaries in China, a 25% EIT on its global income may increase our tax burden. Dividends paid to a PRC resident enterprise from its wholly-owned subsidiaries in China may be regarded as tax-exempt income if such dividends are deemed to be "dividends between qualified PRC resident enterprises"

under the EIT Law and its implementation rules. However, we cannot assure you that such dividends will not be subject to PRC withholding tax, as the PRC tax authorities, which enforce the withholding tax, have not yet issued relevant guidance.

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

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

We are a holding company, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of its respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiary is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, our PRC subsidiary may allocate a portion of its after-tax profits based on PRC accounting standards to a discretionary reserve fund.

Our PRC subsidiaries generate primarily all of their revenue in renminbi, which is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their renminbi revenues to pay dividends to us.

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

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

We and our Shareholders face uncertainties in the PRC with respect to indirect transfers of equity interests in PRC resident enterprises.

The indirect transfer of equity interest in PRC resident enterprises by a non-PRC resident enterprise, or Indirect Transfer, is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises (《國家税務總局關於非居民企業間接轉讓財產企業所得税若干問題的公告》), or SAT Circular 7, sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding PRC assets directly or indirectly in the course of a group's overseas restructuring, and the factors to consider in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under PRC laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the PRC taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in China, or 90% or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the PRC taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-PRC tax payable on the gain derived from the indirect transfer of the PRC taxable assets is lower than the potential PRC income tax on the direct transfer of such assets. Nevertheless, a non-resident enterprise's buying and selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 and will not be subject to PRC tax pursuant to SAT Circular 7. Under SAT Circular 7, the entities or individuals obligated to pay the transfer price to the transferor shall be the withholding agent and shall withhold the PRC tax from the transfer price. If the withholding agent fails to do so, the transferor shall report to and pay the PRC tax to the PRC tax authorities. In case neither the withholding agent nor the transferor complies with the obligations under SAT Circular 7, other than imposing

penalties such as late payment interest on the transferors, the tax authority may also hold the withholding agent liable and impose a penalty of 50% to 300% of the unpaid tax on the withholding agent. The penalty imposed on the withholding agent may be reduced or waived if the withholding agent has submitted the relevant materials in connection with the indirect transfer to the PRC tax authorities in accordance with SAT Circular 7.

However, as these rules and notices are relatively new and there is a lack of clear statutory interpretation, we face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchange or other transactions involving the transfer of shares in our company by investors that are non-PRC resident enterprises, or the sale or purchase of shares in other non-PRC resident companies or other taxable assets by us. Our company and other non-resident enterprises in our group may be subject to filing obligations or being taxed if our company and other non-resident enterprises in our group are transferors in such transactions, and may be subject to withholding obligations if our company and other non-resident enterprises in our group are transferees in such transactions. For the 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 the rules and notices. As a result, we may be required to expend valuable resources to comply with these rules and notices or to request the relevant transferors from whom we purchase taxable assets to comply, or to establish that our company and other non-resident enterprises in our group should not be taxed under these rules and notices, which may have a material adverse effect on our financial condition and results of operations. There is no assurance that the tax authorities will not apply the rules and notices to our offshore restructuring transactions where non-PRC residents were involved if any of such transactions were determined by the tax authorities to lack reasonable commercial purpose. As a result, we and our non-PRC resident investors may be at risk of being taxed under these rules and notices and may be required to comply with or to establish that we should not be taxed under such rules and notices, which may have a material adverse effect on our financial condition and results of operations or such non-PRC resident investors' investments in us. We may conduct acquisition transactions in the future. We cannot assure you that the PRC tax authorities will not, at their discretion, adjust any capital gains and impose tax return filing obligations on us or require us to provide assistance for the investigation of PRC tax authorities with respect thereto. Heightened scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on potential acquisitions we may pursue in the future.

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

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Stock Option Rules. In accordance with the Stock Option Rules and other relevant rules and regulations, PRC citizens or non-PRC citizens

residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. We plan to assist our employees to register their share options or shares. However, any failure of our PRC individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our PRC subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors and employees under PRC law.

Our auditor, like other independent registered public accounting firms operating in China, is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and consequently you are deprived of the benefits of such inspection.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including the independent registered public accounting firm of our company, must be registered with the PCAOB, and are required by the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Because substantially all of our operations are within China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditor is not currently inspected by the PCAOB.

In May 2013, the PCAOB entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or CSRC, and the Ministry of Finance, to establish a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by the PCAOB in the United States or the CSRC or the Ministry of Finance in the PRC. The PCAOB has announced that, since May 2013, cooperation has not been sufficient to enable the PCAOB to obtain timely access to relevant documents and testimony necessary to carry out its mission. The PCAOB continues to address these issues with Chinese regulators, and whether the PCAOB will obtain equivalent access remains an open issue.

In December 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 China. In April 2020, the SEC and the PCAOB issued another joint statement reiterating the greater risk that disclosures will be insufficient in many emerging markets, including China, 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 China, with respect to their audit work of U.S. reporting companies. However, it remains unclear what further actions, if any, the SEC and PCAOB will take to address the problem.

This lack of PCAOB inspections in China prevents the PCAOB from evaluating audits and quality control procedures of any auditors operating in China, including our auditor. As a result, investors may be deprived of the benefits of PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections. Additionally, the SEC, the U.S. Department of Justice and other authorities often have substantial difficulties in bringing and enforcing actions against non-U.S. persons and companies, including those based in China. Investors should understand the attendant risks. Further, as a result, investors may lose confidence in our reported financial information and procedures and the quality of our financial statements as a result thereof.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of Congress that would require the SEC to maintain a list of issuers for which the PCAOB is not able to inspect or investigate an auditor report issued by a foreign public accounting firm. The Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges (EQUITABLE) Act prescribes increased disclosure requirements for such issuers and, beginning in 2025, the delisting from national securities exchanges such as Nasdaq of issuers included for three consecutive years on the SEC's list. In May 2020, the U.S. Senate passed S. 945, the Holding Foreign Companies Accountable Act (the "Kennedy Bill"). If passed by the U.S. House of Representatives and signed by the U.S. President, the Kennedy Bill would amend 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. Enactment of any of such legislations or other efforts to increase U.S. regulatory access to audit information could cause uncertainty for affected issuers, including us. The market price of our Shares and/or ADSs could be adversely affected, and we could be delisted if we are unable to cure the situation to meet the PCAOB inspection requirement in time. It is unclear if and when any of such proposed legislations will be enacted. Furthermore, there have been recent media reports on deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On June 4, 2020, the U.S. President issued a memorandum ordering the President's Working Group on Financial Markets, or the PWG, to submit a report to the President that includes recommendations for actions that can be taken by the executive branch and by the SEC or PCAOB on Chinese 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. In particular, to address companies from non-cooperating jurisdictions, or NCJs, that do not provide the PCAOB with sufficient access to fulfill its statutory mandate, 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 condition as a result of governmental restrictions on access to audit work papers in NCJs may satisfy this condition 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 report permits the 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. If we fail to meet the listing standards, if adopted, before the deadline specified thereunder due to factors beyond our control, we could face possible de-listing from the Nasdaq, deregistration from the SEC and/or other risks, which may materially and adversely affect, or effectively terminate, our ADS trading in the United States.

Proceedings brought by the SEC against the Big Four PRC-based accounting firms, including our independent registered public accounting firm, could result in our inability to file future financial statements in compliance with the requirements of the U.S. Exchange Act.

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

In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major 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 U.S. Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, United States-listed companies and the market price of our Shares and/or ADSs may be adversely affected.

If the accounting firms are subject to additional remedial measures, our ability to file our financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed financial statements in compliance with SEC requirements would substantially reduce or effectively terminate the trading of our ADSs in the United States, which in turn may impair our ability to further raise equity financing in the capital markets of the United States and have a material adverse effect on our liquidity.

Certain of our investments may be subject to review from the Committee on Foreign Investment in the United States, or CFIUS, which may delay or block a transaction from closing.

The U.S. Congress has passed legislation that will expand the jurisdiction and powers of the CFIUS, the U.S. interagency committee that conducts national security reviews of foreign investment. President Trump signed the Foreign Investment Risk Review Modernization Act (FIRRMA) in August 2018. Pursuant to FIRRMA, investments in companies that deal in "critical technology" are subject to filing requirements and, in some instances, review and approval by CFIUS. The term "critical technology" includes, among others, technology subject to U.S. export controls and certain "emerging and foundational technology," a term that is still being defined but that is expected to include a range of U.S. biotechnology. If an investment by a foreign entity in a U.S. business dealing in "critical technology" meets certain thresholds, a filing with CFIUS is mandatory.

Accordingly, to the extent the U.S. portion of our business decides to take investments from foreign persons, such investments could be subject to CFIUS jurisdiction. To date, none of our investments have been subject to CFIUS review but, depending on the particulars of ongoing or future investments, we may be obligated to secure CFIUS approval before closing, which could delay the time period between signing and closing. If we determine that a CFIUS filing is not mandatory (or otherwise advisable), there is a risk that CFIUS could initiate its own review, if it determines that the transaction is subject to its jurisdiction. If an investment raises significant national security concerns, CFIUS has the authority to impose mitigation conditions or recommend that the President block a transaction.

Changes in U.S. and international trade policies and relations, particularly with regard to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that led to changes to U.S. and international trade policies and relations, including imposing several rounds of tariffs affecting certain products manufactured in China, as well as imposing certain sanctions and restrictions in relation to China. 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 China. Recently both China and the United States have each imposed further tariffs as well as certain sanctions and restrictions on each other, indicating the potential for further fallout between the two countries. It is unknown whether and to what extent new tariffs or other new executive orders, laws or regulations will be adopted, or the effect that any such actions would have on us or our

industry. We conduct preclinical and clinical activities and have business operations both in the U.S. and China, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. If any new tariffs, legislation, executive orders and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. or PRC governments takes retaliatory actions due to the recent U.S. – China tension, such changes could have an adverse effect on our business, financial condition and results of operations.

It may be difficult to enforce against us or our management in China any judgments obtained from foreign courts.

On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People's Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排), or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the Mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People's Court and the completion of the relevant legislative procedures in the Hong Kong. The New Arrangement will, upon its effectiveness, supersedes the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Furthermore, China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, most other western countries or Japan. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

We may be subject to fines due to the lack of registration of our leases.

Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we leased certain properties primarily as office space in China and did not register all of our lease agreements as tenant. We may be required by relevant governmental authorities to file these lease agreements for registration within a time limit, and may be subject to a fine for non-registration exceeding such time limit, which may range from RMB1,000 to RMB10,000 for each lease agreement. As of the Latest Practicable Date, we were not aware of any action, claim or investigation being conducted or threatened by the competent governmental authorities with respect to such defects in our leased properties.

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

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

RISKS RELATED TO INTELLECTUAL PROPERTY

If we are unable to obtain and maintain patent protection for our products and drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends, in part, on our ability to protect our products and drug candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the products and drug candidates and technology that we consider commercially important by filing PRC and international patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We also seek to protect our proprietary position by in-licensing intellectual property relating to our technology and drug candidates. We do not own or exclusively license any issued patents with respect to certain of our products and drug candidates in all territories in which we plan to commercialize our products and drug candidates. For example, we do not

own or exclusively license any issued patents covering ZEJULA in Macau. We do not own or exclusively license any issued patents covering margetuximab, tebotelimab and a pre-clinical multi-specific TRIDENT molecule in Macau or Taiwan, but we do non-exclusively in-license issued patents in China and Hong Kong and pending patent applications in China, Hong Kong or Taiwan covering them. We do not own or exclusively license any issued patents or pending patent applications covering Tumor Treating Fields in Hong Kong, Macau, or Taiwan, but we do exclusively license issued patents and pending patent applications covering Tumor Treating Fields in China. We do not own or exclusively license any issued patents covering retifanlimab, but we do in-license two pending patent applications relating to retifanlimab in China, 2 in Taiwan and 1 in Hong Kong. We in-license 1 issued patent in China and 1 in Taiwan, but we also in-license 1 pending patent application relating to durlobactam in China, 1 in Hong Kong, 1 in Taiwan. We cannot predict whether such patent applications or any of our other owned or in-licensed pending patent applications will result in the issuance of any patents that effectively protect our products and drug candidates. If we or our licensors are unable to obtain or maintain patent protection with respect to our products or drug candidates and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, our license and intellectual property-related agreements may not provide us with exclusive rights to use our in-licensed intellectual property rights relating to the applicable products and drug candidates in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. For example, under our agreements with GSK for ZEJULA, our licenses are limited to China, Hong Kong, and Macau. In the case of our agreements with Novocure for Tumor Treating Fields, Paratek for omadacycline (ZL-2401), Five Prime for bemarituzumab (FPA144), and MacroGenics for margetuximab, tebotelimab and a pre-clinical multi-specific TRIDENT molecule, our licenses are limited to China, Hong Kong, Macau, and Taiwan. Also, in the case of our agreement with Entasis for durlobactam, our license is limited to China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. In the case of our agreement with Deciphera for ripretinib, our license is limited to China, Hong Kong, Macau and Taiwan. In the case of our agreement with Incyte for retifanlimab, our licenses are limited to China, Hong Kong, Macau and Taiwan.

Patents may be invalidated and patent applications, including our in-licensed patent application relating to FPA144, Tumor Treating Fields, margetuximab, tebotelimab, durlobactam, a pre-clinical multi-specific TRIDENT molecule or retifanlimab as well as Regeneron's patents relating to odronextamab, may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, the PRC and, recently, the United States have adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology, which we invented.

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 China is required to report to the State Intellectual Property Office, or SIPO, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Moreover, even if patents do grant from any of the applications, the grant of a patent is not conclusive as to its scope, validity or enforceability.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, United States and abroad. We and our licensors and collaboration partners may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology, products or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products or drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we, or

one of our licensors or collaboration partners, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our or our licensor's or collaboration partner's invention or other features of patentability of our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, limit the duration of the patent protection of our technology, or limit the price at which we can sell our products and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology, products or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, the terms of patents are finite. The patents we own or in-license and the patents that may issue from our currently pending owned and in-licensed patent applications generally have a 20-year protection period starting from such patents and patent applications' earliest filing date. Given the amount of time required for the development, testing and regulatory review of products and new drug candidates, patents protecting such products and drug candidates might expire before or shortly after such products or drug candidates are commercialized. As a result, our owned or in-licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

We or our licensors or collaboration partners may become involved in patent litigation against third parties to enforce owned or in-licensed patent rights, to invalidate patents held by such third parties, or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that patents owned or in-licensed by us, our licensors or our collaboration partners do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent we or our licensors or collaboration partners have asserted against them is invalid or unenforceable. In patent litigation, defendant

counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, third parties may initiate legal proceedings before administrative bodies in the United States or abroad, even outside the context of litigation, against us or our licensors with respect to our owned or in-licensed intellectual property to assert such challenges to such intellectual property rights. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our products and drug candidates.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. Even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation.

An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one or more of our products or drug candidates, we would lose at least part, and perhaps all, of the patent protection covering such products or drug candidates. Competing products or drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products or drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property in the PRC.

The validity, enforceability and scope of protection available under the relevant intellectual property 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 China may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or our licensors to determine the

enforceability, scope and validity of our proprietary rights or those of others. As noted above, we may need to rely on our licensors to enforce and defend our technologies. The experience and capabilities of PRC courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management's attention from our operations, which could harm our business, financial condition and results of operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, maintaining and defending patents on products and drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or PRC or from selling or importing products made using our inventions in and into the United States, the PRC or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions, including China. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Furthermore, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the

value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Developments in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws in the United States, PRC and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, including changing the standards of patentability, and any such changes could have a negative impact on our business. For example, in the United States, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system as of March 2013, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post grant proceedings, including post grant review, *inter partes* review, and derivation proceedings. As a result of these changes, patent law in the United States may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions became effective in March 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications and our ability to obtain patents based on our discoveries and to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

In addition to the protection afforded by registered patents and pending patent applications, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We also seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties that have access to them, such as our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally disclosed or misappropriated our trade secrets, including through intellectual property litigations or other proceedings, is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts in China and other jurisdictions inside and outside the United States are less prepared, less willing or unwilling to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. For example, competitors could purchase our products and drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our intellectual property protecting such technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be disclosed or independently developed by a competitor, we would have no right to prevent them, or others to whom they communicate it, from using that technology or information to compete against us, which may have a material adverse effect on our business, prospects, financial condition and results of operations.

If our products or drug candidates infringe, misappropriate or otherwise violate the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to sell or commercialize these products and drug candidates.

Our commercial success depends significantly on our ability to develop, manufacture, market and sell our products and drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. In the PRC and the United States, invention patent applications are generally maintained in confidence until their

publication 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and invention patent applications are filed. Even after reasonable investigation, we may not know with certainty whether any third-party may have filed a patent application without our knowledge while we are still developing or producing that product. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any products or drug candidates we may develop, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any products or drug candidates we may develop and any other products, drug candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. There is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to:

- obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, if at all and even if we were able to obtain such licenses, they could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments;

- defend litigation or administrative proceedings;

- reformulate product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very expensive and time consuming;

- cease developing, manufacturing and commercializing the infringing technology, products or drug candidates; and

- pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. Even if we are successful in such litigations or administrative proceedings, such litigations and proceedings may be costly and could result in a substantial diversion of management resources. Any of the foregoing may have a material adverse effect on our business, prospects, financial condition and results of operations.

Intellectual property litigation and proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to our, our licensor's or other third parties' intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of competitors or their current or former employers or are in breach of non-competition or non-solicitation agreements with competitors or other third parties.

We could in the future be subject to claims that we or our employees, consultants or advisors have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of current or former employers, competitors or other third parties. Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not improperly use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer, competitor or other third parties.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our products and drug candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our products and drug candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products and drug candidates, which would have a material adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary intellectual property rights to drug candidates for our development pipeline through acquisitions and in-licenses.

Although we also intend to develop drug candidates through our own internal research, our near-term business model is predicated, in large part, on our ability to successfully identify and acquire or in-license drug candidates to grow our drug candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such drug candidates from third parties on commercially reasonable terms or at all, including because we are focusing on specific areas of care such as oncology and inflammatory and infectious diseases. In that event, we may be unable to develop or commercialize such drug candidates. We may also be unable to identify drug candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such drug candidates. Any of the foregoing could have a materially adverse effect on our business, financial condition, results of operations and prospects.

The in-licensing and acquisition of third-party intellectual property rights for drug candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for drug candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical

development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable drug candidates, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for drug candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for drug candidates on terms that would allow us to make an appropriate return on our investment.

If we or our licensors or collaboration partners do not obtain patent term extension and data exclusivity for our products or their products or any drug candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our products or any drug candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. The PRC has not established a patent term extension system, but the government proposed to grant patent term extension to new drugs for up to 5 years.

In China, there is currently no effective law or regulation providing for patent term extension, patent linkage, or data exclusivity. Therefore, a lower-cost generic or biosimilar drug can emerge onto the market more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime and for establishing a pilot program for patent term extension. To be implemented, this framework will require promulgation of laws, regulations and detailed implementation measures. To date, no laws, regulations or implementation measures have been promulgated and become effective. Consequently, the absence of currently effective laws and regulations on patent linkage, patent term extension and data exclusivity or the cancellation of the previous five-year administrative exclusivity for domestically manufactured new drugs could result in much weaker protection for us against generic competition in China. For instance, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review

process. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 gene therapy products that are similar to any product or drug candidates we may develop or utilize similar gene therapy technology but that are not covered by the claims of the patents that we license or may own in the future;

- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;

- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;

- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;

- the patents of others may harm our business; and

- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may discover certain technologies containing such trade secrets or know how through independent research and development and/or subsequently file a patent covering such intellectual property.

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

RISKS RELATED TO OUR SHARES, THE ADSS, THE LISTING AND THE GLOBAL OFFERING

As a company applying for listing under Chapter 19C and Chapter 18A, we adopt different practices as to certain matters as compared with many other companies listed on the Hong Kong Stock Exchange.

As we are applying for listing under Chapter 19C and Chapter 18A of the Listing Rules, we will not be subject to certain provisions of the Listing Rules pursuant to Rule 19C.11, including, among others, rules on notifiable transactions, connected transactions, share option schemes, content of financial statements as well as certain other continuing obligations. In addition, in connection with the Listing, we have applied for a number of waivers and/or exemptions from strict compliance with the Listing Rules, the Companies (WUMP) Ordinance, the Takeovers Codes and the SFO. As a result, we will adopt different practices as to those matters as compared with other companies listed on the Hong Kong Stock Exchange that do not enjoy those exemptions or waivers. For additional information, see "Waivers and Exemptions."

Furthermore, if 55% or more of the total worldwide trading volume, by dollar value, of our Shares and ADSs over our most recent fiscal year takes place on the Hong Kong Stock Exchange, the Hong Kong Stock Exchange will regard us as having a dual primary listing in Hong Kong and we will no longer enjoy certain exemptions or waivers from strict compliance with the requirements under the Listing Rules, the Companies (WUMP) Ordinance, the Takeovers Codes and the SFO, which could result in our incurring of incremental compliance costs.

The trading prices of our Shares and/or ADSs can be volatile, which could result in substantial losses to you.

The trading price of our Shares and/or ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. For example, from September 19, 2017 to the Latest Practicable Date, the closing price of our ADSs ranged from a high of US$89.48 to a low of US$14.29 per ADS. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in the PRC that have listed their securities in Hong Kong or the United States may affect the volatility in the price of and trading volumes for our Shares and/or ADSs. The securities of some of these companies have experienced significant volatility since their initial public offerings, including, in some cases, substantial price declines in the trading prices of their securities. The trading performances of these PRC companies' securities may affect the overall investor sentiment towards other PRC companies listed in Hong Kong or the United States and consequently may impact the trading performance of our Shares and/or ADSs, regardless of our actual operating performance. In addition, any negative news or perceptions about inadequate corporate governance practices or fraudulent accounting, corporate structure or matters of other Chinese companies may also negatively affect the attitudes of investors towards Chinese companies in general, including us, regardless of whether we have conducted any inappropriate activities.

In addition to market and industry factors, the price and trading volume for our Shares and/or ADSs may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;

- announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors;

- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;

- any adverse changes to our relationship with manufacturers or suppliers; the results of our testing and clinical trials;

- the results of our efforts to acquire or license additional drug candidates; variations in the level of expenses related to our existing products and drug candidates or preclinical, clinical development and commercialization programs;

- any intellectual property infringement actions in which we may become involved; announcements concerning our competitors or the pharmaceutical industry in general; fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages;

- variations in our results of operations; announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations; publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;

- changes in financial estimates by securities research analysts; media reports, whether or not true, about our business;

- additions to or departures of our management; fluctuations of exchange rates between the RMB, the U.S. dollar and Hong Kong dollar;

- release or expiry of lock-up or other transfer restrictions on our outstanding Shares or ADSs;

- sales or perceived potential sales of additional Shares or ADSs by us, our executive officers and directors or our Shareholders; general economic and market conditions and overall fluctuations in the U.S. or Hong Kong equity markets; changes in accounting principles; and

- changes or developments in the PRC or global regulatory environment.

Furthermore, the stock market, in general, and pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Shares and/or ADSs, regardless of our actual operating performance. Further, the current volatility in the financial markets and related factors beyond our control may cause the ordinary share and/or ADS price to decline rapidly and unexpectedly.

In addition, our directors and employees may face additional exposure to claims and lawsuits as a result of their position in other public companies. The existence of litigation, claims, investigations and proceedings against our directors and employees, even if they do not involve our company, may harm our reputation and adversely affect the trading price of our Shares and/or ADSs.

We may be at an increased risk of securities class action litigation.

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating results. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If we fail to maintain effective internal control over financial reporting in the future, our management and our independent registered public accounting firm may not be able to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of our Shares and/or ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, the ADSs may not be able to remain listed on Nasdaq.

While we currently enjoy exemptions afforded to a foreign private issuer, we will be subject to U.S. domestic issuer disclosure requirements beginning on January 1, 2021, which could result in significant additional costs and expenses.

We currently still enjoy certain exemptions afforded to a foreign private issuer for the year of 2020, during which period we are not required to comply with all of the periodic disclosure and current reporting requirements of the U.S. 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 currently 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 U.S. 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 Shares or ADSs.

In addition, as a foreign private issuer, we are currently permitted to take advantage of certain provisions in Nasdaq 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. We currently follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of Nasdaq in respect of the following: (i) the majority independent director requirement under Section 5605(b)(1) of Nasdaq rules, (ii) the requirement under Section 5605(d) of Nasdaq rules that a compensation committee comprised solely of independent directors governed by a compensation committee charter oversee executive compensation, (iii) the requirement under Section 5605(e) of Nasdaq rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors and (iv) the requirement under Section 5605(b)(2) of Nasdaq rules that our independent directors hold regularly scheduled executive sessions. Therefore, our Shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

However, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, in our case, June 30, 2020. We have determined that, as of July 1, 2020, more than 50% of our Shares were directly or indirectly held by residents of the U.S. and, therefore, we will file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on January 1, 2021, 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 U.S. Exchange Act beginning on January 1, 2021. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under Nasdaq rules described above beginning on January 1, 2021. 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.

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

We have never declared or paid any dividends on our Shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on their Shares and/or ADSs at least in the near term, and the success of an investment in our Shares and/or ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of our Shares and/or ADSs

after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that our Shares and/or ADSs will appreciate in value or even maintain the price at which our investors purchased the Shares and/or ADSs.

Fluctuations in the value of the renminbi may have a material adverse effect on our results of operations and the value of your investment.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. On July 21, 2005, China government changed its decade-old policy of pegging the value of the renminbi to the U.S. dollar, and the renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that China 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 China experienced persistent capital outflows. With the development of the foreign exchange market and progress towards interest rate liberalization and renminbi internationalization, the Chinese government may in the future announce further changes to the exchange rate system. There is no guarantee that the renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the renminbi and the U.S. dollar in the future.

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

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert renminbi into foreign currency.

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

Holders of our ADSs do not have the same rights as our Shareholders and may only exercise the voting rights with respect to the underlying Shares in accordance with the provisions of the deposit agreement. Under our Articles of Association, an annual general meeting and any extraordinary general meeting may be called with not less than seven days' notice. When a general meeting is convened, the holders of ADSs may not receive sufficient notice of a Shareholders' meeting to permit them to withdraw the Shares underlying their ADSs to allow them to vote with respect to any specific matter. If we ask for the instructions of the holders of ADSs, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date and the depositary will send a notice to the holders of ADSs about the upcoming vote and will arrange to deliver our voting materials to them. The depositary and its agents, however, may not be able to send voting instructions to the holders of ADSs or carry out their voting instructions in a timely manner. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to the holders of ADSs in a timely manner, but there can be no guarantee that the holders of ADSs will receive the voting materials in time to ensure that the holders of ADSs can instruct the depositary to vote the Shares underlying their ADSs. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. A holder or beneficial owner of ADSs may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if they wish us or the depositary to participate in legal proceedings. As a result, the holders of ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they request. In addition, in their capacity as an ADS holder, the holders of ADSs will not be able to call a Shareholders' meeting.

In addition, under the deposit agreement, if you do not vote, the depositary may give us a discretionary proxy to vote the ordinary shares underlying the ADSs at shareholders' meetings if we have timely provided the depositary with notice of meeting and related voting materials and with a brief statement as to the manner and timing in which voting instructions may be deemed to have been given in accordance with the depositary agreement if no instructions are received prior to the deadline set for such purposes to the depositary to give a discretionary proxy to a person designated by us.

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

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

Although we do not have any present plan to pay any dividends, the depositary of our ADSs has agreed to pay to the holders of ADSs the cash dividends or other distributions it or the custodian receives on Shares or other deposited securities underlying our ADSs, after

deducting its fees and expenses and any applicable taxes and governmental charges. The holders of ADSs will receive these distributions in proportion to the number of Shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but are not so properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, 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, Shares, rights or anything else to holders of ADSs. This means that the holders of ADSs may not receive distributions we make on our Shares or any value for them if it is illegal or impractical for us to make them available to the holders of ADSs. These restrictions may cause a material decline in the value of our ADSs.

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

We are a Cayman Islands company. Because judicial precedent regarding the rights of Shareholders is more limited under Cayman Islands law than under Hong Kong law or U.S. law, Shareholders may have fewer Shareholder rights than they would have under Hong Kong law or U.S. law and may face difficulties in protecting your interests.

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our Articles of Association (as may be further amended from time to time), the Companies Law (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of Shareholders to take action against the directors, actions by minority Shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The rights of our Shareholders and the fiduciary responsibilities of our

directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in Hong Kong and the United States. In particular, the Cayman Islands has a less developed body of securities law than the Hong Kong or United States In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our Shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of Shareholders of these companies with the exception that the Shareholders may request a copy of the Articles of Association. Our directors have discretion under our Articles of Association to determine whether or not, and under what conditions, our corporate records may be inspected by our Shareholders, but are not obliged to make them available to our Shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a Shareholder motion or to solicit proxies from other Shareholders in connection with a proxy contest. As a Cayman Islands company, we may not have standing to initiate a derivative action in a federal court of the United States. As a result, you may be limited in your ability to protect your interests if you are harmed in a manner that would otherwise enable you to sue in a Hong Kong or U.S. federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in Hong Kong or United States federal courts.

Some of our directors and executive officers reside outside of Hong Kong and the United States and a substantial portion of their assets are located outside of Hong Kong and the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the Cayman Islands or in China in the event that you believe that your rights have been infringed under the securities laws of Hong Kong, the United States or otherwise. In addition, some of our operating subsidiaries are incorporated in China. To the extent our directors and executive officers reside in China or their assets are located in China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if you are successful in bringing an action, the laws of the Cayman Islands and China may render you unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, Hong Kong or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the Board or controlling shareholders than they would as public shareholders of a Hong Kong company or a U.S. company.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are incorporated under the laws of the Cayman Islands and currently have subsidiaries in China, Hong Kong, the Cayman Islands, the United States, Australia and the British Virgin Islands. If we succeed in growing our business we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements

between us, our parent company and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

A tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

There can be no assurance that we will not be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for any taxable year, which could subject U.S. investors in our ADSs or shares to significant adverse U.S. federal income tax consequences.

In general, a non-U.S. corporation will be a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the value of its assets (generally determined on a quarterly average basis) consists of assets that produce, or are held for the production of, passive income (the "asset test"). For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes interest, dividends, gains from certain property transactions, rents and royalties (other than certain rents or royalties derived in the active conduct of a trade or business). For these purposes, cash is a passive asset and the value of a non-U.S. corporation's goodwill (which may be determined by reference to the excess of the sum of its market capitalization and liabilities over its booked assets) generally should be an active asset to the extent attributable to business activities that produce non-passive income.

Based on the current market price of our ADSs and our current and expected composition of income and assets, we do not expect to be a PFIC for our current taxable year. However, our assets other than goodwill are expected to consist primarily of cash and cash equivalents for

the foreseeable future. Therefore, whether we will satisfy the asset test for the current or any future taxable year will depend largely on the quarterly value of our goodwill (which may be determined by reference to the market price of our ADSs, which could be volatile given the nature and early stage of our business). If our market capitalization declines while we continue to hold a significant amount of cash (including cash raised in this offering) the risk that we will be a PFIC will increase. Furthermore, we may be a PFIC for any taxable year in which our interest and other investment income constitutes 75% or more of the sum of (i) such interest and investment income and (ii) the excess of our revenue over cost of goods sold. In addition, a company's PFIC status is an annual determination that can be made only after the end of each taxable year. Therefore, we cannot give any assurance as to whether we are a PFIC for the current or any future taxable year.

Subject to the discussion in the next paragraph, if we are or become a PFIC, U.S. investors generally would be subject to adverse U.S. federal income tax consequences, such as increased tax liabilities on capital gains and certain distributions, and interest charges on taxes deemed to be deferred. If we are a PFIC for any taxable year during which a U.S. investor owns ADSs or shares, we will generally continue to be treated as a PFIC with respect to such investor for all succeeding years during which the investor own ADSs or shares (unless the investor timely makes a valid "deemed sale" election), even if we cease to meet the threshold requirements for PFIC status. A mark-to-market election may be available with respect our ADSs, which would result in U.S. federal income tax consequences to holders of our ADSs that are different from those described above.

U.S. investors would be subject to alternative treatment if we are a PFIC for any taxable year and we provide the information necessary to make a qualified electing fund ("QEF") election. If we determine at our discretion that we were a PFIC for any taxable year, we intend to provide to U.S investors, following their request, the information necessary for them to make a QEF election with respect to us. U.S. investors that make the QEF election for the first taxable year that we are a PFIC will be taxed on a current basis on their pro rata share of our ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that we are a PFIC. Any distributions paid by us out of our earnings and profits that were previously included in the U.S. investor's income under the QEF election would not be taxable to such investors. U.S. investors will increase their tax basis in their ADSs or shares by an amount equal to any income included under the QEF election and will decrease their tax basis by any amount distributed on the ADSs or shares that is not included in income. U.S. investors should consult their tax advisors regarding the consequences of making a valid and timely QEF election if we are a PFIC.

If a U.S. investor owns ADSs or shares during any year in which we are a PFIC, such investor generally will be required to file annual reports on IRS Form 8621 (or any successor form) with respect to us, generally with their U.S. federal income tax return for that year. U.S. investors should consult their tax advisors regarding the determination of whether we are a PFIC for any taxable year and the potential application of the PFIC rules.

Holders of our Shares and/or ADSs may have difficulty enforcing judgments obtained against us.

We are a company incorporated under the laws of the Cayman Islands, and substantially all of our assets are located outside the United States. Substantially all of our current operations are conducted in the PRC. In addition, some of our directors and officers are nationals and residents of countries or regions other than the United States or Hong Kong. A substantial portion of the assets of these persons are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States or Hong Kong upon these persons, or to bring an action against us or against these individuals in the United States or Hong Kong in the event that they believe that their rights have been infringed under the U.S. federal securities laws, Hong Kong laws or otherwise. Even if shareholders are successful in bringing an action of this kind, the laws of the Cayman Islands and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. There is uncertainty as to whether the courts of the Cayman Islands or China would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under China Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of China Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of reciprocity with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to China Civil Procedures Law, China courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC laws 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.

Holders of ADSs may be subject to limitations on transfers of their ADSs.

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

Substantial future sales or perceived potential sales of our Shares, ADSs, or other equity or equity-linked securities in the public market could cause the price of our Shares and/or ADSs to decline.

Sales of our Shares, ADSs, or other equity or equity-linked securities in the public market, or the perception that these sales could occur, could cause the market price of our Shares and/or ADSs to decline significantly. All of our Shares represented by ADSs were freely transferable by persons other than our affiliates without restriction or additional registration under the U.S.

Securities Act. The Shares held by our affiliates are also available for sale, subject to volume and other restrictions as applicable under Rule 144 of the U.S. Securities Act, under trading plans adopted pursuant to Rule 10b5-1 or otherwise.

Divestiture in the future of our Shares and/or ADSs by Shareholders, the announcement of any plan to divest our Shares and/or ADS, or hedging activity by third-party financial institutions in connection with similar derivative or other financing arrangements entered into by Shareholders, could cause the price of our Shares and/or ADSs to decline.

Furthermore, although all of our directors and executive officers have agreed to a lock-up of their Shares, any major disposal of our Shares and/or ADSs by any of them upon expiration of the relevant lock-up periods (or the perception that these disposals may occur upon the expiration of the lock-up period) may cause the prevailing market price of our Shares and/or ADSs to fall which could negatively impact our ability to raise equity capital in the future.

The different characteristics of the capital markets in Hong Kong and the U.S. may negatively affect the trading prices of our Shares and/or ADSs.

Upon the Listing, we will be subject to Hong Kong and Nasdaq listing and regulatory requirements concurrently. The Hong Kong Stock Exchange and Nasdaq have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our Shares and our ADSs may not be the same, even allowing for currency differences. Fluctuations in the price of our ADSs due to circumstances peculiar to the U.S. capital markets could materially and adversely affect the price of our Shares, or vice versa. Certain events having significant negative impact specifically on the U.S. capital markets may result in a decline in the trading price of our Shares notwithstanding that such event may not impact the trading prices of securities listed in Hong Kong generally or to the same extent, or vice versa. Because of the different characteristics of the U.S. and Hong Kong capital markets, the historical market prices of our ADSs may not be indicative of the trading performance of our Shares after the Global Offering.

Exchange between our Shares and our ADSs may adversely affect the liquidity and/or trading price of each other.

Our ADSs are currently traded on Nasdaq. Subject to compliance with U.S. securities law and the terms of the Deposit Agreement, holders of our Shares may deposit Shares with the depositary in exchange for the issuance of our ADSs. Any holder of ADSs may also withdraw the underlying Shares represented by the ADSs pursuant to the terms of the Deposit Agreement for trading on the Hong Kong Stock Exchange. In the event that a substantial number of Shares are deposited with the depositary in exchange for ADSs or vice versa, the liquidity and trading price of our Shares on the Hong Kong Stock Exchange and our ADSs on Nasdaq may be adversely affected.

The time required for the exchange between our Shares and ADSs might be longer than expected and investors might not be able to settle or effect any sale of their securities during this period, and the exchange of Shares into ADSs involves costs.

There is no direct trading or settlement between Nasdaq and the Hong Kong Stock Exchange on which our ADSs and our Shares are respectively traded. In addition, the time differences between Hong Kong and New York and unforeseen market circumstances or other factors may delay the deposit of Shares in exchange of ADSs or the withdrawal of Shares underlying the ADSs. Investors will be prevented from settling or effecting the sale of their securities during such periods of delay. In addition, there is no assurance that any exchange of Shares into ADSs (and vice versa) will be completed in accordance with the timelines investors may anticipate.

Furthermore, the depositary for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of Shares, cancelation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs and annual service fees. As a result, Shareholders who exchange Shares into ADSs, and vice versa, may not achieve the level of economic return the Shareholders may anticipate.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, the market price for our Shares and/or ADSs and trading volume could decline.

The trading market for our Shares and/or ADSs relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades our Shares and/or ADSs or publishes inaccurate or unfavorable research about our business, the market price for our Shares and/or ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for the Shares and/or ADSs to decline significantly.

As the public offering price is higher than our net tangible book value per ordinary share, you will incur immediate and substantial dilution.

If you purchase Shares in the Global Offering, you will pay more for your Shares than the amount paid by existing holders for their Shares or ADSs on a per ordinary share basis. As a result, you will experience immediate and substantial dilution after giving effect to the Global Offering. In addition, you will experience further dilution to the extent that our Shares are issued upon the exercise of share options or vesting of restricted share units. All of the Shares issuable upon the exercise of currently outstanding share options will be issued at a purchase price on a per ordinary share basis that is less than the public offering price per ordinary share in the Global Offering.

An active trading market for our Shares on the Hong Kong Stock Exchange might not develop or be sustained and trading prices of our Shares might fluctuate significantly.

Following the completion of the Global Offering, we cannot assure you that an active trading market for our Shares on the Hong Kong Stock Exchange will develop or be sustained. The trading price or liquidity for our ADSs on Nasdaq might not be indicative of those of our Shares on the Hong Kong Stock Exchange following the completion of the Global Offering. If an active trading market of our Shares on the Hong Kong Stock Exchange does not develop or is not sustained after the Global Offering, the market price and liquidity of our Shares could be materially and adversely affected.

In 2014, the Hong Kong, Shanghai and Shenzhen Stock Exchanges collaborated to create an inter-exchange trading mechanism called Stock Connect that allows international and mainland Chinese investors to trade eligible equity securities listed in each other's markets through the trading and clearing facilities of their home exchange. Stock Connect currently covers over 2,000 equity securities trading in the Hong Kong, Shanghai and Shenzhen markets. Stock Connect allows mainland Chinese investors to trade directly in eligible equity securities listed on the Hong Kong Stock Exchange, known as Southbound Trading; without Stock Connect, mainland Chinese investors would not otherwise have a direct and established means of engaging in Southbound Trading. The ineligibility or any delay of our Shares for trading through Stock Connect will affect mainland Chinese investors' ability to trade our Shares and therefore may limit the liquidity of the trading of our Shares on the Hong Kong Stock Exchange.

Since there will be a gap of several days between pricing and trading of our Shares, the price of our ADSs traded on Nasdaq may fall during this period and could result in a fall in the price of our Shares to be traded on the Hong Kong Stock Exchange.

The pricing of the Offer Shares will be determined on the Price Determination Date. However, our Shares will not commence trading on the Hong Kong Stock Exchange until they are delivered, which is expected to be about four Hong Kong business days after the Price Determination Date. As a result, investors may not be able to sell or otherwise deal in our Shares during that period. Accordingly, holders of our Shares are subject to the risk that the trading price of our Shares could fall when trading commences as a result of adverse market conditions or other adverse developments that could occur between the Price Determination Date and the time trading begins. In particular, as our ADSs will continue to be traded on Nasdaq and their price can be volatile, any fall in the price of our ADSs may result in a fall in the price of our Shares to be traded on the Hong Kong Stock Exchange.

There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of our ADSs following our initial public offering in Hong Kong and Listing of our Shares on the Hong Kong Stock Exchange.

In connection with our initial public offering of Shares in Hong Kong, or the Hong Kong IPO, we will establish a branch register of members in Hong Kong, or the Hong Kong share register. Our Shares that are traded on the Hong Kong Stock Exchange, including those to be issued in the Hong Kong IPO and those that may be converted from ADSs, will be registered on the Hong Kong share register, and the trading of these Shares on the Hong Kong Stock Exchange will be subject to the Hong Kong stamp duty. To facilitate ADS-ordinary share conversion and trading between Nasdaq and the Hong Kong Stock Exchange, we also intend to move a portion of our issued Shares from our register of members maintained in the Cayman Islands to our Hong Kong share register.

Under the Hong Kong Stamp Duty Ordinance, any person who effects any sale or purchase of Hong Kong stock, defined as stock the transfer of which is required to be registered in Hong Kong, is required to pay Hong Kong stamp duty. The stamp duty is currently set at a total rate of 0.2% of the greater of the consideration for, or the value of, shares transferred, with 0.1% payable by each of the buyer and the seller. To the best of our knowledge, Hong Kong stamp duty has not been levied in practice on the trading or conversion of ADSs of companies that are listed in both the United States and Hong Kong and that have maintained all or a portion of their ordinary shares, including ordinary shares underlying ADSs, in their Hong Kong share registers. However, it is unclear whether, as a matter of Hong Kong law, the trading or conversion of ADSs of these dual-listed companies constitutes a sale or purchase of the underlying Hong Kong-registered ordinary shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. If Hong Kong stamp duty is determined by the competent authority to apply to the trading or conversion of our ADSs, the trading price and the value of your investment in our Shares and/or ADSs may be affected.

There can be no assurance of the accuracy or completeness of certain facts, forecasts and other statistics obtained from various independent third party sources, including the industry expert reports, contained in this prospectus.

This prospectus, particularly the sections headed "Business" and "Industry Overview," contains information and statistics relating to the global and China oncology drug markets. Such information and statistics have been derived from a third-party report commissioned by us and publicly available sources. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, we cannot guarantee the quality or reliability of such source materials. The information has not been independently verified by us, the Joint Sponsors, the Joint Representatives, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, or any other party involved in the Global Offering, and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics included in this prospectus being inaccurate or not

comparable to statistics produced for other economies. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. You should consider carefully the importance placed on such information or statistics.

You should read the entire document carefully and should not rely on any information contained in press articles or other media regarding us and the Global Offering. We strongly caution you not to rely on any information contained in press articles or other media regarding us and the Global Offering. Prior to the publication of this prospectus, there has been press and media coverage regarding us and the Global Offering. Such press and media coverage may include references to certain information that does not appear in this prospectus, including certain operating and financial information and projections, valuations and other information. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for any such press or media coverage or the accuracy or completeness of any such information or publication. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. To the extent that any such information is inconsistent or conflicts with the information contained in this prospectus, we disclaim responsibility for it and you should not rely on such information.

You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the Global Offering.

Subsequent to the date of this prospectus but prior to the completion of the Global Offering, there may be press and media coverage regarding us and the Global Offering, which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the Global Offering. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this prospectus, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this prospectus only and should not rely on any other information.

In preparation for the Listing, we have sought the following waivers and exemptions from strict compliance with the relevant provisions of the Listing Rules, the SFO and the Companies (WUMP) Ordinance and have applied for a ruling under the Takeovers Code:

No.	Rules	Subject matter
1.	Rule 2.07A of the Listing Rules	Printed Corporate Communications
2.	Rules 4.04(3)(a), 4.05(2) and 4.13 of the Listing Rules and Paragraph 31(3)(b) of the Third Schedule to the Companies (WUMP) Ordinance	Disclosure Requirements Relating to the Accountants' Report
3.	Paragraphs 27 and 31 of the Third Schedule to the Companies (WUMP) Ordinance	Disclosure of Financial Results for Two Financial Years in the Accountants' Report
4.	Rule 9.09(b) of the Listing Rules	Dealings in Shares prior to Listing
5.	Rule 10.04 and Paragraph 5(2) of Appendix 6 to the Listing Rules	Subscription for Shares by Existing Shareholders
6.	Rules 12.04(3), 12.07 and 12.11 of the Listing Rules	Printed Prospectuses
7.	Rule 13.25B of the Listing Rules	Monthly Return
8.	Rules 19C.07(1), 19C.07(3), 19C.07(4) and 19C.07(7) of the Listing Rules	Shareholder Protection Requirements in Relation to Changes to Class Rights, Approval, Removal and Remuneration of Auditors, Annual General Meeting and Requisition of Extraordinary General Meeting by Shareholders
9.	Paragraph 27 of Appendix 1A to the Listing Rules and Paragraph 10 of the Third Schedule to the Companies (WUMP) Ordinance	Disclosure Requirements of Options
10.	Guidance Letter HKEX-GL37-12	Timing Requirement of Liquidity Disclosure

No.	Rules	Subject matter
11.	Paragraphs 33(2), 33(3), 46(2), 46(3) of Appendix 1A to the Listing Rules	Disclosure Requirements of the Remuneration of Directors and Five Individuals Whose Emoluments Were Highest
12.	Section 4.1 of the Introduction to the Takeovers Code	Determination of Whether a Company is a "Public Company in Hong Kong"
13.	Part XV of the SFO	Disclosure of Interests
14.	Paragraphs 41(4) and 45 of Appendix 1A to and Practice Note 5 of the Listing Rules	Disclosure of Interests Information
15.	Paragraph 15(2)(c) of Appendix 1A to the Listing Rules	Disclosure of Offer Price
16.	Paragraph 4.2 of Practice Note 18 of the Listing Rules	Clawback Mechanism
17.	Rule 13.48(1) and Practice Note 10 of the Listing Rules	Publication of Interim Report

PRINTED CORPORATE COMMUNICATIONS

Rule 2.07A of the Listing Rules provides that a listed issuer may send or otherwise make available to the relevant holders of its securities any corporate communication by electronic means, provided that either the listed issuer has previously received from each of the relevant holders of its securities an express, positive confirmation in writing or the shareholders of the listed issuer have resolved in a general meeting that the listed issuer may send or supply corporate communications to shareholders by making them available on the listed issuer's own website or the listed issuer's constitutional documents contain provision to that effect, and certain conditions are satisfied.

Our ADSs have been listed on Nasdaq since 2017. We have a diverse shareholder base with ADS holders globally.

We do not currently produce or send out any corporate communications to our shareholders or holders of ADSs in printed form unless requested or in limited circumstances. We publicly file or furnish various corporate communications with the SEC which are posted on the SEC's website. Our annual reports on Form 20-F and current reports on Form 6-K and all amendments to these reports are also available free of charge on our website as soon as

reasonably practicable after they are filed with or furnished to the SEC. Further, we will post our proxy materials and notices to our shareholders and holders of ADSs on a publicly accessible website. In addition, the depositary bank which administers our ADS program will send a notice as well as an ADS voting instruction card to our ADS holders.

Apart from the Hong Kong Offer Shares that we will offer for subscription by the public in Hong Kong, the International Offer Shares will be placed to professional, institutional, corporate and other investors in Hong Kong and elsewhere in the world. Given our diverse shareholder base and the potential number of countries in which our shareholders are located, we consider that it would not be practicable for us to send printed copies of all our corporate communications to all of our shareholders. Further, we consider that it would also not be practicable for us to approach our existing shareholders individually to seek confirmation from them of their wish to receive corporate communications in electronic form, or to provide them with the right to request corporate communications in printed form instead.

We have applied for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with Rule 2.07A of the Listing Rules on the conditions that we will:

(a) issue all future corporate communications as required by the Listing Rules on our own website in English and Chinese, and on the Hong Kong Stock Exchange's website in English and Chinese;

(b) provide printed copies of proxy materials in English and/or Chinese to our shareholders at no cost upon request; and

(c) ensure that the "Investor Relations" page of our website (**http://www.zailaboratory.com**) will direct investors to all of our future filings with the Hong Kong Stock Exchange.

DISCLOSURE REQUIREMENTS RELATING TO THE ACCOUNTANTS' REPORT

Rules 4.04(3)(a), 4.05(2) and 4.13 of the Listing Rules and Paragraph 31(3)(b) of the Third Schedule to the Companies (WUMP) Ordinance set out certain historical financial information to be included in a listing document that is not required to be disclosed under U.S. GAAP, including in particular:

(a) balance sheet at a company level;

(b) aging analysis of accounts receivables;

(c) aging analysis of accounts payables; and

(d) adjustments made to show profits of all periods in accordance with the relevant accounting standards in relation to the last fiscal year reported on.

In accordance with U.S. GAAP, we have applied the modified retrospective method or prospective method to account for the impact of the adoption of certain new accounting standards in the Track Record Period. Under the modified retrospective method and prospective method adopted by our Group, comparative periods in the latest consolidated financial statements are not retrospectively adjusted.

During the Track Record Period, we adopted, among other new accounting standards that did not have a material impact on our consolidated financial statements, Accounting Standards Update 2014-09 "*Revenue from Contracts with Customers (Topic 606)*" and related amendments and implementation guidance, or ASC 606, and Accounting Standards Update 2016-02 "*Leases*" *(Topic 842)* including certain transitional guidance and subsequent amendments, or ASC 842, and Accounting Standards Update 2016-13 "*Credit Losses, Measurement of Credit Losses on Financial Instruments*" including related technical corrections and improvements, or ASU 2016-13. The relevant accounting policies upon the adoption of these new accounting standards are disclosed in the Accountants' Report set out in Appendix I to this prospectus.

ASC 606 was adopted beginning January 1, 2018 using the modified retrospective transition method. Given there was no revenue for the periods before January 1, 2018, there were no transition adjustments. Under ASC 606, the Group recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration expected to be received in exchange for those goods or services.

ASC Topic 842, Leases was adopted on January 1, 2019 using the modified retrospective transition approach by applying the new lease standard to all leases existing as of January 1, 2019, the date of initial application, and no adjustments were made to the comparative periods. Adoption of the new lease standard resulted in the recognition of operating lease right-of-use assets and operating lease liabilities on the consolidated balance sheet as of January 1, 2019. The adoption of the new lease standard does not have any significant impact on the consolidated statements of operations and comprehensive income and cash flows of the Group and there was no adjustment to the beginning retained earnings on January 1, 2019.

ASU 2016-13 was adopted on January 1, 2020 using the modified retrospective transition approach. ASU 2016-13 replaces the existing impairment model for most financial assets from an incurred loss impairment model to a current expected credit loss model, which requires an entity to recognize an impairment allowance equal to its current estimate of all contractual cash flows the entity does not expect to collect. Based on the composition of the Group's trade receivables and investment portfolio,the adoption does not have any significant impact on the consolidated statements of operations and comprehensive income and cash flows of the Group and there was no adjustment to the beginning retained earnings on January 1, 2020.

As alternative disclosures with respect to certain items identified above which are relevant to us, the accounting policies for the adoption of ASC 606, ASC 842 and ASU 2016-13 as well as the impact of adoption, if any, are disclosed under notes 2(s), 2(l), 2(g) and 2(ab) respectively in the Accountants' Report set out in Appendix I to this prospectus.

As this prospectus has included the above alternative disclosures and the current disclosure contains all information which is necessary for investors to make an informed assessment of the business, asset and liability, financial position, trading position, management and prospect of our Group, we believe that it would be of no material value to the Hong Kong investors and be unduly burdensome for the Accountants' Report in Appendix I to include

certain required information pursuant to Rules 4.04(3)(a), 4.05(2) and 4.13 of the Listing Rules and Paragraph 31(3)(b) of the Third Schedule to the Companies (WUMP) Ordinance and that the non-disclosure of such information will not prejudice the interests of investors.

We have applied for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with the requirements under Rules 4.04(3)(a), 4.05(2) and 4.13 of the Listing Rules. We have applied for, and the SFC has granted, an exemption from the requirements under Paragraph 31(3)(b) of the Third Schedule to the Companies (WUMP) Ordinance. The SFC has granted an exemption referred to above on the conditions that: (i) the particulars of such exemption are set out in this prospectus and (ii) this prospectus will be issued on or before September 17, 2020.

DISCLOSURE OF FINANCIAL RESULTS FOR TWO FINANCIAL YEARS IN THE ACCOUNTANTS' REPORT

According to paragraph 27 of Part I of the Third Schedule to the Companies (WUMP) Ordinance, we are required to include in the prospectus a statement as to our gross trading income or sales turnover (as the case may be) during each of the three financial years immediately preceding the issue of this prospectus as well as an explanation of the method used for the computation of such income or turnover and a reasonable breakdown of the more important trading activities.

According to paragraph 31 of Part II of the Third Schedule to the Companies (WUMP) Ordinance, we are required to include in this prospectus a report prepared by our auditor with respect to our profits and losses and assets and liabilities in respect of each of the three financial year immediately preceding the issue of this prospectus.

According to Rule 4.04(1) of the Listing Rules, the Accountants' Report contained in the prospectus must include, inter alia, our results in respect of each of the three financial years immediately preceding the issue of the prospectus or such shorter period as may be acceptable to the Stock Exchange.

According to Rule 18A.06 of the Listing Rules, an eligible biotech company shall comply with Rule 4.04 modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years," as the case may be.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants' Report set out in Appendix I to this prospectus cover the two financial years ended December 31, 2018, 2019 and the six months ended June 30, 2020.

We have applied for, and the SFC has granted, an exemption from the requirements under Paragraphs 27 and 31 of the Third Schedule to the Companies (WUMP) Ordinance on the following grounds and on the conditions that particulars of the exemption are set out in this prospectus and that this prospectus will be issued on or before September 17, 2020:

(a) we are primarily engaged in the research and development, application and commercialisation of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. We will fulfill the additional conditions for listing required under Chapter 18A;

(b) the Accountants' Report for each of the two financial years ended December 31, 2018 and 2019 has been prepared and is set out in Appendix I to this prospectus in accordance with Rule 18A.06 of the Listing Rules;

(c) notwithstanding that the financial results set out in this prospectus are only for the two years ended December 31, 2018 and 2019 and the six months ended June 30, 2020 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (WUMP) Ordinance has been adequately disclosed in this prospectus pursuant to the relevant requirements (except for those for which an exemption has been sought). Strict compliance with section 342(1)(b) of the Companies (WUMP) Ordinance in relation to the requirements of paragraphs 27 and 31 of the Third Schedule to the Companies (WUMP) Ordinance would be unduly burdensome, as this would require additional work to be performed by us and the reporting accountants; and

(d) the Accountants' Report covering the two financial years ended December 31, 2018 and 2019 and the six months ended June 30, 2020 (as set out in Appendix I to this prospectus), together with other disclosure in this prospectus, have already provided adequate and reasonable up-to-date information in the circumstances for the potential investors to make an informed assessment of our business, assets and liabilities, financial position, management and prospects and to form a view on our track record. Therefore, the exemption would not prejudice the interest of the investing public.

DEALINGS IN SHARES PRIOR TO LISTING

According to Rule 9.09(b) of the Listing Rules, there must be no dealing in the securities of a new applicant for which listing is sought by any core connected person of the issuer from four clear business days before the expected hearing date until listing is granted (the "Relevant Period").

Our ADSs are widely held, publicly traded and listed on Nasdaq. We are therefore not in a position to control the investment decisions of our shareholders or the investing public in the U.S. Solely based on public filings with the SEC as of the Latest Practicable Date, other than QM11 Limited, there are no shareholders who hold more than 10% of our total issued share capital.

In addition, for a company whose securities are listed and traded in the U.S., it is common practice for substantial shareholders and corporate insiders, including directors, executives and other members of management, to set up trading plans that meet the requirements of Rule 10b5-1 under the U.S. Exchange Act (the "**Rule 10b5-1 Plans**") to buy or sell the company's securities. A Rule 10b5-1 Plan is a written plan, set up with a broker, to trade securities that (a) is entered into at a time when the person trading the securities is not aware of any material non-public information; (b) specifies the amount of securities to be purchased or sold and the price at which and the date on which the securities were to be purchased or sold; and (c) does not allow the person trading the securities to exercise any subsequent influence over how, when, or whether to effect purchases or sales. Persons who trade securities pursuant to a Rule 10b5-1 Plan have an affirmative defense against insider trading allegations under U.S. securities law.

On the basis of the above, we consider that the following categories of persons (collectively, the "Permitted Persons") should not be subject to the dealing restrictions set out in Rule 9.09(b) of the Listing Rules:

(a) all directors and chief executive of our Company and our subsidiaries in respect of their respective dealings pursuant to the Rule 10b5-1 Plans which they have set up prior to the Relevant Period ("Category 1");

(b) our directors and chief executive, and the directors and chief executives of our Significant Subsidiaries and their close associates, only in respect of their respective use of the Shares as security (including, for the avoidance of doubt, using Shares as security in connection with entering into financing transactions during the Relevant Period as well as satisfying any requirements to top-up security under the terms of financing transactions entered into prior to the Relevant Period), provided that there will be no change in the beneficial ownership of the Shares at the time of entering into any such transactions during the Relevant Period ("Category 2");

(c) directors, chief executives and substantial shareholders of our non-Significant Subsidiaries and their close associates, other than those in Categories 1 and 2 ("Category 3"); and

(d) any other person (whether or not an existing Shareholder) who may, as a result of dealings, become our substantial shareholder and who is not our director or chief executive, or a director or chief executive of our subsidiaries, or their close associates ("Category 4").

For the avoidance of doubt,

(a) as the foreclosure, enforcement or exercise of other rights by the lenders in respect of a security interest over the Shares (including, for the avoidance of doubt, any security interest created pursuant to any top-up of security) will be subject to the terms of the financing transaction underlying such security and not within the control of the pledgor, any change in the beneficial owner of the Shares during the Relevant Period resulting from the foreclosure, enforcement or exercise of other rights by the lenders in respect of such security interest will not be subject to Rule 9.09(b) of the Listing Rules; and

(b) persons in Category 1 who are not dealing in the Company's securities according to the Rule 10b5-1 Plans set up before the Relevant Period and persons in Category 2 who use their respective Shares other than as described above in "Dealings in the Shares prior to Listing" are subject to the restrictions under Rule 9.09(b) of the Listing Rules.

We believe, subject to the conditions set forth below, the dealings in our securities by our core connected persons will not prejudice the interests of our potential investors and are aligned with the principles in the Hong Kong Stock Exchange's Guidance Letter GL42-12.

We have applied for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with Rule 9.09(b) of the Listing Rules subject to the following conditions:

(a) Category 1 of the Permitted Persons have no discretion over dealings in the Company's ADSs after the Rule 10b5-1 Plans have been entered into;

(b) Where Category 2 of the Permitted Persons use the Shares as security, there will be no change in the beneficial ownership of the Shares during the Relevant Period;

(c) Categories 3 and 4 of the Permitted Persons do not have any influence over the Global Offering and do not possess any of our non-public inside information given that such persons are not in a position with access to information that is considered material to us taken as a whole. Given our vast ADS holder base, we and our management do not have effective control over the investment decisions of Categories 3 and 4 of the Permitted Persons in our ADSs;

(d) we will promptly release any inside information to the public in the United States and Hong Kong in accordance with the relevant laws and regulations of the U.S. and Hong Kong. Accordingly, the Permitted Persons (other than Categories 1 and 2 persons) are not in possession of any non-public inside information of which we are aware;

(e) we will notify the Hong Kong Stock Exchange of any breaches of the dealing restrictions by any of our core connected persons during the Relevant Period when we become aware of the same other than dealings by the core connected persons who are Permitted Persons within the permitted scopes set out above; and

(f) prior to the Listing Date, other than within the permitted scopes set out above, our directors and chief executive, the directors and chief executives of our Significant Subsidiaries and their close associates will not deal in the Shares or the ADSs during the Relevant Period provided that such prohibited dealing in the Shares shall not include the granting, vesting, payment or exercise (as applicable) of incentive and non-statutory options, restricted and unrestricted shares or share units, dividend equivalents, share appreciation rights and share payments under our Group's Equity Plans.

SUBSCRIPTION FOR SHARES BY EXISTING SHAREHOLDERS

Rule 10.04 of the Listing Rules requires that existing shareholders may only subscribe for or purchase any securities for which listing is sought that are being marketed by or on behalf of a new applicant either in his or its own name or through nominees if the conditions in Rule 10.03 of the Listing Rules are fulfilled. Paragraph 5(2) of Appendix 6 to the Listing Rules states that, without the prior written consent of the Stock Exchange, no allocations will be permitted to be made to directors, existing shareholders of a listing applicant or their close associates, unless the conditions set out in Rules 10.03 and 10.04 are fulfilled.

The Stock Exchange's Guidance Letter HKEX-GL85-16 provides that the Stock Exchange will consider granting a waiver from Rule 10.04 and consent pursuant to paragraph 5(2) of Appendix 6 to the Listing Rules allowing an applicant's existing shareholders or their close associates to participate as a cornerstone investor in an initial public offering if any actual or perceived preferential treatment arising from their ability to influence the applicant during the allocation process can be addressed.

Paragraph 5.2 of Guidance Letter HKEX-GL92-18 provides that the Stock Exchange permits existing shareholders to participate in the initial public offering of a biotech company listed under Chapter 18A of the Listing Rules provided that the issuer complies with Rules 8.08(1) and 18A.07 of the Listing Rules in relation to shares held by the public. Further, pursuant to paragraphs 5.2(i) and (ii) of Guidance Letter HKEX-GL92-18, an existing shareholder holding less than 10% of shares in a listing applicant may subscribe for shares in the Listing as either a cornerstone investor or as a placee, whereas an existing shareholder holding 10% or more of shares in a listing applicant may subscribe for shares in the Listing as a cornerstone investor.

As we are a biotech company seeking a listing under Chapter 18A of the Listing Rules, existing shareholders are permitted to participate in the Listing in accordance with, and subject to, paragraph 5.2 of Guidance Letter HKEx-GL92-18.

In addition, as a company listed on Nasdaq, we are not in a position to prevent any person or entity from acquiring our listed securities prior to the allocation of shares in connection with the Global Offering. It would therefore be unduly burdensome for us to seek the prior consent of the Stock Exchange for each of our existing shareholders or their close associates who subscribe for Shares in the Global Offering.

We have applied for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with the requirements of Rule 10.04 and Paragraph 5(2) of Appendix 6 to the Listing Rules, such that (i) each existing shareholder holding less than 10% of shares as of the Latest Practicable Date and/or their close associates may subscribe for shares in the Listing as a placee; and (ii) each existing shareholder and/or their close associates may subscribe for shares in the Listing as a cornerstone investor, subject to compliance with Rules 8.08(1) and 18A.07 of the Listing Rules in relation to shares held by the public, and the condition that our Company, the Joint Representatives, the Joint Global Coordinators and the Joint Sponsors, to the best of their knowledge and belief (and based on discussions between us and the Joint Representatives and confirmations required to be submitted to the Stock Exchange by our Company and the Joint Representatives), will confirm or have confirmed to the Stock Exchange in writing that, as to existing shareholders and/or their close associates who subscribe for shares in the Listing (such existing shareholders, the "**Participating Shareholders**") as placee, no preference in allocation was given and, as to Participating Shareholders as cornerstone investor, no preference was given other than the preferential treatment of assured entitlement at the International Offer Price and the terms must be substantially the same as other cornerstone investors.

Allocation to the Participating Shareholders and/or their close associates will not be disclosed in our allotment results announcement (other than to the extent that such Participating Shareholders or close associates subscribe for shares as cornerstone investors) unless such Participating Shareholders are interested in 5% or more of our issued share capital after the Global Offering as disclosed in any public filings with the SEC, as it would be unduly burdensome for us to disclose such information given that there is no requirement to disclose interests in equity securities under the U.S. Exchange Act unless the beneficial ownership of such person (including directors and officers of the company concerned) reaches more than 5% of equity securities registered under Section 12 of the U.S. Exchange Act.

PRINTED PROSPECTUSES

Pursuant to Rules 12.04(3), 12.07 and 12.11 of the Listing Rules, we are required to make available copies of the prospectus in printed form.

We do not intend to provide printed copies of the prospectus or of the white and yellow application forms to the public in relation to the Hong Kong Public Offering. The proposed waiver from the requirements to make available printed copies of the Prospectus is in line with recent amendments to the Listing Rules relating to environmental, social and governance ("ESG") matters. As the Hong Kong Stock Exchange noted on page 1 of its Consultation Conclusions on Review of the Environmental, Social and Governance Reporting Guide and Related Listing Rules dated December 2019, such amendments relating to ESG matters "*echo*

the increasing international focus on climate change and its impact on business." Electronic, *in lieu of* printed, prospectuses and application forms will help mitigate the environmental impact of printing, including the exploitation of precious natural resources such as trees and water, the handling and disposal of hazardous materials, air pollution, among others. In July 2020, the Stock Exchange also published a consultation paper in relation to a paperless listing and subscription regime.

We also note that in light of the severity of the ongoing COVID-19 pandemic, the provision of printed prospectuses and printed white and yellow application forms will elevate the risk of contagion of the virus through printed materials. As of the Latest Practicable Date, the government of Hong Kong has put in place strict social distancing measures to restrict public gatherings. It is possible that stricter social distancing measures may be necessary later if the number of cases of infection in the territory dramatically increases or maintains at a high level. In any event, it is impossible to accurately predict the development of the COVID-19 pandemic as of the Latest Practicable Date. In this uncertain environment, an electronic application process with a paperless prospectus will reduce the need for prospective investors to gather in public, including branches of the receiving banks and other designated points of collection, in connection with the Hong Kong Public Offering.

We have adopted a fully electronic application process for the Hong Kong Public Offering and we will not provide printed copies of this prospectus or printed copies of any application forms to the public in relation to the Hong Kong Public Offering. Our Hong Kong Share Registrar has implemented enhanced measures to support **White Form eIPO** Service, including increasing its server capacity and making available a telephone hotline to answer investors' queries in connection with the fully electronic application process. For details of the telephone hotline and the application process, see "How to Apply for Hong Kong Offer Shares."

We will publish a formal notice of the Global Offering on the official websites of the Hong Kong Stock Exchange and our Company and in selected English and Chinese local newspapers describing the fully electronic application process including the available channels for share subscription and the enhanced support provided by our Hong Kong Share Registrar in relation to the Hong Kong Public Offering and reminding investors that no printed prospectuses or application forms will be provided. We will also issue a press release to highlight the available electronic channels for share subscription, and advertise through the White Form eIPO Service Provider the electronic method for subscription of the Hong Kong Offer Shares.

We have applied for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with the requirements under Rule 12.04(3), Rule 12.07 and Rule 12.11 of the Listing Rules in respect of the availability of copies of the prospectus in printed form based on our specific and prevailing circumstances.

MONTHLY RETURN

Rule 13.25B of the Listing Rules requires a listed issuer to publish a monthly return in relation to movements in its equity securities, debt securities and any other securitized instruments, as applicable, during the period to which the monthly return relates.

Under the Joint Policy Statement, a waiver from strict compliance with Rule 13.25B of the Listing Rules is subject to the condition that the issuer can meet one of the following three conditions:

(a) it has received a relevant partial exemption from Part XV of the SFO; or

(b) it publishes a "next day disclosure return" in strict compliance with Rule 13.25A of the Listing Rules, regardless of the waiver of general effect from this Rule for secondary listed issuers; or

(c) it is subject to overseas laws or regulations that have a similar effect to Rule 13.25B of the Listing Rules and any differences are not material to shareholder protection.

As we have obtained a partial exemption from strict compliance with Part XV of the SFO from the SFC, we have applied for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with the continuing obligations under Rule 13.25B of the Listing Rules. We will disclose information about share repurchases, if material, in our quarterly or interim earnings releases and annual reports on Form 20-F which are furnished or filed with the SEC in accordance with applicable U.S. rules and regulations.

SHAREHOLDER PROTECTION REQUIREMENTS

For an overseas issuer seeking a secondary listing on the Hong Kong Stock Exchange, Rule 19.30(1)(b) of the Listing Rules requires the overseas issuer's primary listing is or is to be on an exchange where the standards of shareholder protection are at least equivalent to those provided in Hong Kong. Rule 19C.06 of the Listing Rules provides that Appendix 3 and Appendix 13 of the Listing Rules do not apply to an overseas issuer that is a Non-Greater China Issuer (as defined in the Listing Rules) or a Grandfathered Greater China Issuer seeking a secondary listing under Chapter 19C of the Listing Rules. Rule 19C.07 of the Listing Rules provides that the Hong Kong Stock Exchange will consider that a Non-Greater China Issuer or a Grandfathered Greater China Issuer seeking a secondary listing has met the requirements of Rule 19.30(1)(b) of the Listing Rules if it has met the shareholder protection standards by reference to eight criteria set out in Rule 19C.07 of the Listing Rules. We are a Grandfathered Greater China Issuer under Chapter 19C of the Listing Rules.

Change to Class Rights

Rule 19C.07(1) of the Listing Rules requires that a super-majority vote of the Qualifying Issuer's members in general meeting is required to approve changes to the rights attached to any class of shares of the Qualifying Issuer. However, Article 23 of our Articles of Association provides that the rights attaching to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may be varied or abrogated with the written consent of the holders of a majority of the issued shares of that class or series, or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class or series. Accordingly, under our Articles of Association, a super majority vote of our Company's members in general meeting is not required to approve changes to the rights attached to any class of shares of the Company.

We have applied for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with Rule 19C.07(1) of the Listing Rules for the following reasons and conditions:

(a) as of the date of this prospectus, we only have one class of shares and we will adopt transitional arrangements such that, after the Global Offering and until the following proposed amendment to our Articles of Association is passed, we will not seek to vary or abrogate any class right, and any request by shareholders to vary or abrogate any class right will require the written consent 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 general meeting of the holders of the shares of that class or series;

(b) we will convene our next annual general meeting in the second quarter of 2021 and put forth a resolution at such annual general meeting, to revise our Articles of Association, so that the rights attaching to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may be varied or abrogated with the written consent 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 general meeting of the holders of the shares of that class or series. In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed; and

(c) we have been advised by our legal advisers as to Cayman Islands law that there is no legal impediment on the adoption of the above-mentioned transitional arrangements, and that the adoption of such transitional arrangements is not in breach of our Articles of Association or any rules and regulations in the Cayman Islands.

Approval, removal and remuneration of auditors

Rule 19C.07(3) of the Listing Rules requires the appointment, removal and remuneration of auditors to be approved by a majority of the Qualifying Issuer's members or other body that is independent of the issuer's board of directors (the "Auditors Provision"). However, our Articles of Association do not contain an equivalent Auditors Provision. We have applied for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with Rule 19C.07(3) of the Listing Rules for the following reasons:

(a) although our Company has not held any annual general meeting after our listing on Nasdaq, and has therefore not put forth any resolution at any annual general meeting ratifying the appointment of auditors, our Company's shareholders have multiple channels through which they can express their views in relation to the appointment, removal or remuneration of auditors, including: (i) the shareholders are able to raise any questions or issues in relation to auditors at the annual general meeting of our Company which will be held every year after the Global Offering; and (ii) our

Company holds regular investor meetings after the publication of our annual/interim financials and shareholders will also be able to raise any issues in relation to auditors at such meetings. We will also make available on our website (**http://www.zailaboratory.com**) various channels of communication for shareholders, such as investor relations hotlines and enquiry email addresses, through which shareholders can raise any issue in relation to our auditors;

(b) while our Articles of Associations do not contain an equivalent Auditors Provision, the board of our Company formally delegated its power to appoint, remove and remunerate auditors to our Company's audit committee on August 7, 2017, prior to our listing on Nasdaq. The charter of our audit committee, as determined by the Board, provides that it is responsible for appointing an auditor, determining its compensation and overseeing its work. Our audit committee is akin to an independent body of the Board on the basis of the independence requirements set out in applicable U.S. laws and Nasdaq rules. Our audit committee comprises of three members, all of whom are independent directors as required by the U.S. Exchange Act and applicable Nasdaq rules;

(c) the nomination and appointment of our directors are governed by the rules of Nasdaq and the laws of our place of incorporation, which is the Cayman Islands. Pursuant to Nasdaq Stock Market Rule 5605(e) ("Nasdaq Rule 5605(e)"), director nominees, including independent director nominees, must be selected, or recommended for the board's selection, either by: (i) a majority of the independent directors or (ii) a nominations committee comprised solely of independent directors. While Nasdaq Rule 5605(e) is not mandatory for a foreign private issuer incorporated in the Cayman Islands, such as us, we had chosen to follow this rule on a voluntary basis;

(d) to ensure that auditors are independent of their audit clients, Rule 10A-3 promulgated under the U.S. Exchange Act mandates that the audit committee, whose voting members must consist entirely of independent directors, be directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged (including resolution of disagreements between management and the auditor regarding financial reporting). We believe that this legislative mandate effectively prohibits the Board from revoking the power delegated to our audit committee relating to the operation of the Auditors Provision; and

(e) we are seeking a listing on the Hong Kong Stock Exchange under Chapter 19C and 18A of the Listing Rules.

Annual general meeting

Rule 19C.07(4) of the Listing Rules requires that the Qualifying Issuer must hold a general meeting each year as its annual general meeting and that generally not more than 15 months should elapse between the date of one annual general meeting of the Qualifying Issuer and the next, while there is no such requirement to hold annual general meeting in our Articles of Association.

We have applied for, and the Stock Exchange has granted us, a waiver from strict compliance with Rule 19C.07(4) of the Listing Rules on the condition that we undertake to convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend our Articles of Association in accordance with the requirement under Rule 19C.07(4) of the Listing Rules such that our Articles of Association will require our Company to hold an annual general meeting each year and not more than 15 months should elapse between the date of one annual general meeting of our Company and the next.

Following the Listing, we will continue to hold our annual general meeting each year. In the event that the proposed amendment of our Articles of Association as described above is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed.

Requisition of extraordinary general meeting by shareholders

Rule 19C.07(7) of the Listing Rules requires that members holding a minority shareholding in an issuer's total number of issued shares must be able to requisition an extraordinary general meeting and add resolutions to a meeting agenda. The minimum stake required to do so must not be higher than 10% of the voting rights, on a one vote per share basis, in the share capital of the issuer, while the minimum stake as currently set out in our Articles of Association is not less than one-third of the share capital of the Company. In addition, our Articles of Association provides that one or more members holding not less than an aggregate of one-third of all voting share capital of our Company in issue present in person or by proxy and entitled to vote shall be a quorum for general meetings.

We have applied for, and the Stock Exchange has granted us, a waiver from strict compliance with Rule 19C.07(7) of the Listing Rules for the following reasons and conditions:

(a) we will undertake to convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend the Articles of Association in accordance with the requirement under Rule 19C.07(7) of the Listing Rules, such that (i) members holding not less than 10% of the total number of issued shares of our Company shall be able to convene an extraordinary general meeting and add resolutions to a meeting agenda, and (ii) the quorum for holding general meetings shall be members holding not less than 10% of our Company's total number of issued shares. In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed; and

(b) we will adopt transitional arrangements to ensure that (i) where after the Global Offering and before the above-mentioned proposed amendment to our Articles of Association is passed, if one or more members holding not less than 10% of the total number of issued shares of our Company raise requisition for an extraordinary

general meeting or requests to add resolutions to a meeting agenda, such members will be permitted to do so, and (ii) one or more members holding not less than 10% of our Company's total number of issued shares will also be able to form a quorum at any general meeting which is held after the Global Offering and before our next annual general meeting (the "LR19C.07(7) Transitional Arrangements"). We have been advised by our legal advisers as to Cayman Islands law that there is no legal impediment on the adoption of such transitional arrangements, and that the adoption of such transactional arrangements is not in breach of our Articles of Association or any rules and regulations in the Cayman Islands.

The Company will seek irrevocable undertakings from its existing shareholders holding in aggregate over 50% of the total issued shares of the Company as of the Latest Practicable Date to vote in favor of the resolutions in relation to compliance with Rules 19C.07(1), 19C.07(4) and 19C.07(7) as mentioned above and Rule 19C.07(5) as mentioned in the section headed "Appendix III – General Meetings of Shareholders" and will continue to seek such irrevocable undertakings until our Articles of Association has been amended accordingly, with a view to ensuring that there will be adequate votes in favor of such resolutions.

DISCLOSURE REQUIREMENTS OF OPTIONS

Paragraph 27 of Part A of Appendix 1 to the Listing Rules requires us to set out in the listing document particulars of any capital of any members of our Group which is under option, or agreed conditionally or unconditionally to be put under option, including the consideration for which the option was or will be granted and the price and duration of the option, and the name and address of the grantee.

Paragraph 10 of the Third Schedule to the Companies (WUMP) Ordinance further requires us to set out in the listing document, among other things, details of the number, description and amount of any of our shares or debentures which any person has, or is entitled to be given, an option to subscribe for, together with certain particulars of the option, namely the period during which it is exercisable, the price to be paid for shares or debentures subscribed for under it, the consideration given or to be given (if any) and the names and addresses of the persons to whom it was given.

The only options over the capital of any member of our Group are those issued under the Equity Plans, which are not subject to Chapter 17 of the Listing Rules pursuant to Rule 19C.11 of the Listing Rules. The 2015 Equity Plan provides for the granting of share options, stock appreciation rights, restricted stock, or restricted stock units. The 2017 Equity Plan provides for the granting of share options, stock appreciation rights, restricted and unrestricted shares and share units, performance awards and other awards that are convertible into or otherwise based on our Shares. The waiver and exemption only relate to the options that are granted or may be granted under the Equity Plans. As of June 30, 2020, the outstanding options under the Equity Plans accounted for approximately 13.06% of our total outstanding Shares. As of June 30, 2020, the options held by our directors and executive officers and their affiliates under the Equity Plans represented approximately 9.37% of our total outstanding Shares.

Details of the 2017 Equity Plan and a brief summary of the 2015 Equity Plan are disclosed in "Appendix IV – Statutory and General Information – D. Share Incentive Plans and Other Compensation Programs." These disclosures are substantially the same as those in our 20-F filings and comply with applicable U.S. laws and regulations. Accordingly, the current disclosure in this prospectus is not in strict compliance with the requirements under Paragraph 27 of Part A of Appendix 1 to the Listing Rules and Paragraph 10 of the Third Schedule to the Companies (WUMP) Ordinance.

For the reasons stated above, we believe that strict compliance with the above requirements would be unduly burdensome, unnecessary and/or inappropriate for us, and would not be material or meaningful to potential investors.

We have applied for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with the requirements under Paragraph 27 of Part A of Appendix 1 to the Listing Rules. We have applied for, and the SFC has granted, an exemption from the requirements under Paragraph 10 of the Third Schedule of the Companies (WUMP) Ordinance. The SFC has granted an exemption referred to above on the conditions that: (i) the particulars of such exemption are set out in this prospectus; and (ii) this prospectus will be issued on or before September 17, 2020.

TIMING REQUIREMENT OF LIQUIDITY DISCLOSURE

Paragraph 32 of Part A of Appendix 1 to the Listing Rules requires a listing document to include a statement (or an appropriate negative statement) of a new applicant's indebtedness as at a specified most recent practicable date (the "Most Recent Practicable Date"), and a commentary on its liquidity, financial resources and capital structure (together, the "Liquidity Disclosure").

In accordance with the Hong Kong Stock Exchange's Guidance Letter HKEX-GL37-12 ("GL37-12"), the Hong Kong Stock Exchange normally expects that the Most Recent Practicable Date for the Liquidity Disclosure, including, among other things, commentary on liquidity and financial resources such as net current assets (liabilities) position and management discussion on this position, in a listing document to be dated no more than two calendar months before the final date of the listing document.

As this prospectus is expected to be published on September 17, 2020, we would otherwise be required to make the relevant indebtedness and liquidity disclosures no earlier than July 2020 pursuant to GL37-12. Given that we included in this prospectus our audited consolidated financial statements for the six months ended June 30, 2020, it would be unduly burdensome for us to re-arrange information for similar liquidity disclosures on a consolidated basis shortly after the end of the first half of our current financial year.

Strict compliance with the Liquidity Disclosure requirements would constitute an additional one-off disclosure by us of our liquidity position on a date that would fall within the third quarter of our financial year, which would otherwise not be required to be disclosed to

investors in the U.S. under applicable U.S. regulations and Nasdaq listing rules, because we are required to announce quarterly results at the end and not in the middle of each quarter of our financial year. Such a one-off disclosure would likely confuse our existing investors and deviate from our customary practice and that of other Nasdaq listed companies.

In any event, if there are any material changes to such disclosures, we would be required to make an announcement pursuant to U.S. regulations and Nasdaq rules and disclose relevant material facts in this prospectus pursuant to the Listing Rules.

In the event that there is no material change to such disclosures, any similar disclosures made pursuant to GL37-12 would not give additional meaningful information to investors.

We have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with the timing requirement for Liquidity Disclosure in the listing document under GL37-12, such that the reported date of indebtedness and liquidity information in the listing document will not exceed the requirement under GL37-12 by one calendar month (*i.e.*, the time gap between the reported date of our Company's indebtedness and liquidity information and the date of the listing document would be no more than three calendar months).

DISCLOSURE REQUIREMENTS OF THE REMUNERATION OF DIRECTORS AND FIVE INDIVIDUALS WHOSE EMOLUMENTS WERE HIGHEST

Paragraph 33(2) of Part A of Appendix 1 to the Listing Rules requires the listing document to include information in respect of directors' emoluments during the three financial years ended December 31, 2017, 2018 and 2019. Paragraph 46(2) of Part A of Appendix 1 to the Listing Rules requires the listing document to include the aggregate of the remuneration paid and benefits in kind granted to our directors in respect of the last completed financial year, and Paragraph 46(3) of Part A of Appendix 1 to the Listing Rules requires information in relation to an estimate of the aggregate remuneration and benefits in kind payable to directors in respect of the current financial year to be set out in the listing document.

Paragraph 33(3) of Part A of Appendix 1 to the Listing Rules requires the listing document to include information with respect to the five individuals whose emoluments were highest in our Group for the year if one or more individuals whose emoluments were the highest have not been included under Paragraph 33(2) of Part A of Appendix 1 to the Listing Rules.

The aggregate fees, salaries and benefits paid and accrued to our directors and executive officers as a group are disclosed in "Directors and Senior Management – B. Compensation." We confirm that the current disclosure complies with U.S. annual reporting requirements and is in line with our disclosure in our annual reports on Form 20-F.

We believe that additional disclosure required by Paragraphs 33(2), 33(3), 46(2) and 46(3) of Part A of Appendix 1 to the Listing Rules would be unduly burdensome and would not provide additional meaningful disclosure for potential Hong Kong investors.

We have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with the requirements under Paragraphs 33(2), 33(3), 46(2) and 46(3) of Part A of Appendix 1 to the Listing Rules.

NOT A PUBLIC COMPANY IN HONG KONG

Section 4.1 of the Introduction to the Takeovers Code provides that the Takeovers Code apply to takeovers, mergers and share buy-backs affecting, among others, public companies in Hong Kong and companies with a primary listing in Hong Kong. According to the Note to Section 4.2 of the Introduction to the Takeovers Code, a Grandfathered Greater China Issuer within the meaning of Rule 19C.01 of the Listing Rules with a secondary listing on the Hong Kong Stock Exchange will not normally be regarded as a public company in Hong Kong under Section 4.2 of the Introduction to the Takeovers Code. We have applied for, and the SFC has granted, a ruling that we are not a "public company in Hong Kong" for the purposes of the Takeovers Code. Therefore, the Takeovers Code do not apply to us. In the event that the bulk of trading in our Shares migrates to Hong Kong on a permanent basis such that we would be treated as having a dual-primary listing pursuant to Rule 19C.13 of the Listing Rules, the Takeovers Code will apply to us.

DISCLOSURE OF INTERESTS UNDER PART XV OF SFO

Part XV of the SFO imposes duties of disclosure of interests in Shares. Under the U.S. Exchange Act, which we are subject to, any person (including directors and officers of the company concerned) who acquires beneficial ownership, as determined in accordance with the rules and regulations of the SEC and which includes the power to direct the voting or the disposition of the securities, of more than 5% of a class of equity securities registered under Section 12 of the U.S. Exchange Act must file beneficial owner reports with the SEC, and such person must promptly report any material change in the information provided (including any acquisition or disposition of 1% or more of the class of equity securities concerned), unless exceptions apply. Therefore, compliance with Part XV of the SFO would subject our corporate insiders to a second level of reporting, which would be unduly burdensome to them, would result in additional costs and would not be meaningful, since the statutory disclosure of interest obligations under the U.S. Exchange Act that apply to us and our corporate insiders would provide our investors with sufficient information relating to the shareholding interests of our significant shareholders.

We have applied for, and the SFC has granted, a partial exemption under section 309(2) of the SFO to us, our substantial shareholders, our Directors and chief executive from strict compliance with the provisions of Part XV of the SFO (other than Divisions 5, 11 and 12 of Part XV of the SFO) in respect of the duties of disclosure of interests in securities of the Company, on the conditions that (i) the bulk of trading in the Shares is not considered to have migrated to Hong Kong on a permanent basis in accordance with Rule 19C.13 of the Listing

Rules; (ii) all disclosures of interest filed with the SEC are also filed with the Hong Kong Stock Exchange as soon as practicable, which will then publish such disclosures in the same manner as disclosures made under Part XV of the SFO; and (iii) we will advise the SFC if there is any material change to any of the information which has been provided to the SFC, including any significant changes to the disclosure requirements in the U.S. and any significant changes in the volume of our worldwide share turnover that takes place on the Hong Kong Stock Exchange. This exemption may be reconsidered by the SFC in the event there is a material change in information provided to the SFC.

DISCLOSURE OF INTERESTS INFORMATION

Part XV of the SFO imposes duties of disclosure of interests in shares. Practice Note 5 and Paragraphs 41(4) and 45 of Part A of Appendix 1 to the Listing Rules require the disclosure of interests information in respect of shareholders' and directors' interests in the listing document.

We have applied for, and the SFC has granted, a partial exemption from strict compliance with Part XV of the SFO as set out above under sub-section headed "Disclosure of Interest under Part XV of SFO."

The U.S. Exchange Act and the rules and regulations promulgated thereunder require disclosure of interests by shareholders that are broadly equivalent to Part XV of the SFO. Relevant disclosure in respect of the substantial shareholder's interests can be found in the section headed "Major Shareholders" of this prospectus.

We have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange has granted, a waiver from strict compliance with Practice Note 5 and Paragraphs 41(4) and 45 of Part A of Appendix 1 to the Listing Rules on the following conditions:

(a) the SFC granting us and our shareholders a partial exemption from strict compliance with Part XV of the SFO;

(b) our undertaking to file with the Hong Kong Stock Exchange, as soon as practicable, any declaration of shareholding and securities transactions filed with the SEC; and

(c) our undertaking to disclose in present and future listing documents any shareholding interests as disclosed in an SEC filing and the relationship between our directors, officers, members of committees and their relationship to any controlling shareholders (as defined under the Listing Rules).

DISCLOSURE OF OFFER PRICE

Paragraph 15(2)(c) of Part A of Appendix 1 to the Listing Rules provides that the issue price or offer price of each security must be disclosed in the prospectus. Pursuant to Paragraph 3.1 of the Guidance Letter HKEx-GL-90-18, the Hong Kong Stock Exchange also allows an indicative offer price range to be included in the prospectus, as an alternative to the disclosure

of a fixed offer price. Paragraph 9 of Part 1 of the Third Schedule to the Companies (WUMP) Ordinance further provides that the amount payable on application and allotment on each share must be specified in the prospectus.

Our ADSs have been listed and traded on Nasdaq since September 2017. The Public Offer Price will be determined by reference to, among other factors, the closing price of the ADSs on Nasdaq on the last trading day on or before the Price Determination Date. We have no control over the market price of our ADSs traded on Nasdaq.

As our ADSs will continue to be traded on Nasdaq, setting a fixed price or a price range with a low end of International Offer Price or Public Offer Price may adversely affect the market price of the ADSs and the Hong Kong Offer Shares.

For the information of the potential investors, we will disclose the historical prices of our ADSs and trading volume on Nasdaq for the period from January 1, 2020 up to the Latest Practicable Date in "Structure of the Global Offering – Pricing and allocation – Determining the Offer Price."

It is further submitted that the disclosure of the maximum Public Offer Price in this prospectus shall constitute sufficient disclosure of the "amount payable" on application and allotment on the Offer Shares and hence, shall be in compliance with the disclosure requirement under the Companies (WUMP) Ordinance.

We have applied for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with Paragraph 15(2)(c) of Part A of Appendix 1 to the Listing Rules so that we will only disclose the maximum Public Offer Price for the Hong Kong Offer Shares in this prospectus.

We will set the pricing for the Offer Shares by agreement with the Joint Representatives (for themselves and on behalf of the Underwriters). The Public Offer Price will be determined by reference to, among other factors, the closing price of our ADSs on Nasdaq on the last trading day on or before the Price Determination Date.

We may set the International Offer Price at a level higher than the maximum Public Offer Price if (a) the Hong Kong dollar equivalent of the closing trading price of our ADSs on Nasdaq on the last trading day on or before the Price Determination Date (on a per-Share converted basis) were to exceed the maximum Public Offer Price as stated in this prospectus and/or (b) we believe that it is in our best interests as a listed company to set the International Offer Price at a level higher than the maximum Public Offer Price based on the level of interest expressed by professional and institutional investors during the book-building process.

If the International Offer Price is set at or lower than the maximum Public Offer Price, the Public Offer Price must be set at such price which is equal to the International Offer Price. In no circumstances will we set the Public Offer Price above the maximum Public Offer Price as stated in this prospectus or the International Offer Price.

See the section headed "Structure of the Global Offering – Pricing and allocation – Determining the Offer Price" in this prospectus for the historical prices of our ADS and trading volume on Nasdaq.

CLAWBACK MECHANISM

Paragraph 4.2 of Practice Note 18 of the Listing Rules requires a clawback mechanism to be put in place, which would have the effect of increasing the number of Hong Kong Offer Shares to certain percentages of the total number of Offer Shares offered in the Global Offering if certain prescribed total demand levels are reached. Subject to the Hong Kong Stock Exchange granting the waiver described as below, the Hong Kong Public Offering and the International Offering will initially account for 7.3% and 92.7% of the Global Offering, respectively, subject to the clawback mechanism described below. We have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange has granted to us, a waiver from strict compliance with the requirements of Paragraph 4.2 of Practice Note 18 to the Listing Rules such that the allocation of the Offer Shares in the Hong Kong Public Offering will be adjusted as follows:

- if the number of the Offer Shares validly applied for under the Hong Kong Public Offering represents 14 times or more but less than 45 times the number of the Offer Shares initially available for subscription under the Hong Kong Public Offering, then Offer Shares will be reallocated to the Hong Kong Public Offering from the International Offering, so that the total number of Offer Shares available under the Hong Kong Public Offering will be 1,373,350 Offer Shares, representing approximately 13% of the Offer Shares initially available under the Global Offering;

- if the number of the Offer Shares validly applied for under the Hong Kong Public Offering represents 45 times or more but less than 85 times the number of the Offer Shares initially available for subscription under the Hong Kong Public Offering, then the number of Offer Shares to be reallocated to the Hong Kong Public Offering

from the International Offering will be increased so that the total number of the Offer Shares available under the Hong Kong Public Offering will be 1,901,550 Offer Shares, representing approximately 18% of the Offer Shares initially available under the Global Offering; and

- if the number of the Offer Shares validly applied for under the Hong Kong Public Offering represents 85 times or more the number of the Offer Shares initially available for subscription under the Hong Kong Public Offering, then the number of Offer Shares to be reallocated to the Hong Kong Public Offering from the International Offering will be increased, so that the total number of the Offer Shares available under the Hong Kong Public Offering will be 3,591,800 Offer Shares, representing approximately 34% of the Offer Shares initially available under the Global Offering.

In each case, the additional Offer Shares reallocated to the Hong Kong Public Offering will be allocated between pool A and pool B and the number of Offer Shares allocated to the International Offering will be correspondingly reduced in such manner as the Joint Representatives deem appropriate. In addition, the Joint Representatives would have discretion to allocate Offer Shares from the International Offering to the Hong Kong Public Offering to satisfy valid applications under the Hong Kong Public Offering. On the other hand, if the Hong Kong Public Offering is not fully subscribed, the unsubscribed Offer Shares under the Hong Kong Public Offering may be reallocated to the International Offering.

See "Structure of the Global Offering – The Hong Kong Public Offering – Reallocation" for further details.

PUBLICATION OF INTERIM REPORT

Rule 13.48(1) of the Listing Rules requires an issuer to send an interim report or a summary interim report in respect of the first six months of the financial year within three months after the end of that period. Practice Note 10 of the Listing Rules requires newly listed issuers to prepare and publish interim reports in respect of the first six month period where the deadline for publishing the reports falls after the date on which dealings in the securities of the issuer commenced.

We have applied for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with the requirements of Rule 13.48(1) of the Listing Rules in relation to the six months ended June 30, 2020 on, among others, the following grounds:

(a) as we have included in this prospectus the audited financial information in respect of the six months ended June 30, 2020, strict compliance with such requirements would not provide our shareholders and potential investors with additional material information not already contained in this prospectus; and

(b) to require us to prepare, publish and send to our shareholders an interim report over a short period of time after the publication of this prospectus would incur unnecessary administrative cost and time on the part of our management and be unduly burdensome for us.

We confirm that we would not be in breach of our constitutional documents or laws or regulations of the Cayman Islands or any other regulatory requirements for not preparing, publishing and sending an interim report under the Listing Rules to our shareholders for the six months ended June 30, 2020.

DIRECTORS' RESPONSIBILITY STATEMENT

This prospectus, for which our directors collectively and individually accept full responsibility, includes particulars given in compliance with the Companies (WUMP) Ordinance, the Securities and Futures (Stock Market Listing) Rules (Chapter 571V of the Laws of Hong Kong) and the Listing Rules for the purpose of giving information with regard to us. Our directors, having made all reasonable enquiries, confirm that to the best of their knowledge and belief the information contained in this prospectus is accurate and complete in all material respects and not misleading or deceptive, and there are no other matters the omission of which would make any statement herein or this prospectus misleading.

THE HONG KONG PUBLIC OFFERING AND THIS PROSPECTUS

This prospectus is published solely in connection with the Hong Kong Public Offering, which forms part of the Global Offering. For applicants under the Hong Kong Public Offering, this prospectus set out the terms and conditions of the Hong Kong Public Offering.

The Hong Kong Offer Shares are offered solely on the basis of the information contained and representations made in this prospectus and on the terms and subject to the conditions set out herein and therein. No person is authorized to give any information in connection with the Global Offering or to make any representation not contained in this prospectus, and any information or representation not contained herein must not be relied upon as having been authorized by our Company, the Joint Sponsors, the Joint Representatives, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers and any of the Underwriters, any of their respective directors, agents, employees or advisers or any other party involved in the Global Offering.

The Listing is sponsored by the Joint Sponsors and the Global Offering is managed by the Joint Representatives. The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters under the terms and conditions of the Hong Kong Underwriting Agreement and is subject to us and the Joint Representatives (for themselves and on behalf of the Underwriters) agreeing on the pricing of the Hong Kong Offer Shares. The International Offering is expected to be fully underwritten by the International Underwriters subject to the terms and conditions of the International Underwriting Agreement, which is expected to be entered into on or around the Price Determination Date.

Neither the delivery of this prospectus nor any offering, sale or delivery made in connection with the Shares should, under any circumstances, constitute a representation that there has been no change or development reasonably likely to involve a change in our affairs since the date of this prospectus or imply that the information contained in this prospectus is correct as of any date subsequent to the date of this prospectus.

PROCEDURES FOR APPLICATION FOR THE HONG KONG OFFER SHARES

The procedures for applying for the Hong Kong Offer Shares are set forth in the section headed "How to Apply for Hong Kong Offer Shares" in this prospectus.

STRUCTURE AND CONDITIONS OF THE GLOBAL OFFERING

Details of the structure of the Global Offering, including its conditions, are set forth in the section headed "Structure of the Global Offering" in this prospectus.

OVER-ALLOTMENT OPTION AND STABILIZATION

Details of the arrangements relating to the Over-allotment Option and stabilization are set forth in the section headed "Structure of the Global Offering" in this prospectus.

RESTRICTIONS ON OFFERS AND SALES OF SHARES

Each person acquiring the Hong Kong Offer Shares under the Hong Kong Public Offering will be required to, or be deemed by his acquisition of Offer Shares to, confirm that he is aware of the restrictions on offers of the Offer Shares described in this prospectus.

No action has been taken to permit a public offering of the Offer Shares (except for a registration of Shares on a registration statement on Form F-3ASR filed with the SEC) or the general distribution of this prospectus in any jurisdiction other than in Hong Kong or the United States. Accordingly, this prospectus may not be used for the purposes of, and does not constitute, an offer or invitation in any jurisdiction or in any circumstances in which such an offer or invitation is not authorized or to any person to whom it is unlawful to make such an offer or invitation. The distribution of this prospectus and the offering of the Offer Shares in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdictions and pursuant to registration with or authorization by the relevant securities regulatory authorities or an exemption therefrom.

COMMENCEMENT OF DEALINGS IN OUR SHARES

We expect that dealings in our Shares on the Hong Kong Stock Exchange will commence on September 28, 2020. The Shares will be traded in board lots of 50 Shares each. The stock code of our Shares will be 9688.

SHARES WILL BE ELIGIBLE FOR ADMISSION INTO CCASS

If the Hong Kong Stock Exchange grants the listing of, and permission to deal in, the Shares and we comply with the stock admission requirements of HKSCC, our Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with

effect from the Listing Date or any other date as determined by HKSCC. Settlement of transactions between participants of the Hong Kong Stock Exchange is required to take place in CCASS on the second business day after any trading day.

All activities under CCASS are subject to the General Rules of CCASS and CCASS Operational Procedures in effect from time to time.

Investors should seek the advice of their stockbroker or other professional advisers for details of the settlement arrangement as such arrangements may affect their rights and interests. All necessary arrangements have been made to enable our Shares to be admitted into CCASS.

PROFESSIONAL TAX ADVICE RECOMMENDED

You should consult your professional advisers if you are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of, or dealing in, our Shares or ADSs or exercising any rights attaching to our Shares. We emphasize that none of our Company, the Joint Sponsors, the Joint Representatives, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Underwriters, any of our or their respective directors, officers or representatives or any other person involved in the Global Offering accepts responsibility for any tax effects or liabilities resulting from your subscription, purchase, holding or disposing of, or dealing in, our Shares or ADSs or your exercise of any rights attaching to our Shares.

REGISTER OF MEMBERS AND STAMP DUTY

Our principal register of members will be maintained by our principal share registrar in the Cayman Islands, and our Hong Kong register of members will be maintained by the Hong Kong Share Registrar, Computershare Hong Kong Investor Services Limited, in Hong Kong.

Dealings in our Shares registered on our Hong Kong share register will be subject to Hong Kong stamp duty. The stamp duty is charged to each of the seller and purchaser at the ad valorem rate of 0.1% of the consideration for, or (if greater) the value of, our Shares transferred. In other words, a total of 0.2% is currently payable on a typical sale and purchase transaction of our Shares. In addition, a fixed duty of HK$5.00 is charged on each instrument of transfer (if required).

To facilitate deposits of Shares to and withdrawals of Shares from the ADS facility, we also intend to move a portion of our issued Shares, including all of the Shares deposited in our ADS program, from our Cayman share register to our Hong Kong share register. It is unclear whether, as a matter of Hong Kong law, the trading of ADSs representing Shares constitutes a sale or purchase of the underlying Hong Kong-registered Shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. See "Risk

Factors – Risks related to our Shares, the ADSs, the Listing and the Global Offering – There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of our ADSs following our initial public offering in Hong Kong and Listing of our Shares on the Hong Kong Stock Exchange."

EXCHANGE RATE CONVERSION

Our reporting currency is U.S. dollars. This prospectus contains translations of financial data in Renminbi and Hong Kong dollar amounts into U.S. dollars at specific rates solely for the convenience of the reader. Unless otherwise stated, all translations of financial data in Renminbi and Hong Kong dollars into U.S. dollars and from U.S. dollars into Renminbi in this prospectus were made at a rate of RMB7.0651 to US$1.00 and HK$7.7501 to US$1.00, the respective exchange rate on June 30, 2020 set forth in the H.10 statistical release of the Federal Reserve Board.

No representation is made that any amounts in RMB or US$ were or could have been or could be converted into Hong Kong dollars at such rates or any other exchange rates on such date or any other date.

ROUNDING

Certain amounts and percentage figures included in this prospectus have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them.

LANGUAGE

If there is any inconsistency between the English prospectus and its Chinese translation, the English prospectus shall prevail, provided that if there is any inconsistency between the Chinese names of the entities or enterprises established in the PRC mentioned in this prospectus and their English translations, the Chinese names shall prevail. The English translations of the Chinese names of such PRC entities or enterprises are provided for identification purposes only. Chinese names of entities incorporated outside of China, if provided, are actual registered names.

OTHER

Unless otherwise specified, all references to any shareholdings in our Company following the completion of the Global Offering assume that the Over-allotment Option is not exercised.

THE LISTING

We have applied for a listing of our Shares on the Main Board under Chapter 19C (Secondary Listings of Qualifying Issuers).

We have a track record of good regulatory compliance of at least two full financial years on Nasdaq as required by Rule 19C.04 of the Listing Rules for the purposes of our Listing.

We have applied to the Hong Kong Stock Exchange for the listing of, and permission to deal in, the Shares in issue, the Shares to be issued pursuant to the Global Offering (including the additional Shares that may be issued pursuant to the exercise of the Over-allotment Option), and the Shares to be issued pursuant to the Equity Plans, including pursuant to the exercise of options or other awards that have been or may be granted from time to time.

Our ADSs are currently listed and traded on Nasdaq. Other than the foregoing, no part of our Shares or loan capital is listed on or traded on any other stock exchange and no such listing or permission to list is being or proposed to be sought. All Offer Shares will be registered on the Hong Kong share register in order to enable them to be traded on the Hong Kong Stock Exchange.

Under section 44B(1) of the Companies (WUMP) Ordinance, any allotment made in respect of any application will be invalid if the listing of, and permission to deal in, our Shares on the Hong Kong Stock Exchange is refused before the expiration of three weeks from the date of the closing of the application lists, or such longer period (not exceeding six weeks) as may, within the said three weeks, be notified to us by or on behalf of the Hong Kong Stock Exchange.

REGISTRATION OF SUBSCRIPTION, PURCHASE AND TRANSFER OF SHARES

Our register of members holding unlisted Shares not represented by the ADSs will be maintained by our Principal Share Registrar in the Cayman Islands, and our register of members holding Shares listed on the Hong Kong Stock Exchange and our Shares represented by the ADSs will be maintained by our Hong Kong Share Registrar in Hong Kong.

OWNERSHIP OF ADSs

An owner of ADSs may hold his/her ADSs either by means of an ADR (evidencing certificated ADSs) registered in his/her name, through a brokerage or safekeeping account, or through an account established by the depositary bank in his/her name reflecting the registration of uncertificated ADSs directly on the books of the depositary bank, commonly referred to as the "direct registration system," or DRS. The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary bank to the holders of the ADSs. The direct registration system includes automated transfers between the depositary bank and DTC. If an owner of ADSs decides to hold his/her ADSs through his/her brokerage or safekeeping account, he/she must rely on the procedures of his/her broker or bank to assert his/her rights as an ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. All ADSs held through DTC will be registered in the name of a nominee of DTC.

DEALINGS AND SETTLEMENT OF SHARES IN HONG KONG

Our Shares will trade on the Hong Kong Stock Exchange in board lots of 50 Shares. Dealings in our Shares on the Hong Kong Stock Exchange will be conducted in Hong Kong dollars.

The transaction costs of dealings in our Shares on the Hong Kong Stock Exchange include:

(a) Hong Kong Stock Exchange trading fee of 0.005% of the consideration of the transaction, charged to each of the buyer and seller;

(b) SFC transaction levy of 0.0027% of the consideration of the transaction, charged to each of the buyer and seller;

(c) trading tariff of HK$0.50 on each and every purchase or sale transaction. The decision on whether or not to pass the trading tariff onto investors is at the discretion of brokers;

(d) transfer deed stamp duty of HK$5.00 per transfer deed (if applicable), payable by the seller;

(e) ad valorem stamp duty at a total rate of 0.2% of the value of the transaction, with 0.1% payable by each of the buyer and the seller;

(f) stock settlement fee, which is currently 0.002% of the gross transaction value, subject to a minimum fee of HK$2.00 and a maximum fee of HK$100.00 per side per trade;

(g) brokerage commission, which is freely negotiable with the broker (other than brokerage commissions for IPO transactions which are currently set at 1% of the subscription or purchase price and will be payable by the person subscribing for or purchasing the securities); and

(h) the Hong Kong share registrar will charge between HK$2.50 to HK$20, depending on the speed of service (or such higher fee as may from time to time be permitted under the Listing Rules), for each transfer of Shares from one registered owner to another, each share certificate canceled or issued by it and any applicable fee as stated in the share transfer forms used in Hong Kong.

Investors must settle their trades executed on the Hong Kong Stock Exchange through their brokers directly or through custodians. For an investor who has deposited his/her Shares in his/her stock account or in his/her designated CCASS participant's stock account maintained with CCASS, settlement will be effected in CCASS in accordance with the General Rules of CCASS and CCASS Operational Procedures in effect from time to time. For an investor who holds the physical certificates, settlement certificates and the duly executed transfer forms must be delivered to his/her broker or custodian before the settlement date.

EXCHANGES BETWEEN SHARES TRADING IN HONG KONG AND ADSs

In connection with the initial public offering of our Shares in Hong Kong, or the Hong Kong Public Offering, we have established a branch register of members in Hong Kong, or the Hong Kong share register, which will be maintained by our Hong Kong Share Registrar, Computershare Hong Kong Investor Services Limited. Our principal register of members, or the Cayman share register, will continue to be maintained by our Principal Share Registrar, International Corporation Services Ltd.

All Shares offered in the Hong Kong Public Offering will be registered on the Hong Kong share register in order to be listed and traded on the Hong Kong Stock Exchange. As described in further detail below, holders of Shares registered on the Hong Kong share register will be able to exchange those Shares for ADSs and vice versa.

Our ADSs

Our ADSs representing our Shares are currently traded on Nasdaq. Dealings in our ADSs on Nasdaq are conducted in U.S. Dollars.

ADSs may be held either:

(a) directly: (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs registered in the holder's name; or (ii) by having uncertificated ADSs registered in the holder's name; or

(b) indirectly, by holding a security entitlement in ADSs through a broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC.

The depositary for our ADSs is Citibank N.A., whose office is located at 388 Greenwich Street, New York, New York 10013, United States.

Depositing Shares trading in Hong Kong for delivery of ADSs

An investor who holds the Shares registered in Hong Kong and wishes to receive delivery of ADSs that trade on the Nasdaq must deposit or have his/her broker deposit the Shares with the depositary's Hong Kong custodian, Citibank, N.A., Hong Kong, or the custodian, in exchange for ADSs.

A deposit of Shares trading in Hong Kong in exchange for ADSs involves the following procedures:

(a) If the Shares have been deposited with CCASS, the investor must transfer the Shares to the depositary's account with the custodian within CCASS by following the CCASS procedures for transfer and submit and deliver a duly completed and signed ADS delivery form to the custodian via his/her broker.

(b) If the Shares are held outside CCASS, the investor must arrange for the registration of a transfer of his/her Shares into the depositary's name and delivery of evidence of that registration to the custodian, and must sign and deliver an ADS delivery form to the depositary.

(c) Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, if applicable, the depositary will register the corresponding number of ADSs in the name(s) requested by an investor and will deliver the ADSs as instructed in the ADS delivery form.

For Shares deposited in CCASS, under normal circumstances, the above steps generally require two business days, provided that the investor has provided timely and complete instructions. For Shares held outside CCASS in physical form, the above steps may take 14 business days, or more, to complete. Temporary delays may arise. For example, the transfer books of the depositary may from time to time be closed to ADS issuances. The investor will be unable to trade the ADSs until the procedures are completed.

Surrender of ADSs for delivery of Shares trading in Hong Kong

An investor who holds ADSs and wishes to receive Shares that trade on the Hong Kong Stock Exchange must cancel the ADSs the investor holds and withdraw the Shares from our ADS program and cause his/her broker or other financial institution to trade such Shares on the Hong Kong Stock Exchange.

An investor that holds ADSs indirectly through a broker or other financial institution should follow the procedures of the broker or financial institution and instruct the broker to arrange for cancellation of the ADSs, and transfer of the underlying Shares from the depositary's account with the custodian within the CCASS system to the investor's Hong Kong stock account.

For investors holding ADSs directly, the following steps must be taken:

(a) To withdraw the Shares from our ADS program, an investor who holds ADSs may turn in such ADSs at the office of the depositary (and the applicable ADR(s) if the ADSs are held in certificated form), and send an instruction to cancel such ADSs to the depositary. Those instructions must have a Medallion signature guarantee.

(b) Upon payment or net of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, if applicable, the depositary will instruct the custodian to deliver the Shares underlying the canceled ADSs to the CCASS account designated by the investor.

(c) If an investor prefers to receive the Shares outside CCASS, he/she must so indicate in the instruction delivered to the depositary.

For the Shares to be received in CCASS, under normal circumstances, the above steps generally require two business days, provided that the investor has provided timely and complete instructions. For the Shares to be received outside CCASS in physical form, the above steps may take 14 business days, or more, to complete. The investor will be unable to trade the Shares on the Hong Kong Stock Exchange until the procedures are completed.

Temporary delays may arise. For example, the transfer books of the depositary may from time to time be closed to ADS cancelations. In addition, completion of the above steps and procedures for delivery of Shares in a CCASS account is subject to there being a sufficient number of Shares on the Hong Kong share register to facilitate a withdrawal from the ADS program directly into the CCASS system. We are not under any obligation to maintain or increase the number of Shares on the Hong Kong share register to facilitate such withdrawals.

Depositary requirements

Before the depositary delivers ADSs or permits withdrawal of the Shares, the depositary may require:

(a) production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

(b) compliance with procedures it may establish, from time to time, consistent with the deposit agreement, including completion and presentation of transfer documents.

The depositary may refuse to deliver, transfer, or register issuances, transfers and cancelations of ADSs generally when the transfer books of the depositary or of the Hong Kong Share Registrar are closed or at any time if the depositary or we determine it advisable to do so.

All costs attributable to the transfer of the Shares to effect a withdrawal from or deposit of the Shares into our ADS program will be borne by the investor requesting the transfer or deposit. In particular, holders of Shares and ADSs should note that the Hong Kong Share Registrar will charge between HK$2.50 to HK$20, depending on the speed of service (or such higher fee as may from time to time be permitted under the Listing Rules), for each transfer of the Shares from one registered owner to another, each share certificate canceled or issued by it and any applicable fee as stated in the share transfer forms used in Hong Kong. In addition, holders of the Shares and ADSs must pay up to US$5.00 per 100 ADSs (or portion thereof) for each issuance of ADSs and each cancelation of ADSs, as the case may be, in connection with the deposit of the Shares into, or withdrawal of the Shares from, the ADS facility.

SUMMARY OF EXEMPTIONS AS A FOREIGN PRIVATE ISSUER IN THE U.S.

As required by Rule 19C.14 of the Listing Rules, set out below is a summary of the exemptions from obligations under U.S. securities laws and Nasdaq rules that we enjoy as a foreign private issuer in the U.S.

However, given more than 50% of our Shares were directly or indirectly held by residents of the U.S. on June 30, 2020, we lost our foreign private issuer status as of June 30, 2020. Accordingly, we are required to comply with U.S. securities laws and Nasdaq rules as a U.S. domestic issuer beginning on January 1, 2021, and will no longer enjoy the following exemptions.

Exemptions from Nasdaq rules

Foreign private issuers are exempted from certain Nasdaq rules. Foreign private issuers are permitted to follow home country practice, i.e., for us, the practice of the Cayman Islands, in lieu of such corporate governance requirements, as long as they disclose any significant ways in which their corporate governance practices differ from those required under the Nasdaq listing standards and explain the basis for the conclusion that the exemption is applicable. Specifically, we are currently entitled to rely upon the exemptions from the requirements to:

(a) have a majority of independent directors;

(b) regularly schedule executive sessions without management at which the non-management directors must meet;

(c) have a nominating committee composed entirely of independent directors;

(d) have a compensation committee composed entirely of independent directors, whose members must satisfy the additional independence requirements specific to compensation committee membership; and

(e) give shareholders the opportunity to vote on:

(i) all equity-compensation plans and material revisions thereto, with limited exceptions;

(ii) the issuance of securities in connection with the acquisition of the stock or assets of another company if: (i) where, due to the present or potential issuance of common stock, including shares issued pursuant to an earn-out provision or similar type of provision, or securities convertible into or exercisable for common stock, other than a public offering for cash: (A) the common stock has or will have upon issuance voting power equal to or in excess of 20% of the voting power outstanding before the issuance of stock or securities convertible into or exercisable for common stock; or (B) the number of shares of common stock to be issued is or will be equal to or in excess of 20% of the number of shares of common stock outstanding before the issuance of the stock or securities; or (ii) any director, officer or Substantial Shareholder (as defined by Rule 5635(e)(3) of the Nasdaq rules) of the Company has a 5% or greater interest (or such persons collectively have a 10% or greater interest), directly or indirectly, in the company or assets to be acquired or in the consideration to be paid in the transaction or series of related transactions and the present or potential issuance of common stock, or securities convertible into or exercisable for common stock, could result in an increase in outstanding common shares or voting power of 5% or more;

(iii) private placements (other than a bona fide private placement), if the number of shares of common stock, or of securities convertible into or exercisable for common stock to be issued equals or exceeds 20% of the shares of common stock outstanding before the issuance; or

(iv) an issuance that will result in a change of control of the listed company.

Exemptions from SEC rules and regulations under U.S. federal securities laws

Foreign private issuers are exempted from Regulation FD under the U.S. Exchange Act. Regulation FD provides that when a U.S. domestic issuer, or someone acting on its behalf, discloses material nonpublic information to certain persons (including securities analysts, other securities market professionals, and holders of the issuer's securities who could reasonably be expected to trade on the basis of the information), it must make simultaneous public disclosure of that information (in the case of intentional disclosure) or prompt public disclosure (in the case of non-intentional disclosure). However, the SEC expects foreign private issuers to conduct themselves in accordance with the basic principles underlying Regulation FD.

Section 16 of the U.S. Exchange Act does not apply to foreign private issuers. Therefore, directors, executive officers and 10% beneficial owners of foreign private issuers are not required to file Forms 3, 4 and 5 with the SEC, and are not required to disgorge to the issuer any profits realized from any non-exempt purchase and sale, or non-exempt sale and purchase, of the issuer's equity securities or security-based swap agreements within a period of less than six months.

Foreign private issuers are exempt from the SEC's rules prescribing the furnishing and content of proxy statements under the U.S. Exchange Act, which specify the procedures and required documentation for soliciting shareholder votes. Accordingly, foreign private issuers are not required to disclose certain information in their annual proxy statements, such as whether the work of any compensation consultant has played any role in determining or recommending the form or amount of executive and director compensation has raised a conflict of interest, and, if so, the nature of the conflict and how it is being addressed.

Foreign private issuers are also not required under the U.S. Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. domestic issuers with securities registered under the U.S. Exchange Act. As a result, our shareholders may be afforded less protection than they would under the U.S. Exchange Act rules applicable to U.S. domestic issuers. Unlike U.S. domestic issuers, foreign private issuers are not required to file quarterly reports (including quarterly financial information) on Form 10-Q. They also are not required to use Form 8-K for current reports, and instead furnish (not file) current reports on Form 6-K with the SEC.

Annual reports on Form 10-K by U.S. domestic issuers are due within 60, 75, or 90 days after the end of the issuer's fiscal year, depending on whether the company is a "large accelerated filer," a "accelerated filer," or a "non-accelerated filer." By contrast, the deadline for foreign private issuers to file annual reports on Form 20-F is four months after the end of their fiscal year.

OUR ARTICLES OF ASSOCIATION

We are an exempted company incorporated in the Cayman Islands with limited liability and our affairs are governed by our Articles of Association, the Cayman Companies Law and the common law of the Cayman Islands.

The laws of Hong Kong differ in certain respects from the Cayman Companies Law, and our Articles of Association are specific to us and include certain provisions that may be different from common practices in Hong Kong.

For example,

(a) Rule 19C.07(1) of the Listing Rules requires that a super-majority vote of the Qualifying Issuer's members in general meeting is required to approve changes to the rights attached to any class of shares of the Qualifying Issuer. However, Article 23 of our Articles of Association provides that the rights attaching to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may be varied or abrogated with the written consent of the holders of a majority of the issued shares of that class or series, or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class or series;

(b) Rule 19C.07(3) of the Listing Rules requires a change to the auditors or their remuneration to be approved by the shareholders or another body independent of the board of directors of the issuer; however, our Articles of Association does not contain an equivalent provision;

(c) Rule 19C.07(4) of the Listing Rules requires that the Qualifying Issuer must hold a general meeting each year as its annual general meeting and that generally not more than 15 months should elapse between the date of one annual general meeting of the Qualifying Issuer and the next; however, our Articles of Association does not contain an equivalent provision;

(d) Rule 19C.07(7) of the Listing Rules requires that members holding a minority shareholding in an issuer's total number of issued shares must be able to requisition an extraordinary general meeting and add resolutions to a meeting agenda. The minimum stake required to do so must not be higher than 10% of the voting rights, on a one vote per share basis, in the share capital of the issuer, while the minimum stake as currently set out in our Articles of Association is not less than one-third of the share capital of the Company.

See "Waivers and Exemptions" for further information on how we otherwise provide for these shareholder protections. See "Summary of the Constitution of the Company and Cayman Companies Law" in Appendix III for a further discussion on our Articles of Association.

COMPLIANCE ADVISOR

We have appointed Somerley Capital Limited as our Compliance Advisor upon the Listing in compliance with Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the Compliance Advisor will provide advice to us upon our request in the following circumstances:

(a) before the publication of any regulatory announcement, circular, or financial report;

(b) where a share issue transaction is contemplated;

(c) where we propose to use the proceeds of the Global Offering in a manner different from that detailed in this prospectus or where the business activities, development or results of our Company deviate from any forecast, estimate or other information in this prospectus; and

(d) where the Hong Kong Stock Exchange makes an inquiry to the Company regarding unusual movements in the price or trading volume of its listed securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

The term of the appointment shall commence on the Listing Date and end on the date on which we distribute our annual report in respect of our financial results for the first full fiscal year commencing after the Listing Date.

DIRECTORS

Name	Address	Nationality
Dr. Samantha Du	No. 453, Lane 1883 Hua Mu Road Pudong 201204 Shanghai China	American
Dr. Kai-Xian Chen (陳凱先博士)	158 Da Mu Qiao Road No. 17, Room 801, Xuhui Shanghai China	Chinese
Dr. John Diekman	140 Catalpa Drive Atherton, CA 94027 United States of America	American
Mr. Tao Fu	495 Panchita Way Los Altos, CA 94022 United States of America	American
Ms. Nisa Leung (梁顥宇女士)	1/F., 15 Wang Chiu Road Kowloon Bay, Kowloon Hong Kong	Chinese (Hong Kong)
Mr. William Lis	42 West Poplar Avenue San Mateo California 94402 United States of America	American
Mr. Leon O. Moulder, Jr.	10831 Isola Bella Court Miromar Lakes FL 33913 United States of America	American
Mr. Peter Wirth	37 Hancock Street, Boston, MA 02114 United States of America	American

Please refer to the section entitled "Directors and Senior Management" in this prospectus for further information with respect to our directors.

PARTIES INVOLVED IN THE GLOBAL OFFERING

Joint Sponsors	**J.P. Morgan Securities (Far East) Limited** 28/F, Chater House 8 Connaught Road Central Hong Kong **Goldman Sachs (Asia) L.L.C.** 68/F, Cheung Kong Center 2 Queen's Road Central Hong Kong **Citigroup Global Markets Asia Limited** 50/F, Champion Tower 3 Garden Road Central Hong Kong
Joint Representatives	**J.P. Morgan Securities (Asia Pacific) Limited** 28/F, Chater House 8 Connaught Road Central Hong Kong **Goldman Sachs (Asia) L.L.C.** 68/F, Cheung Kong Center 2 Queen's Road Central Hong Kong **Citigroup Global Markets Asia Limited** 50/F, Champion Tower 3 Garden Road Central Hong Kong
Joint Global Coordinators	**J.P. Morgan Securities (Asia Pacific) Limited** 28/F, Chater House 8 Connaught Road Central Hong Kong **Goldman Sachs (Asia) L.L.C.** 68/F, Cheung Kong Center 2 Queen's Road Central Hong Kong **Citigroup Global Markets Asia Limited** 50/F, Champion Tower 3 Garden Road Central Hong Kong **Jefferies Hong Kong Limited** Suite 2201, 22/F, Cheung Kong Center 2 Queen's Road Central Hong Kong

Joint Bookrunners

J.P. Morgan Securities (Asia Pacific) Limited
(in relation to the Hong Kong Public Offering)
28th Floor, Chater House
8 Connaught Road Central
Hong Kong

J.P. Morgan Securities plc
(in relation to the International Offering)
25 Bank Street
Canary Wharf
London E14 5JP
United Kingdom

J.P. Morgan Securities LLC
(in relation to the International Offering)
383 Madison Avenue
New York NY 10179

Goldman Sachs (Asia) L.L.C.
68/F, Cheung Kong Center
2 Queen's Road Central
Hong Kong

Citigroup Global Markets Asia Limited
(in relation to the Hong Kong Public Offering)
50/F, Champion Tower
3 Garden Road
Central
Hong Kong

Citigroup Global Markets Limited
(in relation to the International Offering)
33 Canada Square
Canary Wharf
London E14 5LB
United Kingdom

Jefferies Hong Kong Limited
Suite 2201, 22/F, Cheung Kong Center
2 Queen's Road Central
Hong Kong

Merrill Lynch (Asia Pacific) Limited
55/F, Cheung Kong Center
2 Queen's Road Central
Central
Hong Kong

Credit Suisse (Hong Kong) Limited
Level 88, International Commerce Centre
1 Austin Road West
Kowloon
Hong Kong

	China International Capital Corporation Hong Kong Securities Limited 29/F, One International Finance Centre 1 Harbour View Street Central Hong Kong
	Haitong International Securities Company Limited 22/F, Li Po Chun Chambers 189 Des Voeux Road Central
Joint Lead Managers	**J.P. Morgan Securities (Asia Pacific) Limited** *(in relation to Hong Kong Public Offering)* 28th Floor, Chater House 8 Connaught Road Central Hong Kong
	J.P. Morgan Securities plc *(in relation to International Offering)* 25 Bank Street Canary Wharf London E14 5JP United Kingdom
	J.P. Morgan Securities LLC *(in relation to the International Offering)* 383 Madison Avenue New York NY 10179
	Goldman Sachs (Asia) L.L.C. 68/F, Cheung Kong Center 2 Queen's Road Central Hong Kong
	Citigroup Global Markets Asia Limited *(in relation to the Hong Kong Public Offering)* 50/F, Champion Tower 3 Garden Road Central Hong Kong
	Citigroup Global Markets Limited *(in relation to the International Offering)* 33 Canada Square Canary Wharf London E14 5LB United Kingdom
	Jefferies Hong Kong Limited Suite 2201, 22/F, Cheung Kong Center 2 Queen's Road Central Hong Kong

Merrill Lynch (Asia Pacific) Limited
55/F, Cheung Kong Center
2 Queen's Road Central
Central
Hong Kong

Credit Suisse (Hong Kong) Limited
Level 88, International Commerce Centre
1 Austin Road West
Kowloon
Hong Kong

China International Capital Corporation Hong Kong Securities Limited
29/F, One International Finance Centre
1 Harbour View Street
Central
Hong Kong

Haitong International Securities Company Limited
22/F, Li Po Chun Chambers
189 Des Voeux Road Central

Legal Advisers to our Company

As to Hong Kong law and United States law:
Davis Polk & Wardwell
18/F, The Hong Kong Club Building
3A Chater Road
Hong Kong

As to PRC law:
Zhong Lun Law Firm
6/10/11/16/17F, Two IFC, 8 Century Avenue
Pudong New Area
Shanghai
China

As to Cayman Islands law:
Travers Thorp Alberga
1205A The Centrium
60 Wyndham Street
Hong Kong

Legal Advisers to the Underwriters

As to Hong Kong law and United States law:
Simpson Thacher & Bartlett
35/F, ICBC Tower
3 Garden Road
Hong Kong

	As to PRC law: **Commerce & Finance Law Offices** 6/F, NCI Tower A12 Jianguomenwai Avenue Chaoyang District Beijing China
Auditors*	**Deloitte Touche Tohmatsu** **Certified Public Accountants LLP** 30/F Bund Center 222 Yan An Road East Shanghai China
Reporting Accountants	**Deloitte Touche Tohmatsu** *Certified Public Accountants* 35/F, One Pacific Place 88 Queensway Hong Kong
Industry Consultant	**Frost & Sullivan Limited** 1706, One Exchange Square 8 Connaught Place Central Hong Kong
Receiving Banks	**Bank of China (Hong Kong) Limited** 1 Garden Road Hong Kong

Note:

* Deloitte Touche Tohmatsu Certified Public Accountants LLP is currently the auditor of the Company's consolidated financial statements that are prepared in conformity with U.S. GAAP. After listing, the Company will propose to appoint, Deloitte Touche Tohmatsu, a registered public interest entity auditor in Hong Kong, to audit the consolidated financial statements which will be included in the coming annual report to be published in Hong Kong.

Registered Office	Harbour Place 2nd Floor 103 South Church Street P.O. Box 472 George Town Grand Cayman KY1-1106 Cayman Islands
Head office and Principal Place of Business in China	4560 Jinke Road Bldg. 1, 4/F Pudong, Shanghai China 201210
Principal Place of Business in Hong Kong	Room 2301, 23/F. Island Place Tower 510 King's Road North Point Hong Kong
Company's Website	**http://www.zailaboratory.com** *(The information contained in this website does not form part of this prospectus.)*
Audit Committee	Dr. John Diekman *(Chairman)* Mr. William Lis Mr. Leon O. Moulder, Jr.
Compensation Committee	Mr. Peter Wirth *(Chairman)* Ms. Nisa Leung Mr. Leon O. Moulder, Jr.
Nominating Committee	Dr. Samantha Du *(Chairwoman)* Dr. John Diekman Ms. Nisa Leung
Authorized Representatives	Dr. Samantha Du 4560 Jinke Road Bldg. 1, 4/F Pudong, Shanghai China 201210 Mr. Tao Fu 4560 Jinke Road Bldg. 1, 4/F Pudong, Shanghai China 201210

Compliance Adviser	**Somerley Capital Limited** 20/F., China Building 29 Queen's Road Central Hong Kong
Principal Share Registrar and Transfer Agent	**International Corporation Services Ltd.** P.O. Box 472, Harbour Place 2nd Floor, 103 South Church Street George Town, Grand Cayman KY1-1106 Cayman Islands
Hong Kong Share Registrar	**Computershare Hong Kong Investor Services Limited** Shops 1712-1716, 17th Floor Hopewell Centre 183 Queen's Road East Wanchai Hong Kong
Principal Banks	**Silicon Valley Bank** 3003 Tasman Drive Santa Clara, CA 95054 United States of America
	Citibank N.A., Hong Kong Branch 21/F., Citi Tower, One Bay East 83 Hoi Bun Road, Kwun Tong Kowloon Hong Kong
	Bank of Ningbo 350 Chun Xiao Road Pudong New Area Shanghai China

KEY MILESTONES

Our Company was founded in the Cayman Islands on March 28, 2013 as an exempted company with limited liability under the Cayman Companies Law. The following is a summary of our key business milestones:

Year	Event
2013	Founding of our business
2015	Opened our R&D center in Shanghai, China
2017	Launched new global R&D center in Zhangjiang, Shanghai
	Built a small molecule drug product facility in Suzhou, China capable of supporting clinical and commercial production
	Completed our initial public offering in the United States, listing on Nasdaq, raising approximately US$157.7 million in net proceeds
2018	Built a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates
	Completed a registered offering of ADSs, raising approximately US$140.3 million in net proceeds
2019	Completed a registered offering of ADSs, raising approximately US$215.4 million in net proceeds
2020	Completed a registered offering of ADSs, raising approximately US$280.6 million in net proceeds
	Expanded our portfolio to 16 potential best-in-class/first-in-class products and drug candidates, including two commercialized products and seven assets in pivotal or potentially registration-enabling trials with the addition of odronextamab and repotrectinib, through our partnership with Regeneron and Turning Point Therapeutics

SIGNIFICANT SUBSIDIARIES

Our Company's significant operating subsidiaries during the Track Record Period are as follows:

Name of subsidiary	Principal business activities	Date of incorporation
Zai Lab HK	Business development and R&D activities and commercialization of innovative medicines and device	April 29, 2013
Zai Lab Shanghai	R&D activities and commercialization of innovative medicines and devices	January 6, 2014
Zai Lab Suzhou	Development and commercialization of innovative medicines	October 20, 2015
Zai Biopharmaceutical (Suzhou) Co., Ltd. (再創生物醫藥(蘇州)有限公司)	Development and commercialization of innovative medicines	June 15, 2017
Zai Lab (US) LLC	Business development and R&D activities	April 21, 2017
Zai Lab International Trading (Shanghai) Co., Ltd. (再鼎國際貿易(上海)有限公司)	Commercialization of innovative medicines	November 6, 2019

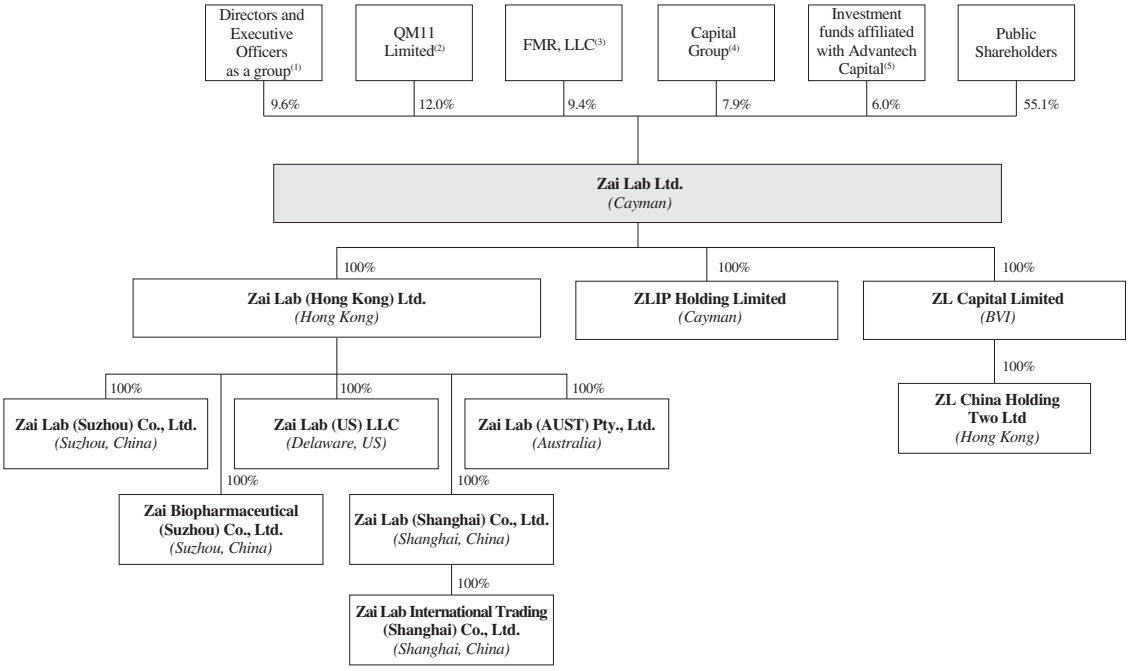
LISTING ON NASDAQ AND REASONS FOR THE LISTING

We have since September 2017 been listed on Nasdaq. Our board is of the view that the net proceeds from the Global Offering will provide us with the necessary funding for us to further develop and commercialize our drugs and support our in-house research and clinical development capabilities as disclosed in "Business – Our Strategies" in this prospectus.

Since the date of our listing on Nasdaq and up to the Latest Practicable Date, our Directors confirm that we had no instances of non-compliance with the rules of Nasdaq in any material respects and to the best knowledge of our Directors after having made all reasonable enquiries, there is no matter that should be brought to investors' attention in relation to our compliance record on Nasdaq.

CORPORATE AND SHAREHOLDING STRUCTURE

The following diagram illustrates our corporate structure, including principal subsidiaries, immediately prior to the completion of the Global Offering (assuming no Shares are issued pursuant to our Equity Plans):



(1) Represents an aggregate of 7,604,401 Shares, including Shares that the directors and executive officers have the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. 6,083,054 Shares were beneficially owned by Samantha Du as of the Latest Practicable Date. See "Major Shareholders" for further details.

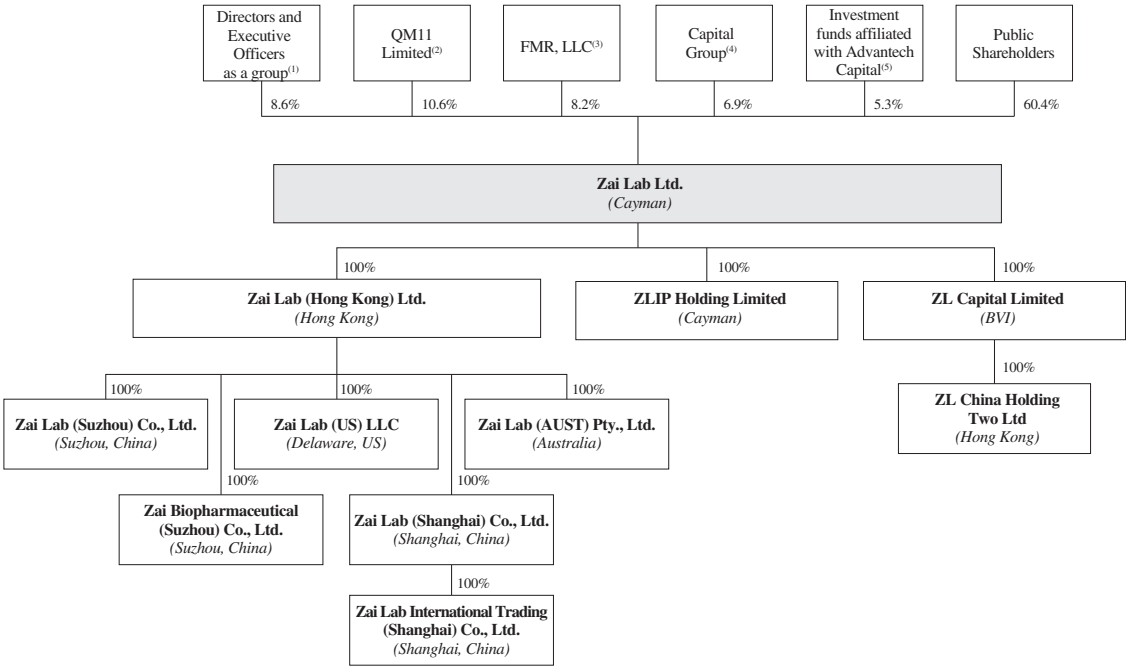
(2) Based on a Schedule 13G/A filed on February 14, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. The address for QM11 Limited is Units 4205-06 Gloucester Tower, The Landmark, Central, Hong Kong.

(3) As of June 30, 2020 based on a Form 13F filed on August 14, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly-owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02110.

(4) As of June 30, 2020 based on a Form 13F filed on August 14, 2020. The address for Capital Group is 333 South Hope Street, Los Angeles, CA 90071.

(5) Based on a Schedule 13G/A filed on February 11, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. Consists of (i) 4,246,791 Shares held by Maxway Investment Limited and (ii) 304,981 Shares held by Harbor Front Investment Limited. The address for Maxway Investment Limited and Harbor Front Investment Limited is c/o DMS House, 20 Genesis Close, George Town, Grand Cayman, KY1-1103, Cayman Islands.

The following diagram illustrates our corporate structure, including principal subsidiaries, immediately upon completion of the Global Offering (assuming the Over-allotment Option is not exercised and no Shares are issued pursuant to our Equity Plans):



(1) Represents an aggregate of 7,604,401 Shares, including Shares that the directors and executive officers have the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. 6,083,054 Shares were beneficially owned by Samantha Du as of the Latest Practicable Date. See "Major Shareholders" for further details.

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("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly-owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02110.

(4) As of June 30, 2020 based on a Form 13F filed on August 14, 2020. The address for Capital Group is 333 South Hope Street, Los Angeles, CA 90071.

(5) Based on a Schedule 13G/A filed on February 11, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. Consists of (i) 4,246,791 Shares held by Maxway Investment Limited and (ii) 304,981 Shares held by Harbor Front Investment Limited. The address for Maxway Investment Limited and Harbor Front Investment Limited is c/o DMS House, 20 Genesis Close, George Town, Grand Cayman, KY1-1103, Cayman Islands.

QM11 Limited is an investment holding company incorporated in Hong Kong and is owned by Qiming Venture Partners IV, L.P. ("QVP IV") and Qiming Managing Directors Fund IV, L.P. ("QMD IV"). QVP IV and QMD IV are venture capital funds incorporated in the Cayman Islands and operated under Qiming Venture Partners, focusing on investments in companies in the media and Internet, information technology, consumer and retail, healthcare and clean technology sectors across China.

Qiming Venture Partners is a Sophisticated Investor (as referred to in the Guidance Letter HKEx-GL92-18 issued by the Hong Kong Stock Exchange in April 2018). It has over US$5 billion assets under management, and many of its portfolio companies are today's most influential firms in their respective sectors, including Xiaomi (Stock Exchange: 1810), Meituan Dianping (Stock Exchange: 3690), Bilibili (Nasdaq: BILI), Roborock (Shanghai Stock Exchange: 688169), Gan & Lee (Shanghai Stock Exchange: 603087), Tigermed (Shenzhen Stock Exchange: 300347, Stock Exchange: 3347), Venus MedTech (Stock Exchange: 2500), CanSino (Shanghai Stock Exchange: 688185, Stock Exchange: 6185), Schrödinger (Nasdaq: SDGR), Sanyou Medical (Shanghai Stock Exchange: 688085), AmoyDx (Shenzhen Stock Exchange: 300685), Berry Genomics (Shenzhen Stock Exchange: 000710), SinocellTech (Shanghai Stock Exchange: 688520), WeDoctor Group and UBTech.

The information and statistics set out in this section and other sections of this prospectus were extracted from different official government publications, available sources from public market research and other sources from independent suppliers. In addition, we engaged Frost & Sullivan for preparing the Frost & Sullivan Report, an independent industry report in respect of the Global Offering. We believe that the sources of the information in this section and other sections of this prospectus are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information from official and non-official sources has not been independently verified by us, the Joint Representatives, the Joint Global Coordinators, Joint Sponsors, Joint Bookrunners, Joint Lead Managers, any of the Underwriters, any of their respective directors and advisers, or any other persons or parties involved in the Global Offering, save for Frost & Sullivan, and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon. Our Directors confirm that, after making reasonable enquiries, there is no adverse change in the market information since the date of the Frost & Sullivan Report that would qualify, contradict or have a material impact on the information in this section.

SOURCE OF INFORMATION

In connection with the Global Offering, we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the global and China pharmaceutical markets. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries. We incurred a total of US$100,000 in fees and expenses for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful Listing or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the Global Offering.

We have included certain information from the Frost & Sullivan Report in this prospectus because we believe such information facilitates an understanding of the global and China pharmaceutical markets for potential investors. Frost & Sullivan prepared its report based on its in-house database, independent third party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analysed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

OVERVIEW OF THE GLOBAL AND CHINA PHARMACEUTICAL MARKETS

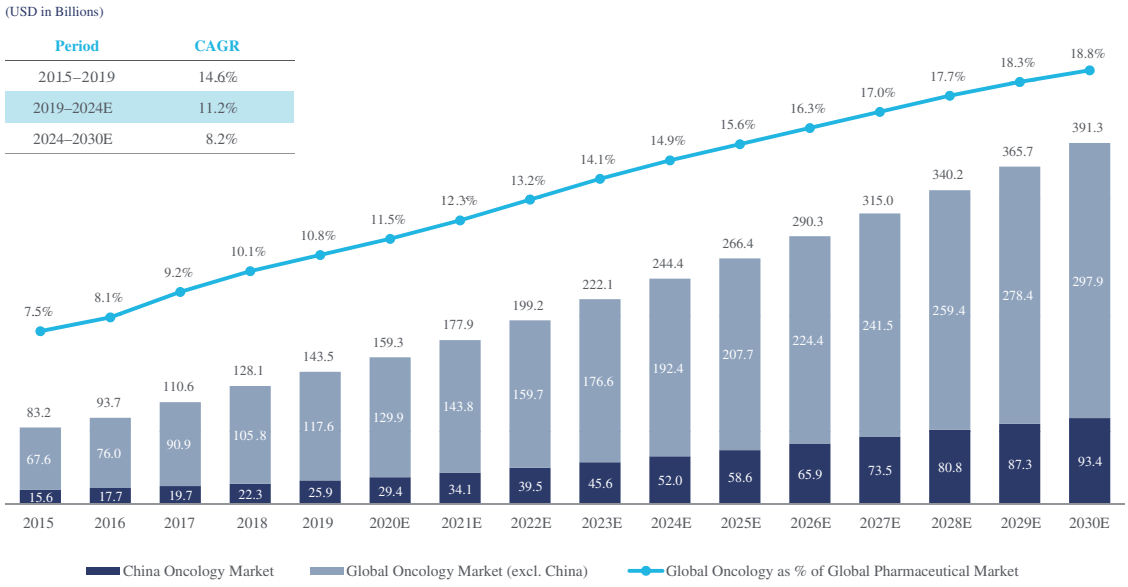
The global pharmaceutical market grew from US$1,105.0 billion in 2015 to US$1,324.5 billion in 2019, representing a CAGR of 4.6% from 2015 to 2019. The market is expected to further grow to US$1,639.5 billion in 2024, at a CAGR of 4.4% from 2019 to 2024, and to US$2,078.5 billion in 2030, at a CAGR of 4.0% from 2024 to 2030. Such growth will be primarily driven by an aging population, increasing prevalence of chronic diseases, increasing affordability, rising public health awareness, as well as continuous innovation and product launches as the result of increasing capital investment into the pharmaceutical industry.

China's pharmaceutical market, the second largest in the world, has benefited from strong momentum in healthcare demand, having increased in size from RMB1,220.7 billion in 2015 to RMB1,633.0 billion in 2019, representing a CAGR of 7.5% from 2015 to 2019. The market is expected to grow to RMB2,228.8 billion in 2024, representing a CAGR of 6.4% from 2019 to 2024. By 2030, China's pharmaceutical market is estimated to reach RMB3,194.5 billion in sales. This growth rate, surpassing the expected growth rate of the global pharmaceutical market during the same period, is driven by growing demand for effective treatments as well as by regulatory tailwinds and expanding reimbursement coverage for innovative drugs, which are expected to improve the population's access to more effective therapeutics while reducing the innovation gap between China and more developed pharmaceutical markets.

OVERVIEW OF THE GLOBAL ONCOLOGY DRUG MARKET

The global oncology drug market has demonstrated strong growth momentum, having increased from US$83.2 billion in 2015 to US$143.5 billion in 2019, representing a CAGR of 14.6% between 2015 and 2019. According to the Frost & Sullivan Report, the market is expected to further grow to US$244.4 billion in 2024 at a CAGR of 11.2% from 2019 to 2024. By 2030, the global oncology market is estimated to reach US$391.3 billion in sales, representing a 2024-2030 CAGR of 8.2%. This growth is mainly driven by the aging global population and growing incidence of cancer, as well as by scientific progress and the launch of new therapies.

Global Oncology Drug Market



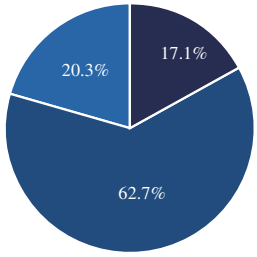
Note:

The translation of renminbi into U.S. Dollars was made at a rate of RMB7.0651 to US$1.00, being the exchange rate on June 30, 2020 set forth in the H.10 statistical release of the Federal Reserve Board.

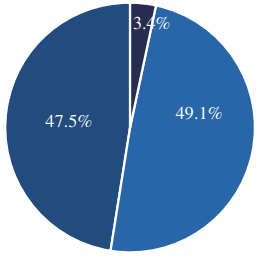
Source: Frost & Sullivan

The field of cancer treatment has developed significantly in the past decades. Main treatment methods today include surgery, radiotherapy, chemotherapy, targeted therapy, and immuno-oncology therapy ("IO Therapy"). Targeted therapy and immuno-oncology therapy have revolutionized cancer treatment and are expected to further drive the growth of global oncology drug market.

Breakdown of Global Oncology Market by Therapy, 2019



Breakdown of Global Oncology Market by Therapy, 2030E



Source: Frost & Sullivan Analysis

Key Growth Drivers of the Global Oncology Market

According to the Frost & Sullivan Report, the global oncology market will be primarily driven by an aging population and rising incidence of cancer, scientific progress, the emergence of combination therapies and the launch of new therapies:

- *Aging Population and Rising Incidence of Cancer* – The probability of developing cancer increases with age. It is projected that the total global population aged over 65 years old will exceed 800 million by 2025. As the result of the aging of the world's population, it is expected that cancer will have a higher incidence in the future and result in increasing demand for effective therapies.

- *Scientific Progress* – Over the past decade, there has been a rapid evolution in the treatment of cancer, driven by advances in personalized medicine and immuno-oncology therapies. From 2015 through 2019, 57 novel therapies were approved by the FDA for the treatment of cancer. These developments and novel treatments have led to improved outcomes for patients and an increased number of patients receiving treatment.

- *Emergence of Combination Therapies* – An increasing trend in the oncology area is the emergence of combination therapies, which offer low toxicity and robust efficacy associated with molecularly-targeted and immuno-oncology therapies. There is a wide academic and industry understanding that these combination therapies have the potential to improve efficacy, treatment response rates and durability as compared to single-agent therapies.

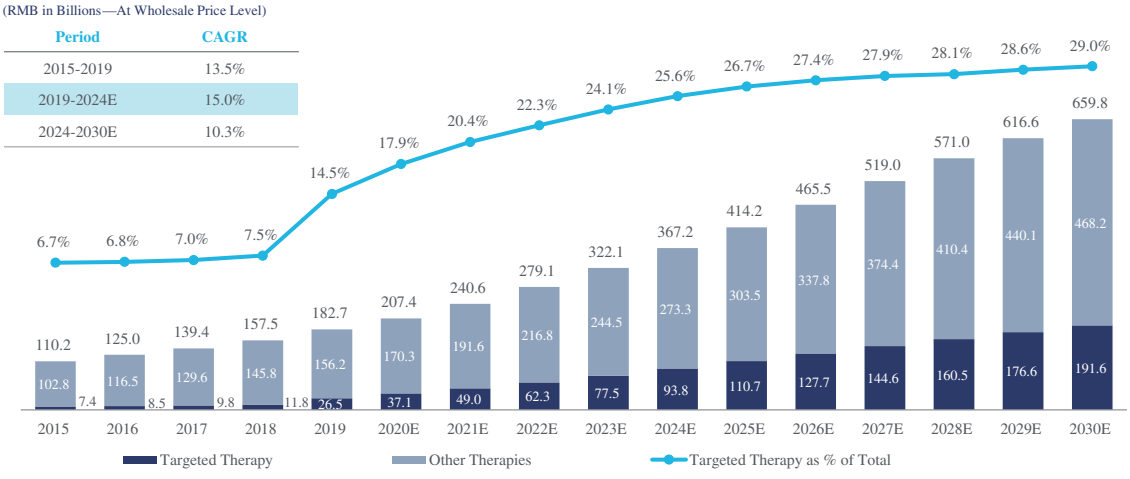
- *Launch of New Therapies* – The pipeline of oncology drugs in clinical development has expanded by 77% over the past ten years and remains robust, with over 800 molecules in late stage development. The pharmaceutical industry's focus on oncology will remain high over the next decade, driven by ongoing investment in research and development seeking to address unmet medical needs.

OVERVIEW OF CHINA'S ONCOLOGY DRUG MARKET

Historical and Estimated Size of China's Oncology Drug Market

China's oncology drug market has grown rapidly in recent years. The total sales of oncology drugs in China grew from RMB110.2 billion in 2015 to RMB182.7 billion in 2019, representing a CAGR of 13.5% between 2015 and 2019, according to the Frost & Sullivan Report. The market is expected to further grow to RMB367.2 billion in 2024 at a CAGR of 15.0% from 2019 to 2024, and to RMB659.8 billion in 2030 at a CAGR of 10.3% from 2024 to 2030. Compared to other therapeutic areas, oncology has the highest growth rate in healthcare expenditures. The strong growth prospects of China's oncology drug market are increasingly driving the growth of the global oncology market in general.

China Oncology Market (2015-2030E)



Source: Frost & Sullivan

Key Growth Drivers for the Oncology Market in China

According to the Frost & Sullivan Report, China's oncology market is largely driven by the following key growth drivers.

- *Large and Increasing Patient Base* – Cancer incidence in China has increased steadily in the past five years, climbing from 4.0 million in 2015 to 4.4 million in 2019. The incidence is expected to grow at an accelerated pace, and is projected to reach 5.0 million by 2024 and 5.7 million in 2030, which is primarily attributable to changes in life style, diet, and the aging population in China. The large and growing cancer patient base in China not only generates substantial market demand for cancer treatments, but also provides a favourable clinical trial environment for the rapid development of new therapeutics.

- *Increasing Healthcare Expenditure and Affordability* – Healthcare expenditure in China is expected to grow due to rising incomes, continued urbanization and strong governmental support. The expansion of the National Reimbursement Drug List ("NRDL") is expected to make oncology treatments more accessible, contributing to an increasing market size of oncology drugs. The 5th NRDL was adjusted in the negotiation that occurred in November 2019 to add 97 drugs, which mainly consist of oncology, chronic disease, and rare disease drugs.

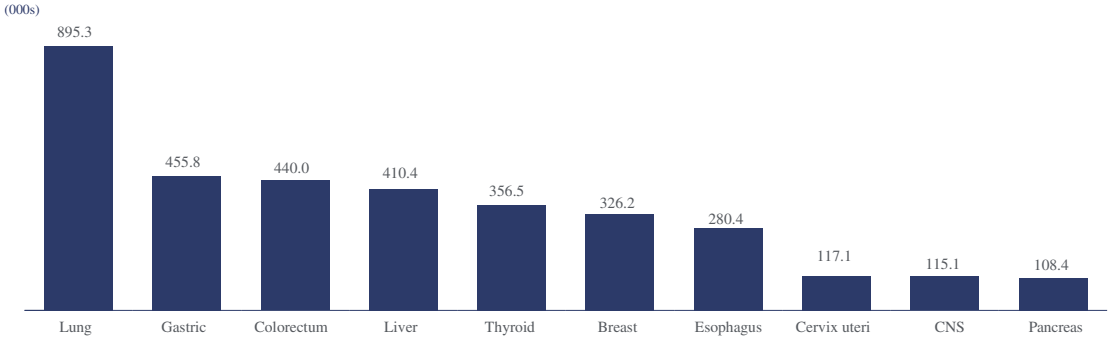
- *Transformation of the Drug Approval Process in China* – On October 8, 2017, the General Office of the State Council released the Opinions on Reform of the Drug and Medical Device Review and Approval (the "Opinions"), which has shifted the regulatory landscape of China's pharmaceutical market. The Opinions aim to accelerate the drug development and approval process in China, and to encourage greater innovation in drug and medical devices by 1) reforming clinical trial management; 2) accelerating review and approval; 3) improving China's participation in global clinical trials and acceptance of foreign clinical data; and 4) protecting innovators.

- *Accelerated Penetration of Innovative Therapies* – According to *Frost* & Sullivan, the market share of chemotherapy as a percentage of the total oncology market in China was above 70% in 2019, which is more than four times that of the total global oncology market. The lower penetration rate of targeted therapies and immunotherapies in China indicates that oncology treatment in China is lagging behind the advancement of oncology treatment globally. The growth of targeted therapies and immunotherapies in China are expected to outpace those of the global market. China's small molecule targeted therapy grew from RMB7.4 billion in 2015 to RMB26.5 billion in 2019, representing a CAGR of 37.6% from 2015 to 2019. It is expected to further grow to RMB93.8 billion in 2024 at a CAGR of 28.7% from 2019 to 2024, and to RMB191.6 billion in 2030 at a CAGR of 12.6% from 2024 to 2030. The penetration rate of targeted therapy in China oncology market reached 14.5% in 2019 and is expected to rise further to 29.0% by 2030.

Epidemiology by Cancer Type in China

Cancer incidence and mortality have been increasing in China, making cancer the leading cause of death (accounting for more than 25% of all causes of death) in 2019 and a major public health problem in the country. The increasing incidence of cancer is mainly attributable to population growth and aging, as well as socio-demographic changes such as pollution, changing lifestyles and dietary patterns, such as increasing consumption of tobacco and alcohol. The following chart shows the top 10 cancers by incidence in China in 2019:

New Cases for Top 10 Cancers in China, 2019



Source: Frost & Sullivan

In China, the top 5 most commonly diagnosed cancers are lung, gastric, colorectum, liver and thyroid cancers, which in aggregate accounted for approximately 60% of all cancer incidence. According to Frost & Sullivan, China has the highest number of cancer-related deaths in the world in 2019, and a higher mortality rate of 187 per 100,000 individuals, compared to the global average of 128 per 100,000 individuals.

China has a differentiated epidemiology profile than the rest of the world. In the rest of the world, top 5 cancer types in terms of annual incidence are lung, breast, colorectum, skin and prostate cancer. Only lung cancer and colorectum cancer are top 5 cancers, in terms of annual incidence, both around the globe and in China.

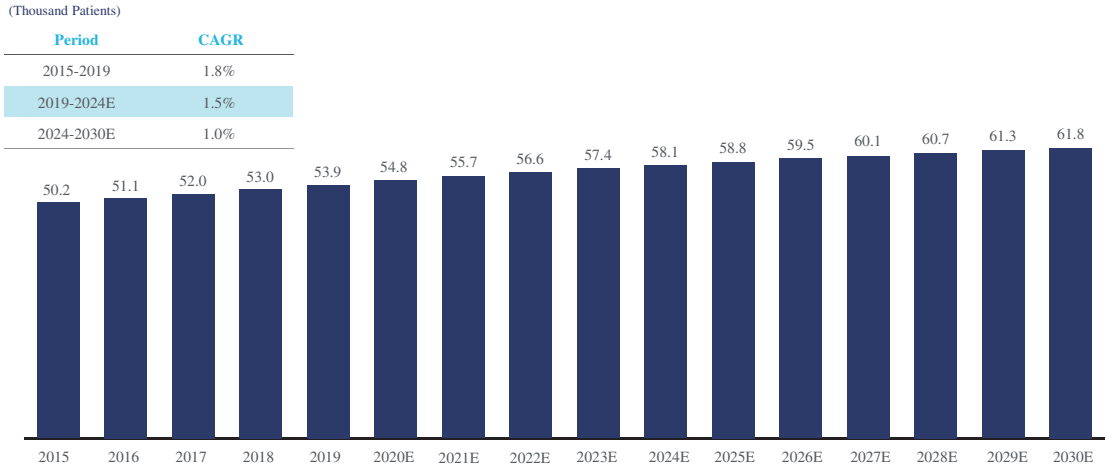
Overview of Selected Cancer Disease Areas

We have established our broad oncology portfolio and oncology strategy with a focus on specific diseases areas. At the moment, we are targeting the leading prevalent tumor disease areas in China, namely gynecologic cancer, breast cancer, gastro-intestinal cancer, brain cancer, lung cancer and hematological malignancies. According to the Frost & Sullivan report, novel therapies will demonstrate significant market potential in all these disease areas given the large patient incidence and tremendous unmet needs as the result of limited treatment options, lack of satisfactory or durable efficacy of current treatments, poor prognosis and others.

Ovarian Cancer

In 2015, the incidence of ovarian cancer in China reached 50.2 thousand, which increased to 53.9 thousand in 2019 with a CAGR of 1.8% from 2015 to 2019. According to the Frost & Sullivan Report, it is estimated that the incidence of ovarian cancer will continue to grow and reach 58.1 thousand by 2024 with a CAGR of 1.5% from 2019 to 2024, and 61.8 thousand by the year of 2030 with a CAGR of 1.0% from 2024 to 2030.

Incidence of Ovarian Cancer in China (2015-2030E)



Source: Frost & Sullivan

Globally, 70% of patients with ovarian cancer are in advanced stage when they are first diagnosed, according to the Frost & Sullivan Report. The previous standard of care in China mainly consists of radical surgery and platinum-based chemotherapy. Although platinum-based chemotherapy is effective at inducing an initial response, an estimated 85% of patients with epithelial ovarian cancer who achieve a full remission following first-line therapy will develop recurrent disease. According to the Frost & Sullivan Report, the 5-year survival rate of ovarian cancer is less than 40%. Historically, there have been limited treatment options for relapsed ovarian cancer patients. Moreover, the interval between recurrences decreases with the increase in the number of recurrences.

According to the Frost & Sullivan Report, the current ovarian cancer treatment paradigm is facing multiple significant challenges including:

- *Limited Clinical Efficacy of First-Line Maintenance Treatment with Chemotherapy* – The standard first-line maintenance treatment which is typically chemotherapy, has shown limited efficacy, with approximately 85% of first-line patients eventually relapsing.

- *Limited Treatment Options for Relapsed Patients* – While the time interval of recurrence becomes shorter after each relapse, effective treatment options for subsequent lines of treatments are limited.

According to the Frost & Sullivan Report, clinical evidence shows that PARP inhibitors, a novel drug class, can significantly delay the recurrence time and prolong PFS of patients when used in the maintenance of ovarian cancer. This has resulted in a series of new therapy approvals globally which have transformed the standard of care in the ovarian maintenance treatment setting. Indeed, PARP inhibitors have now been included in the clinical guidelines (2020 Guidelines for Clinical Application of PARP Inhibitors in Ovarian Cancer) for treatment of ovarian cancer, according to the Frost & Sullivan Report. Main adverse events associated with PARP inhibitors include nausea, thrombocytopenia, anemia, fatigue, decreased appetite, headache, neutropenia, leukopenia etc.

The below table set forth maintenance and treatment options for ovarian cancer under the clinical guidelines as referenced in China:

Stage	**Treatment**
First-line treatment	• Postoperative adjuvant chemotherapy

First-line maintenance treatment	• BRCA1/2 mutation:
	  • Olaparib ± Bevacizumab
	  • Niraparib
	• Wild type BRCA1/2, HRD positive:
	  • Olaparib ± Bevacizumab
	  • Niraparib
	• Wild type BRCA1/2, HRD negative:
	  • Niraparib

Second-line treatment	• Chemotherapy

Maintenance treatment after second-line treatment	• Platinum-sensitive relapse
	  • Olaparib
	  • Niraparib
	  • Rucaparib(1)

Subsequent line treatment	• Platinum-sensitive relapse
	  • BRCA1/2 mutation:
	  – Olaparib
	  – Rucaparib
	  • HRD positive:
	  – Niraparib
	• Platinum-resistant relapse
	  • BRCA1/2 mutation:
	  – Olaparib
	  – Niraparib ± Pembrolizumab
	  – Rucaparib(1)

Note:

(1) Rucaparib is a PARP inhibitor from Clovis, which has not begun clinical trial or been approved in China as of the Latest Practicable Date.

2018 Guideline for Diagnosis and Treatment of Ovarian Cancer
2020 Guidelines for Clinical Application of PARP Inhibitors in Ovarian Cancer
Source: Frost & Sullivan Report

Hong Kong and Macau follow the NCCN Guidelines with respect to the standard of care and treatment guidelines for ovarian cancer, which is largely consistent with the standard of care and treatment guidelines recognized in China described above, according to the Frost & Sullivan Report.

As of July 2020, there were only two marketed PARP inhibitors in China, one is LYNPARZA (olaparib) from AstraZeneca, which was approved in 2018; the other one is ZEJULA (niraparib), which was approved in 2019, according to the Frost & Sullivan Report.

ZEJULA is a potential best-in-class PARP inhibitor, given it is the only PARP inhibitor approved as monotherapy for all-comer patients in the first-line and recurrent maintenance treatment settings, according to Frost & Sullivan. We believe that our early entrant status as one of the first PARP inhibitors in the China market, coupled with the global recognition, differentiated profile and availability of global and China clinical evidence for ZEJULA, position us favourably in China's PARP inhibitor market.

The main competitive drug, LYNPARZA of AstraZeneca, was (i) approved by the FDA in December 2018 in first-line maintenance therapy but only for BReast CAncer gene ("BRCA")-positive patients, and (ii) approved by the FDA in May 2020 for patients whose cancer is associated with homologous recombination deficiency (HRD) positive status, which represent 50% of the advanced ovarian cancer patients, but only in combination with Avastin (bevacizumab). On the other hand, ZEJULA was approved (i) for all advanced ovarian cancer patients regardless of biomarker status, and (ii) as a monotherapy.

Four additional PARP inhibitors are in phase III clinical development or at NDA stage in China, comprising both China developed and global drug candidates. Three of these PARP inhibitors' lead indications focus on late-stage ovarian cancer while one focuses on metastatic prostate cancer. In the late stage ovarian cancer indications, one of the products is targeting BRCA+ patients only. We believe that, pending on the NMPA's approval of our supplemental new drug application (sNDA) for ZEJULA as a maintenance in first-line ovarian cancer, ZEJULA would target the broadest patient population.

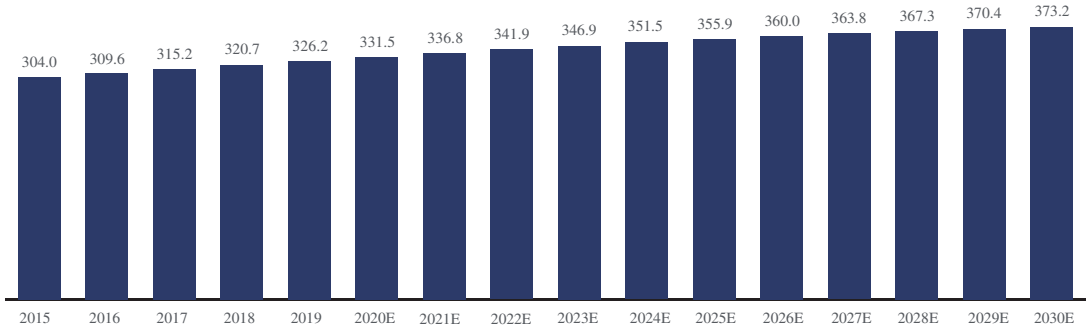
Breast Cancer

According to the Frost & Sullivan Report, breast cancer is the most common cancer in women.

Incidence of Breast Cancer in China (2015-2030E)

(Thousand Patients)

Period	CAGR
2015-2019	1.8%
2019-2024E	1.5%
2024-2030E	1.0%



Source: Frost & Sullivan

The incidence of breast cancer in China grow from 304.0 thousand in 2015 to 326.2 thousand in 2019 with a CAGR of 1.8% from 2015 to 2019, according to the Frost & Sullivan Report. It is estimated that the number will continue to grow and will reach 351.5 thousand by the year of 2024 and 373.2 thousand by the year of 2030, representing a CAGR of 1.5% from 2019 to 2024 and 1.0% from 2024 to 2030, respectively, according to the Frost & Sullivan Report. According to the Frost & Sullivan Report, the 5-year survival rate for breast cancer in China is 82.0%.

Globally, HER2+ represents 25% of breast cancer cases. According to Frost & Sullivan, the current HER2+ breast cancer treatment is facing multiple significant challenges including:

- *Limited Treatment Options in the Late-Stage Setting* – The HER2 oncoprotein drives the aggressive behavior of HER2+ breast and other cancers and has proven to be a good target for cancer therapeutics. However, after treatment failure or disease progression after second-line anti-HER2 treatment, there is no approved effective treatment in late-stage setting in China and globally. There is a significant need for new and effective HER2 targeted therapeutics that can be administered to patients with HER2+ metastatic breast cancer who have previously been treated with other anti-HER2-targeted therapies.

- *Recurrence and Metastases for HER2+ Patients* – Even with treatment, breast cancer patients sometimes have recurrence or even brain metastases since most of the therapies do not penetrate the blood-brain barrier. A study published on the Oncologist has shown that more than 35% of patients with HER2+ metastatic breast cancer (MBC) treated with trastuzumab (Herceptin)-based therapy developed breast cancer brain metastases. The aims of this study were to evaluate the incidence of central nervous system (CNS) metastases in HER-2-positive MBC patients, to define the outcome of patients with CNS metastases, and to identify the risk factors for CNS relapse. At a median follow-up of 28 months from the occurrence of metastatic disease, 43 patients (35.2%) developed CNS metastases. See "Central Nervous System Metastases in HER-2-Positive Metastatic Breast Cancer Patients Treated with Trastuzumab: Incidence, Survival, and Risk Factors." in The Oncologist, 12: 766-773. doi:10.1634/theoncologist.12-7-766.

The below table set forth maintenance and treatment options for HER2+ metastatic breast cancer under the clinical guidelines as referenced:

Stage	**Treatment**
First-line treatment	• Chemotherapy + trastuzumab + pertuzumab • Chemotherapy + trastuzumab/pertuzumab
Second-line treatment	• T-DM1 • Lapatinib/pyrotinib + chemotherapy • Trastuzumab + chemotherapy (other chemotherapy drugs that have not been used before) • Trastuzumab + lapatinib

2019 Guidelines and Norms for Diagnosis and Treatment of Breast Cancer by Chinese Anti-Cancer Association
Source: Frost & Sullivan Report

Gastrointestinal Cancer

Gastrointestinal cancer refers to malignant conditions of the gastrointestinal (GI) tract and other organs involved in digestion, including the oesophagus, stomach, biliary system, pancreas, small intestine, large intestine, rectum and anus. The following table illustrates the incidence of major gastrointestinal cancer types in China for the periods indicated.

Incidence of Major Gastrointestinal Cancer Types in China (2015-2030E)

																	CAGR		
(Thousand Patients)	2015	2016	2017	2018	2019	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2015-2019	2019-2024E	2024E-2030E
Gastric Cancer	403.0	415.9	429.0	442.3	455.8	469.5	483.3	497.3	511.5	525.8	540.3	554.9	569.6	584.4	599.2	613.8	3.1%	2.9%	2.6%
Colorectum Cancer	388.0	400.7	413.6	426.7	440.0	453.5	467.3	481.2	495.3	509.6	524.1	538.8	553.6	568.6	583.6	598.8	3.2%	3.0%	2.7%
Liver Cancer	370.0	380.0	390.1	400.2	410.4	420.7	431.1	441.6	452.1	462.8	473.4	484.1	494.7	505.2	515.6	526.0	2.6%	2.4%	2.2%
Esophageal Cancer	246.0	254.4	262.9	271.6	280.4	289.4	298.5	307.7	317.1	326.6	336.2	345.9	355.5	365.1	374.6	383.9	3.3%	3.1%	2.7%
Pancreatic Cancer	95.0	98.2	101.5	104.9	108.4	112.0	115.6	119.4	123.2	127.1	131.1	135.2	139.4	143.6	147.9	152.2	3.4%	3.2%	3.0%
GIST	28.1	29.0	30.0	31.0	31.9	32.7	33.6	34.6	35.6	36.6	37.6	38.6	39.6	40.9	42.1	43.3	3.2%	2.8%	2.8%

According to the Frost & Sullivan Report, gastric cancer is the largest type of gastrointestinal cancer and also one of the most frequently occurring cancers in China. Gastric cancer includes certain cancer types of the gastroesophageal junction or GEJ, while esophageal cancer also includes other types, as GEJ lies in between the two organs. The incidence of gastric cancer in China was 455.8 thousand in 2019, and it is expected to increase to 525.8 thousand in 2024 and to 613.8 thousand in 2030, according to the Frost & Sullivan Report. The 5-year survival rate for gastric cancer in China is 35.1%, according to the Frost & Sullivan Report.

According to Frost & Sullivan, the current gastric cancer treatment options are limited:

- *Chemotherapy being Only First-Line Treatment* – Gastric cancer has very poor prognosis and is often diagnosed at an advanced stage, which leads to a low 5-year survival rate of 35.1%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for the approximately 20% of patients whose tumors are HER2+. For HER2- gastric cancer, there is no currently available targeted drug for first-line treatment other than chemotherapy.

- *Limited Availability of Targeted Therapies* – Despite an incidence of approximately 455.8 thousand in gastric cancer, there are only three targeted treatment options for advanced gastric cancer: trastuzumab, apatinib, and nivolumab. For HER2+ advanced gastric cancer, trastuzumab is the only HER2-targeted antibody. There has been a strong demand for new reliable and affordable treatment options for advanced gastric cancer.

The below table set forth maintenance and treatment options for gastric cancer under the clinical guidelines as referenced:

Stage	Treatment
First-line treatment	• Chemotherapy (with trastuzumab if patients are HER2-positive advanced metastatic gastric cancer)
Second-line treatment	• Chemotherapy (with trastuzumab if patients are HER2-positive advanced metastatic gastric cancer)
Third-line treatment	• Apatinib • Single agent chemotherapy • Anti-PD-1 monoclonal antibody

2019 CSCO Guidelines for Diagnosis and Treatment of Gastric Cancer
Source: Frost & Sullivan Report

GIST is another type of gastrointestinal cancer and the most common mesenchymal tumor of the gastrointestinal tract. GIST are believed to arise from the interstitial cells of Cajal or their precursors and are heterogeneous histologically, showing spindle cells, epitheloid cells and mixed cells. KIT mutations and PDGFRα mutations drive 80% and 8% of GIST, respectively. Estimates for 5-year survival range from 48% to 90% depending upon the stage of the disease at diagnosis. In China, there was an incidence of 31.9 thousand in 2019.

According to Frost & Sullivan, the currently available GIST treatment standard in China has faced various limitations:

- *Limited Treatment Modalities* – GIST are generally resistant to conventional chemotherapy and radiotherapy treatments. Surgery and Tyrosine Kinase Inhibitors (TKIs) are the only two main treatment modalities to treat GIST. Only 3 TKI therapies have been approved for treating GIST currently, namely Glivec (imatinib) from Novartis, Sutent (sunitinib) from Pfizer and Stivarga (regorafenib) from Bayer. Limited treatment modalities restrict treatment options for patients.

- *Most Responding Patients Acquire Drug Resistance* – Although TKIs are initially effective in treating advanced GIST, patients eventually develop drug resistance resulting in disease progression. Genomic alterations contribute to tumorigenic progression in GIST such as secondary KIT mutations. Available TKIs can only target a limited spectrum of primary/secondary KIT and PDGFRα mutations. New therapies which could target a broader spectrum of primary/secondary KIT mutations and PDGFRα mutations are needed.

- *No Approved Treatment Option for Fourth-Line Therapy or Beyond* – TKIs were approved in the first-line, second-line and third line therapies to provide significant survival benefits for the patients. However, there is no available treatment if patients have a recurrence after third-line therapy. While ripretinib and avapritinib are recommended as fourth-line therapies in the guidelines, they are still awaiting for approval in China.

The below table set forth maintenance and treatment options for GISTs that are unresectable, recurrent, or metastatic under the clinical guidelines as referenced:

Stage	Treatment

First-line treatment	• GISTs with unknown genotype
	  • Imatinib
	  • Dasatinib
	• GISTs with C-kit exon 9 mutation
	  • Imatinib
	• GISTs with PDGFRα D842V
	  • Avapritinib (recommended for PDGFRα mutation only with Level 2A evidence)
	• GISTs with mutation except for C-kit exon 9 mutation and PDGFRα D842V
	  • Imatinib
	• GISTs with PDGFRα exon 18 mutation
	  • Imatinib
	  • Avapritinib (recommended for PDGFRα mutation only with Level 2A evidence)

Second-line treatment	• Limited progression
	  • Resection if feasible
	  • Sunitinib
	  • Imatinib
	  • TACE/RFA for GISTs with liver metastases
	  • Radiotherapy
	• Widespread progression
	  • Sunitinib
	  • Imatinib
	  • Dasatinib

Third-line treatment	• Regorafenib
Fourth-line treatment	• Ripretinib (recommended with Level 1 evidence) • Avapritinib • Imatinib(1)

Note:

(1) Although imatinib is recommended as fourth-line treatment with Level 3 recommendation, in clinical practice patients may not be able to re-use imatinib again as it has been highly recommended in previous lines of the treatment.

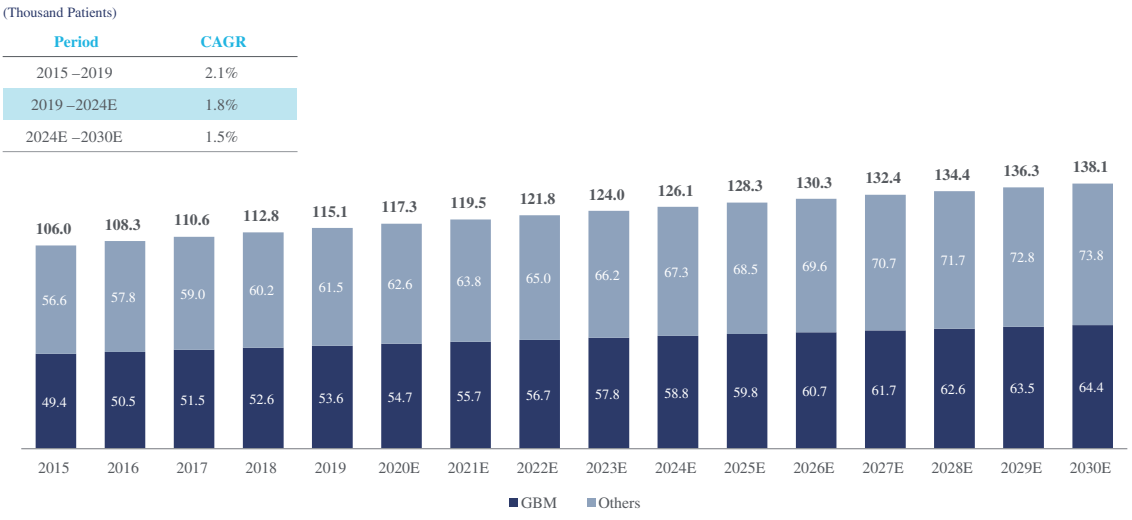
2017 Consensus on Diagnosis and Treatment of Gastrointestinal Stromal Tumors
2020 CSCO Guidelines for Diagnosis and Treatment of Gastrointestinal Stromal Tumors, or 2020 CSCO Guidelines
Source: Frost & Sullivan Report

According to the Frost & Sullivan, in the newly published 2020 CSCO Guidelines, for fourth-line treatment, ripretinib gets Level 1 recommendation, whereas avapritinib gets Level 2 recommendation.

Brain cancer

Malignant gliomas are the most common brain cancers. They originate in the glial cells of the central nervous system (CNS). Gliomas can be divided into 3 main types: astrocytomas, oligodendrogliomas, and ependymomas. Glioblastoma multiforme (GBM) is the most common and aggressive type of primary brain tumor. About 50% of gliomas are GBM, which is classified as Grade IV (most serious) astrocytoma. According to Frost & Sullivan, the incidence of brain cancer in China has reached 115.1 thousand in 2019 with a CAGR of 2.1% from 2015 to 2019. It is estimated that the incidence will further reach 126.1 thousand in 2024 and 138.1 thousand in 2030, according to the Frost & Sullivan Report.

Incidence of Brain Cancer in China (2015-2030E)



Source: Frost & Sullivan

GBM grows rapidly and is the most invasive type of glioma. There are multiple challenges in treating GBM, such as tumor heterogeneity, the blood brain barrier, glioma stem cells, drug efflux pumps and DNA damage repair mechanisms. In 2019, GBM had 53.6 thousands incidences in China, representing 46.6% of all brain cancer incidence in China, according to the Frost & Sullivan Report. GBM's 5 year survival rate in China is less than 5%, according to the Frost & Sullivan Report.

According to the Frost & Sullivan Report, there are two treatments approved for GBM globally in the past fifteen years, namely TMZ and Optune (Tumor Treating Fields). TMZ is a chemotherapy drug approved in 2007 in China and is the only currently available drug approved to treat newly diagnosed GBM cases in China, according to the Frost & Sullivan Report. Optune (Tumor Treating Fields) is a novel cancer therapy that uses electric fields to inhibit tumor growth, which was approved in May 2020 in China. In addition, there are also generics of two drugs, which were approved globally over 40 years ago, available in China, namely carmustine and lomustine; however, their respective recommendation level is not as high as TMZ and they are recommended for recurrent cases only. Developing drugs for GBM is particularly challenging as the result of the blood-brain barrier, which hinders small molecule transport. Factors such as drug resistance mechanisms also need to be resolved.

The below table set forth maintenance and treatment options for GBM under the clinical guidelines as referenced in China:

Stage	Treatment
Treatment for newly diagnosed GBM	• Radiation ± TMZ ± Tumor Treatment Fields
Subsequent treatment after relapse	• Bevacizumab ± Chemotherapy • TMZ • Lomustine/Carmustine • PCV • Cyclophosphamide • Chemotherapy

2018 Guidelines for Diagnosis and Treatment of Glioma
Source: Frost & Sullivan Report

Hong Kong, Macau and Taiwan follow the NCCN Guidelines with respect to the standard of care and treatment guidelines for GBM, which is largely consistent with the standard of care and treatment guidelines recognized in China described above, according to the Frost & Sullivan Report.

Optune (Tumor Treating Fields) is recommended in the national treatment guideline in the U.S. with category 1 recommendation for newly diagnosed GBM. Tumor Treating Fields was recommended with Level 1 evidence as a treatment for newly diagnosed GBM patients in the first Glioma Treatment Guideline (2018 Version) (腦膠質瘤診療規範(2018年版) published by the National Health Commission of China. In addition, Optune is the first innovative treatment approved for GBM treatment since 2007 in China. Major adverse events associated with Tumor Treating Fields include thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, such as treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infection at the sites of electrode contact with the skin, headache, convulsions, and depression.

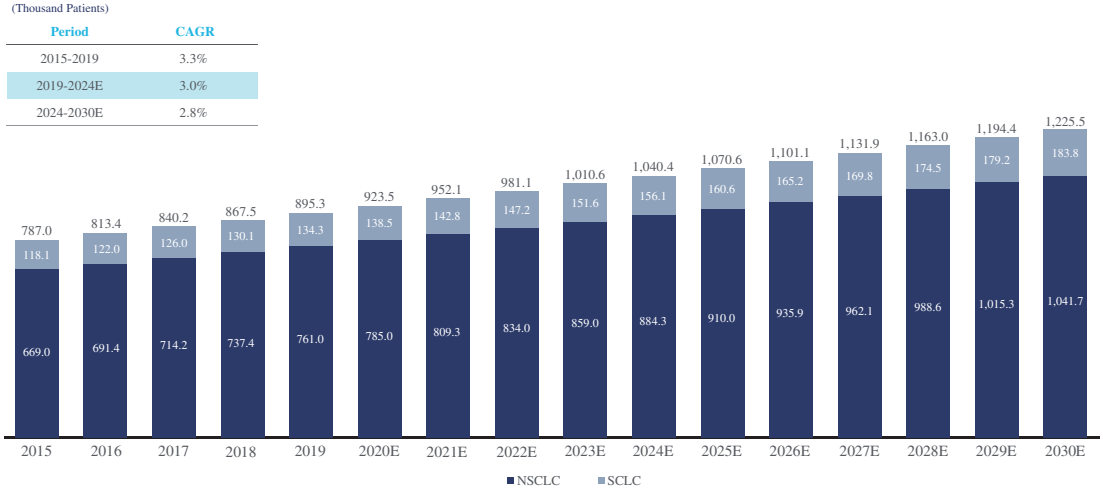
Optune is indicated for the treatment of adult patients (22 years of age or older) with histologically-confirmed recurrence in the supra-tentorial region of GBM. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. Optune with TMZ is indicated for the treatment of adult patients with newly diagnosed, supratentorial GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

Lung cancer

According to the Frost & Sullivan Report, the incidence of lung cancer in China is estimated at 895.3 thousand in 2019 and is expected to reach 1,040.4 thousand in 2024 and 1,225.5 thousand in 2030.

Lung cancer can be categorized into non-small-cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC is any type of epithelial lung cancer other than SCLC. The most common types of NSCLC are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. All types can occur in unusual histologic variants and developed as mixed cell-type combinations. NSCLC accounts for approximately 85% of total lung cancer patients in China. The incidence of NSCLC in China reached 761.0 thousand in 2019, with a CAGR of 3.3% from the year of 2015 to the year of 2019; such number is expected to reach 884.3 thousand in 2024 representing a CAGR of 3.0% from 2019 to 2024, and 1.0 million in 2030 with a CAGR of 2.8% from 2024 to 2030, according to the Frost & Sullivan Report. The 5-year survival rate for lung cancer in China is 19.7% according to the Frost & Sullivan Report.

Incidence of Lung Cancer in China (2015-2030E)



Source: Frost & Sullivan

With the successful identification of activating oncogenic mutations found in NSCLC, molecularly targeted therapy has been used to treat NSCLC and has provided significant survival benefits for NSCLC patients. However, almost all patients ultimately develop acquired resistance, limiting the duration of the clinical benefits and reducing the mean Progression Free Survival (PFS) range to 9.2–13.1 months. Thus, it is important to find effective therapies for patients with acquired resistance.

According to Frost & Sullivan, currently available NSCLC treatment options have shown clinical limitations:

- *Poor Survival Rate* – The 5-year survival rate of lung cancer in China stands only at 19.7% and the rate is also comparable to the U.S. level. The significantly low survival rate is also due to the lack of early detection tools and to the recognition of the symptoms at late stage. In China, the majority of non-small cell lung cancer patients are diagnosed when their disease is already at late stage, with approximately 17.0% patients at stage III and 50.0% at stage IV, resulting in low chance of survival, given current treatment options.

- *Drug Resistance* – Drug resistance is a major cause for therapeutic failure in NSCLC, leading to tumor recurrence and disease progression. For early treatment of NSCLC, there are multiple established predictive biomarkers for target therapy include ALK rearrangements, ROS1 rearrangements, sensitizing EGFR mutations, BRAF V600E point mutations, and PD-L1 expression levels. Unfortunately, despite disease control in the initial stage of treatment, targeted therapy fails to prolong the Overall Survival (OS) of these patients, since almost all patients develop acquired resistance limiting the duration of the clinical benefits and reducing the mean PFS range to 9.2-13.1 months.

As of July 2020, there were three ROS1/NTRK/ALK targeted drugs marketed in China, of which there is only one approved targeted therapy for patients with advanced ROS1-positive lung cancer and despite its efficacy, most patients eventually acquire resistance. The unmet need in the ROS1-positive lung cancer patient population is significant. The preliminary clinical activity and safety data generated to date for repotrectinib represent a promising clinical profile. ROS1 rearrangement is estimated to be an oncogenic driver in approximately 3 percent of patients with advanced NSCLC in China, while NTRK is estimated to be an oncogenic driver in approximately 0.5-1 percent of patients with wide range of solid tumors in China, according to the Frost & Sullivan Report.

The below table set forth maintenance and treatment options for NSCLC under the clinical guidelines as referenced:

Stage	Treatment					
	EGFR mutations	ALK Rearrangement+	ROS1 Rearrangement+	BRAF V600E mutation	NTRK Rearrangement	Driver Gene-/Unknown Genotype
First-line treatment. .	- Gefitinib ± Chemotherapy - Erlotinib ± Chemotherapy/ Bevacizumab - Icotinib - Afatinib - Osimertinib - Chemotherapy ± Bevacizumab (Non-squamous carcinoma)	- Alectinib - Crizotinib - Chemotherapy ± Bevacizumab (Non-squamous carcinoma) - Brigatinib(1)	- Crizotinib - Chemotherapy ± Bevacizumab (Non-squamous carcinoma) - Entrectinib(1)	- Dabrafenib ± Trametinib - Refer to the fist-line treatment of NSCLC with Driver Gene-/Unknown Genotype	- Larotrectinib(1) - Entrectinib(1) - Refer to the fist-line treatment of NSCLC with Driver Gene-/Unknown Genotype	- Chemotherapy - Bevacizumab ± Chemotherapy - Pembrolizumab ± Chemotherapy - Camrelizumab + Chemotherapy - Atezolizumab + Chemotherapy ± Bevacizumab - Recombinant human endostatin ± Chemotherapy
Second-line treatment. .	- T790M positive: Osimertinib - T790M negative: Chemotherapy ± Bevacizumab (Non-squamous carcinoma) - Almonertinib	- Continued EGFR-TKI Therapy - Alectinib/ Ceritinib - Chemotherapy ± Bevacizumab (Non-squamous carcinoma) - Brigatinib(1) - Lorlatinib(1)	- Crizotinib(2) - Chemotherapy ± Bevacizumab (Non-squamous carcinoma)	- Refer to the subsequent line treatment of NSCLC with Driver Gene+/-.	- Refer to the subsequent line treatment of NSCLC with Driver Gene+/-.	- Chemotherapy - Nivolumab - Pembrolizumab - Atezolizumab
Third-line treatment. .	- Single agent chemotherapy ± Bevacizumab (Non-squamous carcinoma) - Anlotinib	- Single agent chemotherapy ± Bevacizumab (Non-squamous carcinoma) - Anlotinib	- Single agent chemotherapy ± Bevacizumab (Non-squamous carcinoma)	- Refer to the subsequent line treatment of NSCLC with Driver Gene+/-.	- Refer to the subsequent line treatment of NSCLC with Driver Gene+/-.	- Nivolumab - Chemotherapy - Anlotinib

Notes:

(1) Larotrectinib, brigatinib, lorlatinib and entrectinib have not been approved in China as of the Latest Practicable Date.

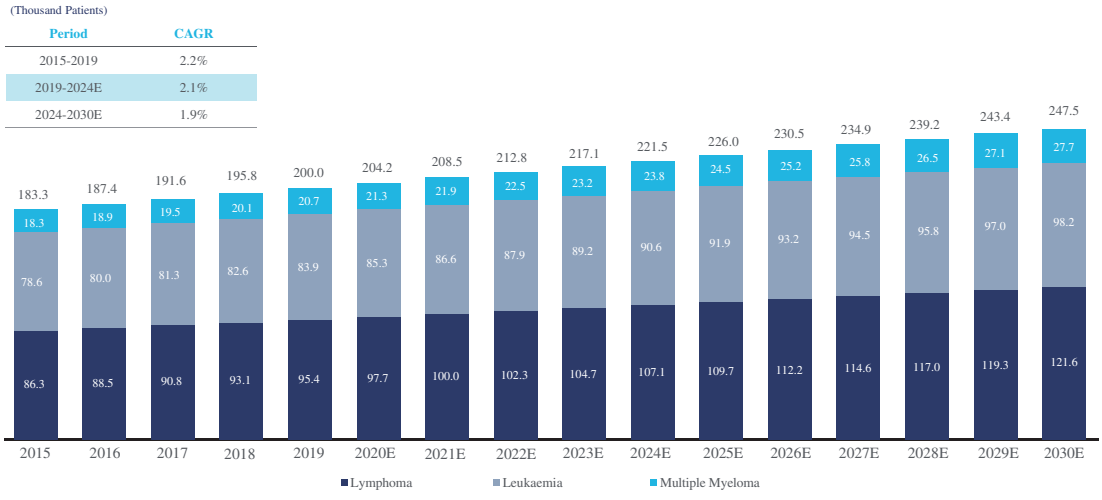
(2) Crizotinib is only recommended for CNS metastasis or oligometastases patients in the second-line treatment.

2020 CSCO Guidelines for Diagnosis and Treatment of NSCLC
Source: Frost & Sullivan Report

Hematological Malignancy

Hematological malignancy, also called blood cancer, is cancer that begins in blood-forming tissue, such as the bone marrow, or in the cells of the immune system. According to Frost & Sullivan, hematological malignancy had an incidence of 200.0 thousand in China in 2019, and the biggest sub-type of hematological malignancy was lymphoma, with an incidence of 95.4 thousand in 2019. The two main categories of lymphomas are Hodgkin's lymphomas (HL) and the non-Hodgkin lymphomas (NHL). NHL accounts for approximately 90% of lymphoma and has a variety of subtypes, which are categorized by the characteristics of the lymphoma cells, including their appearance, the presence of proteins on the surface of the cells and their geneticfeatures.

Incidence of Hematological Malignancy in China (2015-2030E)



Source: Frost & Sullivan

NHL originating in B-cells (B-NHL) makes up 85% of all NHL cases, with the three most common subtypes in China being DLBCL (Diffuse large B-cell lymphoma), MZL (Marginal zone lymphoma) and FL (Follicular lymphoma), according to the Frost & Sullivan Report. DLBCL alone accounts for about 41% of all NHL cases while MZL and FL accounts for 8% and 6%, respectively in China, according to Frost & Sullivan. DLBCL is an aggressive or fast-growing NHL that affects B-lymphocytes. MZL is a group of indolent or slow growing NHL B-cell lymphomas, FL is typically a slow-growing or indolent form of NHL that arises from B-lymphocytes, making it a B-cell lymphoma.

According to Frost & Sullivan, there are multiple critical obstacles in NHL treatment:

- *Limited Efficacy* – In China, the prevalence of NHL reached 485.0 thousand patients in 2019, with an overall 5-year survival rate of NHL of 37.0%, lower than that of cancer in general in China. Some aggressive types of NHL, such as DLBCL, can involve organs other than the lymph nodes, progressing rapidly and becoming fatal due to invasion across all areas of the body if treatment is not administered at an early stage. Only early-stage detection and treatment can lead to a higher chance of survival. On the other hand, indolent subtypes of NHL, such as FL, despite slow progression, can be long-standing over years and are less likely to be cured with current treatment methods. The current treatment paradigm and survival rate have demonstrated the difficult nature of NHL, indicating significant unmet clinical needs.

- *Drug Resistance* – Anti-CD20 antibodies in combination with chemotherapy (or R-CHOP) are the standard of care for the treatment of B-NHLs; however, despite initial responses, about 50% of NHL patients will eventually experience disease progression due to drug resistance, indicating a need for new treatment options. In particular, around 15% of DLBCL (the most common subtype of NHL) patients are characterized as primary refractory towards first-line R-CHOP therapy. For these refractory patients, treatments options with new modalities are highly necessary. According to the Frost & Sullivan Report, there are currently no marketed bispecific antibody drugs for hematological malignancy in China as of July 2020.

The below table set forth maintenance and treatment options for DLBCL under the clinical guidelines as referenced:

Stage	Treatment
First-line treatment	• Monoclonal antibody + Chemotherapy - R-CHOP - R-miniCHOP - R-CHOEP - R-DAEPOCH
Second-line treatment	• Monoclonal antibody + Chemotherapy - R-DHAP - R-ICE - R-GDP - R-ESHAP - R-GD - R-DAEPOCH - R-GemOx - R-MINE • Small molecule targeted therapy - Ibrutinib (BTK inhibitor)(1)
Third-line treatment	• Monoclonal antibody + Chemotherapy - R-DHAP - R-ICE - R-GDP - R-ESHAP - R-DAEPOCH - R-GemOx - R-MINE • Small molecule targeted therapy - Ibrutinib (BTK inhibitor)(1) • Monoclonal antibody + Small molecule targeted therapy - R2

Note: R-CHOP(rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); R-CHOEP(rituximab, cyclophosphamide, doxorubicin, vincristine,etoposide, prednisone); R-DAEPOCH(rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin); R-miniCHOP(rituximab, lower dosage of CHOP); R-DHAP(rituximab, dexamethasone, cisplatin, cytarabine); R-ESHAP(rituximab, etoposide, methylprednisolone, cytarabine, cisplatin); R-GemOx(rituximab, gemcitabine, oxaliplatin); RICE(irituximab, fosfamide, carboplatin, etoposide); RMINE(rituximab, mesna, ifosfamide, mitoxantrone, etoposide);R2(rituximab, lenalidomide); R-GD (rituximab, gemcitabine, dexamethasone); R2 (rituximab, revlimid)(2); R-GDP(rituximab, gemcitabine, dexamethasone, cisplatin).

(1) BTK is only approved for relapsed or refractory MCL and chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), although it has been recommended in the guidelines of NHL for the treatment of refractory or relapsed DLBCL (>=2) who are not eligible for haematopoietic stem cell transplant, and with Level 3 recommendation.

(2) Revlimid has not been approved for treatment of DLBCL in China as of the Latest Practicable Date.

2019 CSCO Guidelines for Diagnosis and Treatment of Lymphoma
Source: Frost & Sullivan Report

The below table set forth maintenance and treatment options for FL under the clinical guidelines as referenced:

Stage	Treatment
First-line treatment	• Monoclonal antibody - Rituximab - Obinutuzumab • Chemotherapy - Chlorambucil - Cyclophosphamide • Monoclonal antibody + Chemotherapy - R-CHOP - R-CVP - R-Bendamustine - R-Alkylating agent • Monoclonal antibody + Small molecule targeted therapy - R-Lenalidomide
Second-line treatment	• Monoclonal antibody - Rituximab • Chemotherapy - Chlorambucil - Cyclophosphamide • Monoclonal antibody + Chemotherapy - R-CHOP - R-CVP - R-Bendamustine - Alkylating agent + Rituximab • Monoclonal antibody + Small molecule targeted therapy - R-Lenalidomide • Small molecule targeted therapy - Idelalisib - Copanlisib (PI3K inhibitors)

Note: R(rituximab); R-CHOP(rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); R-CVP(rituximab, cyclophosphamide, vincristine, prednisone); Alkylating agent(Chlorambucil or Cyclophosphamide);

2019 CSCO Guidelines for Diagnosis and Treatment of Lymphoma
Source: Frost & Sullivan Report

The below table set forth maintenance and treatment options for MCL under the clinical guidelines as referenced:

Stage	Treatment
First-line treatment	• Monoclonal antibody - Rituximab • Monoclonal antibody + Chemotherapy - R-CHOP - R-DHAP - R-HyperCAVD - R-Bendamustine - VR-CAP - RBAC • Monoclonal antibody + Small molecule targeted therapy - R-Lenalidomide
Second-line treatment	• Small molecule targeted therapy - Lenalidomide - Bortezomib - Ibrutinib (BTK inhibitor) • Monoclonal antibody + Small molecule targeted therapy - R-Lenalidomide - R-Bortezomib - R-Ibrutinib - R-Ibrutinib-Lenalidomide • Monoclonal antibody + Chemotherapy - R-Bendamustine • Monoclonal antibody + Chemotherapy + Small molecule targeted therapy - R-Bendamustine-Bortezomib

Note: R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); R-CHOEP (rituximab, cyclophosphamide, doxorubicin, vincristine,etoposide, prednisone); R-DAEPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin); R-miniCHOP (rituximab, lower dosage of CHOP); R-DHAP(rituximab, dexamethasone, cisplatin, cytarabine); R-ESHAP(rituximab, etoposide, methylprednisolone, cytarabine, cisplatin); R-HyperCVAD(Regimen A: rituximab, cyclophosphamide, mesna, doxorubicin, dexamethasone, vincristine; Regimen B: rituximab, methotrexate, cytarabine); VR-CAP(bortezomib, rituximab, vincristine, doxorubicin, prednison); RBAC(rituximab, bendamustine, cytarabine)

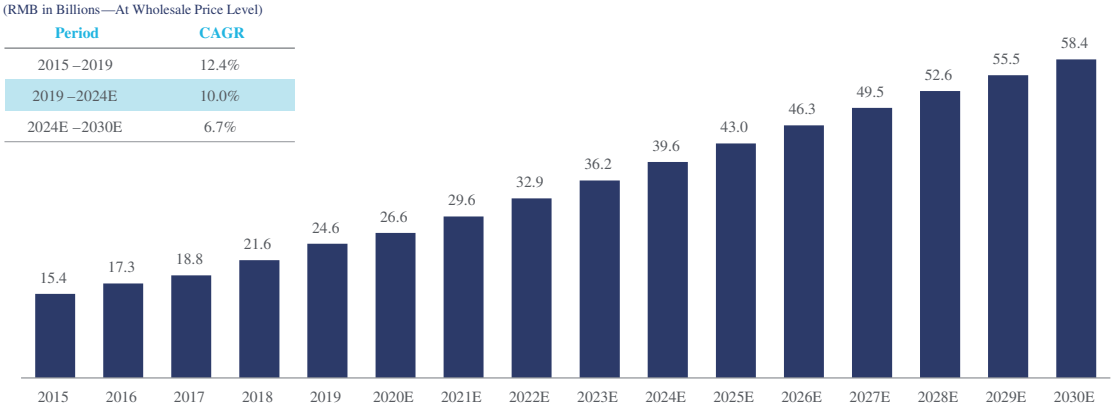
2019 CSCO Guidelines for Diagnosis and Treatment of Lymphoma
Source: Frost & Sullivan Report

OVERVIEW OF CHINA'S ANTI-INFECTIOUS DISEASE DRUG MARKET

The market size of anti-infective drugs in China amounted to RMB225.5 billion in 2019, accounting for 13.8% of the entire pharmaceutical market in China, and is expected to increase to RMB260.7 billion by 2024, growing at a CAGR of 2.9% from 2019 to 2024, according to the Frost & Sullivan Report. The recent slowdown of the overall anti-infective market growth is the result of improved health conditions together with the government restriction on use of antibiotics. Over the past ten years, there were eight novel antibiotics approved in China, namely Tigecycline (替加環素) from Pfizer, Morinidazole (嗎啉硝唑) from Hansoh, Nemonoxacin (奈諾沙星) from Zhejiang Medicine, Carrimycin (可利黴素) from Shanghai Tonglian, Tedizolid (特地唑胺) from Merck Sharp & Dohme B.V., Sitafloxacin (西他沙星) from Daiichi Sankyo, Garenoxacin (加諾沙星) from Toyama Chemical and Ceftazidime/Avibactam (頭孢他啶/阿維巴坦) from Pfizer, according to the Frost & Sullivan Report.

Multi-Drug Resistance (MDR) is defined as acquired non-susceptibility to at least one agent in three or more antimicrobial categories. MDR is are increasingly problematic in healthcare settings, primarily because of the small availability of effective antimicrobial agents that are available to treat infections with these organisms. The growth rate of China MDR antibiotics market, on the other hand, remained stable in the past 5 years, increasing from RMB15.4 billion in 2015 to RMB24.6 billion in 2019 at a CAGR of 12.4%, according to the Frost & Sullivan Report. The market will further grow to RMB39.6 billion from 2019 to 2024, representing a CAGR of 10.0%, and is estimated to reach RMB58.4 billion in 2030.

China MDR Antibiotics Market (2015–2030E)



Source: Frost & Sullivan

The evolving resistance to anti-infective drugs of has become a pressing public health issue, which has to be addressed through the prudent use of such drugs and the replacement with new anti-infective drugs. As a result, the growth rate of anti-infective drugs treating multi-drug resistant bacteria is expected to be much higher than that of the anti-infective drug market as a whole.

According to the Frost & Sullivan Report, for multi-drug resistant bacteria infections, the major recommended antibiotics include Vancomycin, Tigecycline, Linezolid, Teicoplanin, Daptomycin, Carbapenem, Polymxin and BL/BLI combinations (Cefoperazone/Sulbactam, Piperacilin/Tazobactam), which are recommended to treat infections caused by MDR bacteria such as Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Enterococci (VRE) and Multidrug-resistant Acinetobacter, etc. Zai Lab's omadacycline is a type of tetracycline, a category that tigecycline also falls in. However, compared to tigecycline, omadacycline has both IV and oral formulation which rendering more flexibility for clinical use.

Key Growth Drivers of China's MDR Antibiotic Drug Market

According to Frost & Sullivan, the growth of MDR is driven by the following key factors:

- *Increasing in Health Awareness and Patient Pool* – The disposable income and health awareness are increasing in China; whereas, the number of patients suffering from infections is increasing as well.

- *Growing Drug Resistance* – Bacterial resistance to commonly used antibiotics is still on the rise in China. For example, in 2018, the drug resistance rate of *Streptococcus pneumoniae* to erythromycin was as high as 95.4%; meanwhile, the resistance of *Escherichia coli* to third generation cephalosporins was 53%, and the resistence of *A. baumannii* to carbapenems was 56.1%.

- *The Need for Reliable Treatments* – Both G+ bacteria and G-bacteria experience high drug resistance rates, while antibiotics to treat resistant organisms are very limited. Despite high demand from China's patient population and medical community, China has approved only eight novel antibiotics in the last ten years. Besides, many currently approved drugs have significant safety issues, including allergic reactions, renal toxicity, bone marrow toxicity, vomiting, nausea and diarrhea.

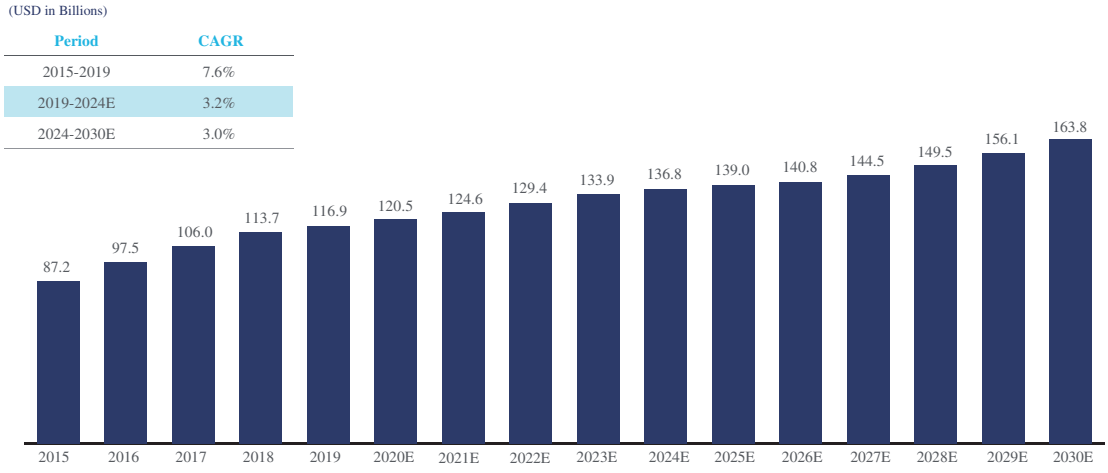
- *Favourable Policies* – The government has introduced various policies to encourage and support research and development of the next-generation antibiotics.

- *Improving Affordability* – In the 2019 NRDL update, 200 anti-infective drugs were included, which achieved a large coverage in this therapeutic area. In addition, in the NRDL negotiation in 2019, 11 new therapies were successfully included. Since the government implements a dynamic adjustment mechanism for NRDL, there is a possibility that more new anti-infective drugs will be included in the future.

OVERVIEW OF THE GLOBAL AUTOIMMUNE DISEASES MARKET

Autoimmune diseases are conditions in which the human body's immune system mistakenly attacks the body and can be associated with over-activity of the immune system. According to the Frost & Sullivan Report, the global autoimmune disease market was US$87.2 billion in 2015 and reached US$116.9 billion in 2019 at a CAGR of 7.6% from 2015 to 2019. The market is expected to grow to US$136.8 billion in 2024 and US$163.8 billion in 2030, representing a CAGR of 3.2% from 2019 to 2024 and a CAGR of 3.0% from 2024 to 2030, according to the Frost & Sullivan Report. The chart below illustrates the historical and forecast size of the global autoimmune diseases market.

Global Autoimmune Diseases Market



Source: Frost & Sullivan

Autoimmune disease remains a major burden on health systems around the world and significantly impacting the patients' quality of life. With few exceptions, autoimmune diseases have proven very challenging to treat, and impossible to cure. Although much progress has been made in understanding the mechanism of autoimmune disease, effective and highly targeted treatments have proven elusive. Most current therapeutic agents broadly suppress the body's immune system, require continued and sometimes life-long therapy, and result in an increased risk of malignancy and infection. Biologics have established themselves as a new effective drug class used when older systemic treatments, such as methotrexate and cyclosporine, fail to control the disease. As a result, biologics such as monoclonal antibodies have become an increasingly important contributor to the growth of the global autoimmune market, and represent a key areas of focus for the research and development of novel therapies that would provide more treatment options to patients. However, there remain limitations associated with current biologics. For example, TNFα inhibitors are recommended for a number of autoimmune disease types, however they fail to obtain sufficient response in other types. Furthermore, some patients who initially responded tend to lose response over time due to the development of anti-drug antibodies. Some TNFα inhibitors are also associated with several shortcomings as a life-long therapy, including inconvenient intravenous or

subcutaneous formulation and an FDA black-box warning of potential serious infections and malignancy. Similarly, while IL-17 blockers are used in psoriasis with unprecedented efficacy, they can nevertheless result in certain safety issues due to immunosuppression, are restricted to more severely affected patient populations, and have to be administered by IV or SC injection. There is therefore significant unmet need for novel therapies with better safety profiles and better efficacy, as well as more convenient dosing, which can expand the market, providing additional options to patients.

We are subject to various laws and regulations of the PRC, the U.S. and rest of the world that are material to our operations and are discussed below.

PRC REGULATION ON COMPANY ESTABLISHMENT AND FOREIGN INVESTMENT

The establishment, operation and management of corporate entities in China are governed by the Company Law of PRC (《中華人民共和國公司法》, the "PRC Company Law"), which was promulgated by the Standing Committee of the National People's Congress (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 (《指導外商投資方向規定》), 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) (《外商投資准入特別管理措施(負面清單)(2020年版)》, the "Negative List"), which was promulgated by the Ministry of Commerce (the "MOFCOM") and National Development and Reform Commission (the "NDRC") in June 2020 and came into effect in July 2020. The Negative List set 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 for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "Foreign Investment Law") was promulgated by the NPC in March 2019 and came into effect in January 2020. After the Foreign Investment Law came into effect, the Law on Wholly Foreign-owned Enterprises of the PRC (《中華人民共和國外資企業法》), the Law on Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》) and the Law on Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as "foreign investors") directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: 1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; 2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) investing by foreign investors in new projects in China alone or jointly with other investors; 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 (《中華人民共和國外商投資法實施條例》), which came into effect in January 2020. After 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 (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law of the PRC (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-Foreign Cooperative Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合作經營企業法實施細則》) have been repealed simultaneously.

In December 2019, the MOFCOM and the State Administration for Market Regulation (the "SAMR") promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect in January 2020. After 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 (《外商投資企業設立及變更備案管理暫行辦法》) have been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities according to the Measure on Reporting of Foreign Investment Information.

PRC REGULATION OF PHARMACEUTICAL PRODUCT DEVELOPMENT AND APPROVAL

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

In October 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of the PRC Communist Party jointly issued the Opinion on Deepening the Reform of the Regulatory Approval System to Encourage Innovation in Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), or the Innovation Opinion, which is a mandatory plan to further the reform of the review and approval system and encourage the innovation of drugs and medical devices. The expedited programs and other advantages under this and other recent reforms encourage drug manufacturers to seek marketing approval in China first and develop drugs in high priority disease areas, such as oncology, or rare disease.

To implement the regulatory reform introduced by the Innovation Opinion, the Standing Committee of the NPC and National Medical Products Administration, or NMPA, are currently revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which includes the framework laws known as the Administrative Measures for Drug Registration and the Drug Administration Law of the PRC.

Regulatory Authorities

In the PRC, the newly formed NMPA is the authority under the State Administration for Market Regulation that monitors and supervises the administration of pharmaceutical products, medical appliances and equipment, and cosmetics. The NMPA was established in March 2018 as part of the institutional reform of the State Council. Predecessors of the NMPA include the former China Food and Drug Administration, or the CFDA, that was established in March 2013, the State Food and Drug Administration, or the SFDA, that was established in March 2003 and the previous State Drug Administration, that was established in August 1998.

The primary responsibilities of the NMPA include:

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

According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs (《國家食品藥品監督管理總局關於調整部分藥品行政審批事項審批程序的決定》), promulgated by the CFDA in March 2017 and came into effect in May 2017, the approval of clinical trial application should be issued by the Center for Drug Evaluation (the "CDE") in the name of the CFDA.

The National Health and Family Planning Commission, or NHFPC, is rebranded as the National Health Commission, or NHC. The NHC is an authority at the ministerial level under the State Council and is primarily responsible for national public health. The NHC combines the responsibilities of the former NHFPC, the Leading Group Overseeing Medical and Healthcare Reform under the State Council, the China National Working Commission on Aging, partial responsibilities of the Ministry of Industry and Information Technology in relation to tobacco control, and partial responsibilities from the State Administration of Work Safety in relation to occupational safety. The predecessor of NHFPC is the Ministry of Health, or MOH. Following the establishment of the former SFDA in 2003, the MOH was put in charge of the overall administration of the national health in the PRC excluding the pharmaceutical industry. The NHC performs a variety of tasks in relation to the health industry such as establishing and overseeing the operation of medical institutes, which also serve as clinical

trial sites, regulating the licensure of hospitals and producing professional codes of ethics for public medical personnel. The NHC plays a significant role in drug reimbursement. The NHC and its local counterparts at or below provincial-level local governments also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, which is the chief means through which public hospitals and their internal pharmacies acquire drugs. The NHC is also responsible for overseas affairs, such as dealings with overseas companies and governments.

Drug Administration Laws and Regulations

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), or the Drug Administration Law, was promulgated by the Standing Committee of the NPC, in September 1984. The last two 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 (《藥品管理法實施條例》) was promulgated by the State Council in August 2002, and was last amended in March 2019. The Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law have jointly laid down the legal framework for administration of pharmaceutical products in China, including the research, development and manufacturing of drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which 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 August 2019, the Standing Committee of the NPC promulgated the new Drug Administration Law (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 system (the "MAH System"), conditional approvals of drugs, traceability system of drugs, and the cancellation of relevant certification according to the Good Manufacturing Practice and the Good Supply Practice. To further implement the 2019 Amendment, the amended Administrative Measures for Drug Registration (《藥品註冊管理辦法》), the amended Good Clinical Trial Practice for Drugs (《藥物臨床試驗質量管理規範》) and the amended Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) etc. have been promulgated and come into effect in July 2020. See "– PRC Regulation of Pharmaceutical Product Development and Approval – Administrative Measures for Drug Registration," "– PRC Regulation of Pharmaceutical Product Development and Approval – Regulations on the Clinical Trials and Registration – Compliance with GCP and Drug Clinical Institutions," "– Permits and Licenses for Manufacturing and Distributing of Drugs – Pharmaceutical Manufacturing Permit and GMP Requirements."

Good Laboratories Practice Certification for Pre-clinical Research

To improve the quality of animal research, the former SFDA promulgated the Good Laboratories Practice of Pre-clinical Laboratory (《藥物非臨床研究質量管理規範》) in 2003, or the GLP 2003, and began to conduct the certification program of the GLP. The GLP 2003 was then abolished and replaced by the Good Laboratories Practice of Pre-clinical Laboratory promulgated in 2017. In April 2007, the former SFDA promulgated the Administrative Measures for Certification of Good Laboratory Practice of Preclinical Laboratory (《藥物非臨床研究質量管理規範認證管理辦法》), providing that the former SFDA (now the NMPA) is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, the former SFDA (now the NMPA) decides whether an institution is qualified for undertaking pharmaceutical nonclinical research upon the evaluation of the institution's organizational administration, personnel, laboratory equipment and facilities and its operation and management of nonclinical pharmaceutical projects. If all requirements are met, a GLP Certification will be issued by the former SFDA (now the NMPA) and published on the government website.

Collecting and Using Patients' Human Genetic Resources

In June 1998, the Ministry of Science and Technology, or MOST, and the former MOH, jointly established the Rules for Protecting and Utilizing Human Genetic Resources (《人類遺傳資源管理暫行辦法》). In July 2015, the MOST issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of China (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》), which provides that foreign-invested sponsors that collect and use patients' human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Administrative Office, or the HGRAO, through its online system.

In October 2017, the MOST issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which simplified the approval for collecting and using human genetic resources for the purpose of commercializing a drug in China.

In May 2019, the State Council of PRC issued the Regulation on the Administration of PRC Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), which formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for international clinical trials using PRC patients' human genetic resources at clinical study sites without involving the export of such human genetic resources outside of China. Under the new rule, a notification filing specifying the type, quantity and usage of the human genetic resources, among others, with the HGRAO is required before conducting such clinical trials. The collection and use of PRC patients' human genetic resources in international collaboration in basic scientific research involving export are still subject to the approval of the HGRAO.

Data Privacy and Data Protection

The Cyber Security Law of the PRC (《中華人民共和國網絡安全法》) was promulgated by the Standing Committee of the NPC in November, 2016, which regulates network operators, a broad category that covers all organizations in China that own, operate or manage computer networks, and requires them to take certain technical measures and other necessary measures to ensure the security of their networks and data stored on their networks. In addition, network operators shall obtain the prior consent of an individual before collecting and use his or her personal information or providing his or her personal information to others and shall adopt measures to prevent the personal information they have collected from being divulged, damaged or lost. Additional regulations, guidelines and other measures under the framework of the Cyber Security Law of the PRC or personal information protection are expected to be published or adopted, including the Measures for Security Assessment for Cross-border Transfer of Personal Information and Important Data (Draft for Comment) (《個人信息和重要數據出境安全評估辦法(徵求意見稿)》), published in 2017, and the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment) (《個人信息出境安全評估辦法(徵求意見稿)》), published in 2019, which indicate a trend of more stringent compliance requirement, and if adopted, may require security assessment and review before transferring personal health information out of China.

Administrative Measures for Drug Registration

The Administrative Measures for Drug Registration ("Registration Measures") was promulgated by SFDA in July 2007 and then amended by the SAMR in January 2020, which became effective in July 2020. The Registration Measures mainly cover: (1) definitions of drug marketing registration applications and regulatory responsibilities of the drug administration; (2) general requirements for drug marketing registration; (3) clinical trials; (4) application, examination and approval of drugs; (5) supplemental applications and re-registrations of drugs; (6) inspections; (7) registration standards and specifications; (8) time limit; (9) associated review of drugs, excipients and packaging materials; (10) expedited registration of drugs; and (11) liabilities and other supplementary provisions.

Drug Categorization

According to the Registration Measures, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of chemical drugs shall be categorized by innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

In March 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》), which aims to reclassify the registration application of chemical drugs stipulated by the Registration Measures promulgated in 2007. According to the Reform Plan for Registration Category of Chemical Medicine, Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category

2 drugs, among which, chemical drugs contain new indications with known active ingredients would be classified as Category 2.4 drugs. Generic chemical drugs, that have equivalent quality and efficacy to the originator's drugs 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.

As a support policy and implementing rule of the Registration Measures newly amended in 2020, the NMPA issued the Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) in June 2020, effective in July 2020, which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Medicine, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

Accelerated Approval for Clinical Trial and Registration

The CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, including but not limited to an one-time umbrella approval procedure allowing the overall approval of all phases of a drug's clinical trials, replacing the phase-by-phase application and approval procedure, will be adopted for drugs' clinical trial applications.

The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment. The Innovation Opinions indicated enhancing the standard of approval for drug marketing registration and accelerating the evaluation and approval process for innovative drugs as well as improving the approval of drug clinical trials.

The CFDA promulgated the Opinions on Encouraging the Priority Review and Approval for Drug Innovations (《關於鼓勵藥品創新實行優先審評審批的意見》) in December 2017, which further clarified that a fast track clinical trial approval or drug marketing registration pathway will be available to innovative drugs. Particularly, concurrent applications for new drug clinical trials which are already approved in the United States or the European Union are also eligible for fast track clinical trial approval.

According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC in May 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

The Registration Measures has incorporated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduces four procedures for expedited marketing 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:

- Procedures for ground-breaking therapeutic drugs: during the drug clinical trials, for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approach, the applicant may request for application of procedures for ground-breaking therapeutic drugs.

- Procedures for conditional approval: during the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, its benefits outweigh the risks according to the evaluation.

- Procedures for prioritized reviews and approval: at the time of the drug marketing registration, drugs have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drug, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drug included in the procedures for ground-breaking therapeutic drug; (v) drug which comply with conditional approval criteria; and (vi) other circumstances of prioritized review stipulated by the NMPA.

- Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency. Drug included in the special examination and approval procedures may, based on special needs of disease prevention and control, be restricted for use within a certain period and scope.

Regulations on the Clinical Trials and Registration of Drugs

Four Phases of Clinical Trials

According to the Registration Measures, a clinical development program consists of Phases I, II, III and IV clinical trial as well as bioequivalence trial. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research.

However, according to the Technical Guiding Principles for Clinical Trials of Anti-tumor Drugs (《抗腫瘤藥物臨床試驗技術指導原則》) issued by the SFDA in May 2012, the clinical study staging of anti tumor drugs is not a fixed developmental sequence. The rapid development of anti-tumor drug research theories and technologies is likely to have an impact on future anti-cancer drug development models. Therefore, applicants can actively explore more scientific and rational research methods and promptly seek advice from the drug registration department under the SFDA.

Approval Authority and Process for Clinical Trial Applications

According to the Registration Measures, upon the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying of a Clinical Trial Application, or the CTA, to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. The Registration Measures further requires that the applicant shall, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trial Information Platform. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion. The applicant shall be responsible for the authenticity of the drug clinical trial information published on the platform. Pursuant to the Notice on the Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) promulgated by SFDA in September 2013, the applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial application 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, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the clinical trial application shall automatically expire.

Compliance with GCP and Drug Clinical Institutions

The conduct of clinical trials must adhere to the Good Clinical Trial Practice for Drugs (the "GCP Rules") which was promulgated by the SFDA in August 2003 and further amended in April 2020 and came into effect in July 2020. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

The GCP Rules stipulated that the sponsor shall bear the expenses for medical treatment and the corresponding compensation for any human subject who is harmed or dies due to reasons connected with the clinical trial. The sponsor and investigator shall pay the human subject the compensation or indemnification in a timely manner. However, the GCP Rules promulgated in 2020 abolishes the compulsory insurance the sponsor provides to human subjects participating in a clinical trial compared with the GCP Rules promulgated in 2003.

The GCP Rules also set out the qualifications and requirements for the investigators and drug clinical trial institutions, including: (i) professional certification at a drug clinical trial institutions, professional knowledge, training experience and capability of clinical trial, and being able to provide the latest resume and relevant qualification documents per request; (ii) being familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) being familiar with and comply with the Revised GCP Rules and relevant laws and regulations relating to clinical trials; (iv) keeping a copy of the authorization form on work allocation signed by investigators; (v) investigators and drug clinical trial institutions shall accept supervision and inspection organized by the applicant and inspection by the drug regulatory authorities; and (vi) in the case of investigators and drug clinical trial institutions authorizing other individual or institution to undertake certain responsibilities and functions relating to clinical trial, they shall ensure such individual or institution are qualified and establish complete procedures to ensure the responsibilities and functions are fully performed and generate reliable data.

The GCP Rules also summarizes the role of ethic committee in clinical trial process. An ethic committee shall consist of experts working in the medical, pharmaceutical and other fields. The clinical trial protocol may not be executed unless approved by the ethic committee. In November 2019, the NMPA and the NHC jointly promulgated the Notice on Issuing the Administration Rules of Drug Clinical Trial Institution (《關於發布藥物臨床試驗機構管理規定的公告》), which stipulates that each drug clinical trial institution shall maintain an ethic committee responsible for the ethical review of drug clinical trial.

According to the Notice on Issuing the Administration Rules of Drug Clinical Trial Institution, drug clinical trial institutions refer to institutions eligible to undertake the drug clinical trials and shall have been duly recorded with the online platform designated by NMPA. These rules have specified the requirements for drug clinical trial institutions and require that a clinical trial institution should evaluate or engage a third party to evaluate whether it has met such requirements before applying for recordal. A drug clinical trial applicant should only engage a duly recorded clinical trial institution to carry out a drug clinical trial and the clinical trial institution engaged must, during the conduct of clinical trials, comply with the GCP Rules and other technical guidelines for drug clinical trials.

Drug Marketing Registration

According to the Registration Measures, the applicant may submit an application for drug marketing registration to CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The CDE will organize pharmaceutical, medical and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certificate will be issued containing the information of the drug approval number, the MAH and the manufacturer.

Marketing Authorization Holder System

The MAH System was formally established by the 2019 Amendment and symbolized the general application of the MAH System throughout the country. According to which: (i) an MAH refers to enterprise or drug research and development institute which has obtained a drug registration certificate; (ii) an MAH shall be responsible for managing the whole manufacturing and marketing chain and the whole life cycle of drugs and assumes the full legal liability for non-clinical study, clinical trial, manufacturing and operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the drugs; (iii) the legal representative and the key person-in-charge of a drug MAH shall be fully responsible for the quality of drugs; (iv) an MAH shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently; and (v) an MAH shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities. As a part of the healthcare reform in China in recent years, the MAH System is embedded with favorable governmental policies in terms of drug manufacturing, distribution and transfer, etc. MAH may either engage in drug manufacturing on its own or may engage licensed contract manufacturers for manufacturing. An MAH may either engage in drug sales on its own or may engage licensed contract distributor for drug sales. Upon approval by the drug administrative

department of the State Council, an MAH may transfer the drug registration certificate for a certain drug obtained by it to a qualified transferee and upon the completion of the transfer, such transferee will be the new MAH for that drug.

Non-Inferiority Standard

In China, a drug may receive regulatory approval without showing superiority in its primary endpoint. Rather, a drug may be approved for use if it shows non-inferiority in its primary endpoint and superiority in one of its secondary endpoints.

International Multi-Center Clinical Trials Regulations

In January 2015, the former CFDA promulgated Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Tentative) (《國際多中心藥物臨床試驗指南(試行)》), or the Multi-Center Clinical Trial Guidelines, which took effect in March 2015, aiming to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China,or IMCCT. Pursuant to the Multi-Center Clinical Trial Guidelines, IMCCT applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the IMCCTs for application for approval of a drug marketing registration, such IMCCTs shall satisfy, in addition to the requirements set forth in Drug Administration Law and its implementation regulations, Registration Measures and relevant laws and regulations, the following requirements:

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

- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the drug under clinical trial, and satisfy the statistical and relevant legal requirements; and

- The onshore and offshore IMCCT research centers shall be subject to on-site inspections by competent PRC governmental agencies.

IMCCTs shall follow international prevailing GCP principles and ethics requirements. Applications shall ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers shall have the qualification and capability to perform relevant clinical trials; and an ethics committee shall continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the IMCCT, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researchers and clinical trial organizations on the NMPA's drug clinical trial information platform.

Data derived from international multi-center clinical trials can be used for the drug marketing registration with the NMPA. When using international multi-center clinical trial data to support drug marketing registration in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; 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 unnecessary repetitive clinical trials and thus further accelerate the drug marketing registration process in China.

In October, 2017, the former CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration (《國家食品藥品監督管理總局關於調整進口藥品註冊管理有關事項的決定》), which includes the following key points:

- If the IMCCT of a drug is conducted in China, the IMCCT drug does not need to be approved or entered into either a Phase II or III clinical trial in a foreign country, except for preventive biological products. Phase I IMCCT is permissible in China.

- If the IMCCT is conducted in China, the application for drug marketing registration can be submitted directly after the completion of the IMCCT.

- With respect to clinical trial and drug marketing registration applications for imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required.

Acceptance of Foreign Clinical Trial Studies

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) 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 marketing registration applications in China. Such applications can be in the form of waivers to China-based clinical trials, bridging trials and direct drug marketing registration. 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 marketing registration in China, provided that sponsors must ensure the authenticity, integrity, 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 (the "ICH"). Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous

R&D at home and abroad and forthcoming clinical trials in China, the sponsors may, prior to implementing pivotal clinical trials, contact the CDE to ensure the compliance of pivotal clinical trials' design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug marketing 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 (《關於臨床急需境外新藥審評審批相關事宜的公告》) in October 2018, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent, or treat serious life-threatening illnesses for which there is either no effective therapy in China, or for which the foreign-approved drug would have clear clinical advantages. Applicants 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.

Import of Urgently Needed Drug in Boao Pilot Zone

According to the Drug Administration Law, based on urgent medical need by medical institution of certain drug that is not yet registered domestically (the "Urgently Needed Drug"), subject to the approval of NMPA or competent provincial government, a small amount of such Urgently Needed Drug may be imported but shall be solely applied for specific medical purpose at the designated medical institution.

The State Council issued the Official Reply of the State Council to Approve the Establishment of Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《國務院關於同意設立海南博鰲樂城國際醫療旅遊先行區的批復》) in February 2013, according to which, Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (the "Boao Pilot Zone") shall be established as a pilot zone where accelerated approval of the import of the Urgently Needed Drug is available. The State Council further issued the Decision on Temporarily Adjusting the Implementation of the Relevant Provisions of the Implementing Measures of the Drug Administration Law in the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《國務院關於在海南博鰲樂城國際醫療旅遊先行區暫時調整實施<中華人民共和國藥品管理法實施條例>有關規定的決定》) in December 2018, according to which, the State Council empowers the People's Government of Hainan Province (the "Hainan Government") to approve the import of the Urgently Needed Drug (excluding vaccines).

The Hainan Government promulgated the Interim Provisions on the Administration of Imported Drugs of Urgent Need in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《海南博鰲樂城國際醫療旅遊先行區臨床急需進口藥品管理暫行規定》) in April 2019, according to which, a qualified medical institution in the Boao Pilot Zone may

apply for the import of certain Urgently Needed Drug (excluding vaccines and other drugs under special management) and apply to patient on case by case basis. Such application shall be subject to the evaluation and approval of Hainan Provincial Health Commission and the Medical Products Administration of Hainan Province, as well as the customs formalities with Haikou Customs.

Medical Products Administration of Hainan Province promulgated the Interim Measures for the Administration of Taking Away the Imported Urgently Needed Drug from the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《海南博鰲樂城國際醫療旅遊先行區臨床急需進口藥品帶離先行區使用管理暫行辦法》) in March 2020, according to which, a patient may apply for taking away a small amount of the legally imported Urgently Needed Drug from the Boao Pilot Zone following his therapeutic schedule issued by a medical institution. Such application shall be subject to the evaluation and approval of Hainan Provincial Health Commission and the Medical Products Administration of Hainan Province.

PERMITS AND LICENSES FOR MANUFACTURING AND DISTRIBUTING OF DRUGS

Pharmaceutical Manufacturing Permit and GMP Requirements

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

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

The World Health Organization encourages the adoption of good manufacturing practice, or GMP, standards in pharmaceutical production in order to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final products.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) was promulgated in March 1988 and was amended in June 1999 and January 2011. The Good Manufacturing Practice for Drugs comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

Pharmaceutical Operation Permit and GSP Requirements

The Administration of Pharmaceutical Operation Permit (《藥品經營許可證管理辦法》) promulgated in February 2004 and amended in November 2017 by the CFDA provides the application procedures and requirements for Pharmaceutical Operation Permit. According to which, a Pharmaceutical Operation Permit is valid for five years. Each holder of the Pharmaceutical Operation Permit 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 the provincial medicine administrative authorities. Upon approval, the authority will grant a Pharmaceutical Operation Permit 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 Pharmaceutical Operation Permit in respect of the retail pharmacy store.

According to the Drug Administration Law and its implementing regulations and the Measures for the Supervision and Administration of Circulation of Pharmaceuticals (《藥品流通監督管理辦法》), which was promulgated by the SFDA in January 2007 and came into effect in May 2007, a pharmaceutical enterprise shall be responsible for the quality of pharmaceuticals they manufacture, operate or use, purchase, sale, transportation, storage, including activities carried out by its staff on its behalf, and it shall not store or sell, pharmaceuticals at a place other than the address approved by the pharmaceutical regulatory authority. Where a pharmaceutical enterprise knows or ought to know that any person operates pharmaceutical business without the Pharmaceutical Operation Permit but still supplies such person with pharmaceutical products, the pharmaceutical regulatory authority may give a disciplinary warning to the pharmaceutical enterprise, order such enterprise to rectify the non-compliance and impose a fine of no more than RMB10,000. In the case of a serious violation, such enterprise may be fined in an amount ranging from RMB10,000 to RMB30,000.

The Good Supply Practice for Drugs (《藥品經營質量管理規範》) was promulgated in April 2000 and was amended respectively in November 2012, May 2015 and June 2016. The Good Supply Practice for Drugs is laid down as the basic rules for drug operation and quality control, sets forth the requirements for enterprises through out the process of drug purchase, storage, sales and transportation.

U.S. REGULATION OF PHARMACEUTICAL PRODUCT DEVELOPMENT AND APPROVAL

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining marketing approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement-related letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or DOJ, or other governmental entities. Drugs are also subject to other federal, state and local statutes and regulations.

Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's GLP regulations;

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;

- approval by an independent IRB representing each clinical site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable good clinical practices, or GCPs and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication;

- preparation and submission to the FDA of an NDA;

- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review and review by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced to assess compliance with the FDA's cGMP;

- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA; and

- payment of user fees and FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies

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

Clinical Studies

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

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical trials.

Phase I: The drug is initially introduced into a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients with the target diseases.

Phase II: The drug is administered to a limited patient population to determine dose tolerance and optimal dosage required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.

Phase III: The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a drug during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA. A pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the drug. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need. Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase IV clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and FDA Review Process

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

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2020, the user fee for an application requiring clinical data, such as an NDA, is approximately US$2.9 million. PDUFA also imposes an annual prescription drug program fee for human drugs of approximately US$325,000. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA conducts a preliminary review of an NDA within 60 days of receipt and informs the sponsor by the 74th day after FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for a "priority review" NDA. The FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may re-analyze the clinical trial data, which can result in extensive discussions between the FDA and us during the review process.

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

If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient populations or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of a drug or biological product outweigh its risks. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Pediatric Trials

Under the Pediatric Research Equity Act of 2003, a NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product 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. With the enactment of FDASIA, a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials, and/or other clinical development programs.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but the product will be entitled to orphan product exclusivity, meaning that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

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

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Health Care Reform Law, as amended by the Health Care and Education Affordability Reconciliation Act, or ACA. If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

REST OF THE WORLD REGULATION OF PHARMACEUTICAL PRODUCT DEVELOPMENT AND APPROVAL

For other countries outside of China and the United States, such as countries in Europe, Latin America or other parts of Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and ethical principles.

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

COVERAGE AND REIMBURSEMENT

PRC Coverage and Reimbursement

Reimbursement under the National Medical Insurance Program

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council in December 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) in July 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. According to the Social Insurance Law of Peoples' Republic of China (《中華人民共和國社會保險法》) which was promulgated by the Standing Committee of the NPC in October 2010 and amended in December 2018, all employees are required to enroll in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees as required by the state.

The Opinions on Deepening the Reform of the Healthcare Security System (《中共中央、國務院關於深化醫療保障制度改革的意見》) was promulgated jointly by Central Committee of the PRC Communist Party and the State Council in February 2020. which envisages that a higher level healthcare system should be established by 2030, which centers on basic medical insurance, is underpinned by medical aid and pursues the common development of supplementary medical insurance, commercial health insurance, charitable donations and medial mutual assistance. To this end, such opinions map out tasks in several respects, including making the mechanism of medical insurance benefits guarantee more impartial and appropriate, improving the robust and sustainable operating mechanism for funds raised, establishing more effective and efficient healthcare payment mechanism and enhancing the supervision and administration on medical security fund and etc.

The Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) was promulgated by NHSA in April 2020 and came into effect in September 2020. According to which, expenses of drugs listed in the Basic Medical Insurance Catalog will be paid in full or part from the basic medical insurance fund in accordance with applicable provisions, and the drugs with the same generic names as those specified in the Basic Medical Insurance Catalog will be automatically regulated by the Basic Medical Insurance Catalog and shall also be eligible for the reimbursement by the basic medical insurance fund. These measures further clarify that the Basic Medical Insurance Catalog shall be promulgated by the healthcare security department under the State Council and adjusted on an annual basis. Provinces shall have the right to add eligible ethnic drugs, preparations of medical institutions, and traditional Chinese medicine decoction pieces into the provincial medical insurance-based payment scope, which shall be implemented after being filed with the healthcare security department under the State Council for record.

The PRC Ministry of Human Resources and Social Security, together with other government authorities, has the power to determine the medicines included in the National Reimbursement Drug List, or the NRDL. In August 2019, the PRC Ministry of Human Resources and Social Security released the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (《關於印發國家基本醫療保險、工傷保險和生育保險藥品目錄的通知》), or the 2019 NRDL. In November 2019, NHSA organized another round of price negotiation with drug companies for 119 new drugs that had not been included in the NRDL at the time of the negotiation, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation; subsequently, the NRDL was expanded to include the 70 new drugs.

Medicines included in the NRDL are divided into two parts, Part A and Part B.

Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price. The percentage of reimbursement for Part B medicines differs from region to region in the PRC. According to 2019 NRDL, all provinces shall implement the 2019 NRDL in a strict manner, and shall not have the discretion to formulate the catalogue or increase the drugs of Part B in any form, or adjust the scope of limited payment, except for eligible ethnic drugs, preparations of medical institutions, and traditional Chinese medicine decoction pieces. For those drugs that were already added to Part B of the provincial catalogue in accordance with the previous NRDL, the drugs shall be gradually removed within 3 years.

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

In August 2020, the NHSA promulgated the Work Plan for the Adjustment of 2020 National Medical Insurance Catalog (《2020年國家醫保藥品目錄調整工作方案》) (the "2020 Work Plan"), according to which, drugs listed in the Urgently Needed Overseas New Drugs List (臨床急需境外新藥名單) promulgated by the CDE which have been granted the approval for drug marketing registration by the NMPA on and before August 17, 2020 may be considered as candidates to be included into the 2020 NRDL. The 2020 Work Plan further provides that the price negotiation with drug companies for 2020 NRDL will be arranged between October and November 2020 and the 2020 NRDL will be finalized and published between November and December 2020.

Supplementary Insurance

The Circular of Ministry of Finance, Ministry of Labor and Social Security on Issues Related to the Supplementary Medical Insurance Established by Enterprises (《財政部、勞動保障部關於企業補充醫療保險有關問題的通知》) was promulgated jointly by the Ministry of Finance and Ministry of Labor and Social Security in May 2002. According to which, enterprises may, on the basis of participation in basic medical insurance program, at their own discretion whether or not to establish the supplementary medical insurance to contribute reasonable allowance for the medical fees borne by their employees other than those paid by the basic medical insurance program for urban employees, so as to reduce the burden of medical expenses of the employees participating in the insurance. The Opinions on Deepening the Reform of the Healthcare Security System (《中共中央、國務院關於深化醫療保障制度改革的意見》) was promulgated jointly by Central Committee of the PRC Communist Party and the State Council in February 2020, which envisages that a higher level healthcare system should be established by 2030, which centers on basic medical insurance, is underpinned by medical aid and pursues the joint development of supplementary medical insurance, commercial health insurance, charitable donations and medical mutual assistance.

National List of Essential Drugs

In August 2009, the former MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Drugs (《國家基本藥物目錄管理辦法》) and the Guidelines on the Implementation of the National List of Essential Drugs System (《關於建立國家基本藥物制度的實施意見》), which aimed to promote essential medicines sold to consumers at fair prices in the PRC and ensured that the general public in the PRC has equal access to the drugs contained in the National List of Essential Drugs. The Provisional Measures on the Administration of the National List of Essential Drugs was then amended in February 2015. The former MOH promulgated the National List of Essential Drugs (《國家基本藥物目錄》) in August 2009, and promulgated the revised National List of Essential Drugs in March 2013 and September 2018. According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in National List of Essential Drugs. The drugs listed in National List of Essential Drugs shall be purchased by centralized tender process and shall be subject to the price control by NDRC.

Commercial Insurance

The State Council and the PRC Communist Party jointly issued the Plan for Healthy China 2030 (《「健康中國2030」規劃綱要》) in October 2016. According to the Plan, the country will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

Price Controls and Two-invoice System

Instead of direct price controls which were historically used in China, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若幹規定》) promulgated in July 2000 and the Notice on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《國家藥品監督管理局關於進壹步做好醫療機構藥品集中招標採購工作的通知》) promulgated in August 2001, not-for-profit medical institutions established by county or higher level government are required to implement centralised tender procurement of drugs.

The MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation) (《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) in March 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. The Notice of the Financial Planning Department of Ministry of Health on Issue of Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions (《衛生部財務規劃司關於印發<進一步規範醫療機構藥品集中採購工作的意見>的通知》) was promulgated in January 2009. According to the notice, not-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralised procurement. Each provincial government shall formulate its catalogue of drugs subject to centralised procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by not-for-profit medical institutions shall be covered by the catalogue

of drugs subject to centralised procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) promulgated in January 2017 by the General Office of the State Council aims to deepen the reform of medicine health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralised Procurement and Use of the Drug Organised by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》) promulgated in January 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and mode of centralised procurement.

The centralized tender process takes the form of public tender operated and organised by provincial or municipal government agencies. The centralised tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralised tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council in April 2016, the ''two-invoice System'' (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) 《印發〈關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)〉的通知》), which came into effect in December 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital.

Insurance Reform

In January 2016, the State Council issued the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《關於整合城鄉居民基本醫療保險制度的意見》), which call for the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangement who participate in the basic medical insurance for urban employees.

In August 2018, the General Office of the State Council issued the Notice on the Main Tasks of Strengthening the Reform of Healthcare System in second half of 2018 (《關於印發深化醫藥衛生體制改革2018年下半年重點工作任務的通知》). Highlights of these healthcare reform policies and regulations include (1) establishing a basic healthcare system to cover both urban and rural residents and providing the Chinese people with safe, effective, convenient and affordable healthcare services, (2) improving the healthcare system through the reform and development of a graded hierarchical healthcare system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision, and (3) improving the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population.

In May 2019, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2019 (《深化醫藥衛生體制改革2019年重點工作任務》), highlighting the following policies and regulations (1) reinforcing the degree of cancer prevention and treatment, accelerating the registration and approval of anti-cancer new drugs at home and abroad and remaining the temporary channel of imperative anti-cancer drugs importation open, (2) consolidating and improving the basic medicine system and establishing an inventive and restrictive mechanism for preferential use. Improving the dynamic adjusting mechanism of the NRDL and incorporating the eligible therapeutic drugs listing in the National List of Essential Drugs into the NRDL first in accordance with the procedure.

In July 2020, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in the Second Half of 2020 (《深化醫藥衛生體制改革2020下半年重點工作任務》), which set forth six major tasks covering 26 concrete measures, including but not limited to boosting the reform of medical insurance payment methods, strengthening the management of medical insurance funds, and accelerating the development of commercial health insurance.

In December 2019, the Standing Committee of the NPC promulgated the Law of the People's Republic of China on Promotion of Basic Medical and Health Care (《中華人民共和國基本醫療衛生與健康促進法》), which established the legal framework for the administration of basic medical and health services for citizens in China, including the administration of basic medical care services, medical care institutions, medical staff, guarantee of drug supply, health promotion and guarantee of medical funds.

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

U.S. Coverage and Reimbursement

Successful sales of our products or drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new product acceptance. These third-party payors are increasingly reducing reimbursements for medical drugs and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Inadequate third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

Healthcare reform initiatives have resulted in significant changes to the coverage, reimbursement and delivery of health care, including drugs. Health care reform efforts are likely to continue and such efforts have included, and may include in the future, attempts to repeal or otherwise challenge prior healthcare reform. The spread of COVID-19 has resulted in widespread federal and state legislative and administrative action to impose new or revise existing health care regulation, sometimes on a temporary basis, to limit the spread of the disease, ensure access to necessary health care and address adverse financial impacts.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act of 2011, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and, except for a suspension from May 1, 2020 through December 31, 2020, will remain in effect through 2030 unless additional Congressional action is taken. If we obtain approval to market a drug candidate in the United States, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

OTHER HEALTHCARE LAWS

Other PRC Healthcare Laws

Insert Sheet and Labels of Pharmaceutical Products

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品説明書和標簽管理規定》) effective in June 2006, the insert sheets and labels of drugs should be reviewed and approved by the former SFDA. A drug insert sheet should include the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use if drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage and adverse reaction.

Packaging of Pharmaceutical Products

According to the Measures for the Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) effective in September 1988, pharmaceutical packaging must comply with the national and industry standards. If no national or industry standards are available, the enterprise can formulate its own standards and put into implementation after obtaining the approval of administration of medical products or bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its own packaging standard. Drugs that have not developed and received approval for packing standards must not be sold or traded in PRC (except for drugs for the military).

Other U.S. Healthcare Laws

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

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

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians and teaching hospitals (and other healthcare professionals starting in 2021) to the federal government for re-disclosure to the public; and

- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

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

OTHER SIGNIFICANT PRC REGULATION AFFECTING OUR BUSINESS ACTIVITIES IN CHINA

PRC Regulation of Commercial Bribery

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) which became effective in March 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of failure to monitor their operating activities.

PRC Regulation of 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 law, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the PRC (《中華人民共和國民法通則》), or the PRC Civil Law, promulgated in April 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. The Civil Code of the PRC (《中華人民共和國民法典》), which was promulgated in May 2020 and will become effective on 1 January 2021, will amalgamate and replace a series of specialized laws in civil law area, including the PRC Civil Law. The rules on product liability in the Civil Code of the PRC remain consistent with the rules in the PRC Civil Law.

In February 1993, the Product Quality Law of the PRC (《中華人民共和國產品質量法》), 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. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated in October 1993 and was amended in August 2009 and October 2013 to protect consumers' rights when they purchase or use goods and accept services. According to which, all business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the latest amendment, all business operators shall pay high attention to protect the customers' privacy and strictly keep it confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

PRC Tort Law

Under the Tort Law of the PRC (《中華人民共和國侵權責任法》) 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 a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as 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. Civil Code of the PRC will amalgamate and replace the Tort Law from 1 January 2021. The rules on tort in the Civil Code of the PRC are generally consistent with the Tort Law.

PRC Regulation of Intellectual Property Rights

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

Patents

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

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

Article 20 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China.

Patent Enforcement

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

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

Trade Secrets

According to the PRC Anti-Unfair Competition Law (《反不正當競爭法》) promulgated by the Standing Committee of the NPC in September 1993, as amended in November 2017 and in April 2019 respectively, the term "trade secrets" refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders.

Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the abovementioned 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 and Domain Names

Trademark. The PRC Trademark Law (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its implementation rules (《中華人民共和國商標法實施條例》) promulgated by the State Council in August 2002, as amended in April 2014 protect registered trademarks. The PRC Trademark Office of the National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout the PRC. The Trademark Law has adopted a "first-to-file" principle with respect to trademark registration.

Domain Name. Domain names are protected under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology in August 2017 and effective from November 2017. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names.

PRC Regulation of Labor Protection

Under the Labor Law of the PRC (《中華人民共和國勞動法》), effective in January 1995 and subsequently amended in August 2009 and December 2018, the PRC Employment Contract Law (《中華人民共和國勞動合同法》), effective in January 2008 and subsequently amended in December 2012 and the Implementing Regulations of the Employment Contract Law (《中華人民共和國勞動合同法實施條例》), effective in September 2008, employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the PRC.

Pursuant to the Law of Manufacturing Safety of the PRC (《中華人民共和國安全生產法》) effective in November 2002 and amended in August 2009 and August 2014, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products (《藥品生產質量管理規範》) effective in March 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable PRC laws, rules and regulations, including the Social Insurance Law (《中華人民共和國社會保險法》) which became effective in July 2011 and amended in December 2018, the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》) which became effective in January 1999 and amended in March 2019, Interim Measures concerning the Maternity Insurance of Employees (《企業職工生育保險試行辦法》) which become effective in December 1994, and the Regulations on Work-related Injury Insurance (《工傷保險條例》) which became effective in January 2004 and was subsequently amended in December 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Regulations Relating to Foreign Exchange Registration of Offshore Investment by PRC Residents

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

Regulations Relating to Employee Stock Incentive Plan

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Stock Option Rules. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Dividend Distribution

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

In January 2017, the SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通知》), which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Regulations Relating to Foreign Exchange

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

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises (《國家外匯管理局關於完善外商投資企業外匯資本金支付結匯管理有關業務操作問題的通知》), or SAFE Circular 142, regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into RMB by restricting how the converted RMB may be used. SAFE Circular 142 provides that the RMB capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within China. SAFE also strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such RMB capital may not be changed without SAFE's approval, and such RMB capital may not in any case be used to repay RMB loans if the proceeds of such loans have not been used. In March 2015, SAFE issued the Circular of the State Administration of Foreign Exchange on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or SAFE Circular 19, which took effective and replaced SAFE Circular 142 in June 2015. Although SAFE Circular 19 allows for the use of RMB converted from the foreign currency-denominated capital for equity investments in China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted RMB for purposes beyond the business scope, for entrusted loans or for inter-company RMB loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》), or SAFE Circular 16, effective in June 2016, which reiterates some of the rules set forth in SAFE 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 nonassociated enterprises. Violations of SAFE Circular 19 or SAFE Circular 16 could result in administrative penalties.

The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) was promulgated by SAFE in November 2012 and amended in May 2015, which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e.g. profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents (《國家外匯管理局關於印發<外國投資者境內直接投資外匯管理規定>及配套文件的通知》) in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), or SAFE Circular 13, which took effect in June 2015. SAFE Circular. 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment.

Other PRC National- and Provincial-Level Laws and Regulations

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

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control.

HONG KONG REGULATIONS

Our Company has commercialized ZEJULA and launched Optune in Hong Kong, and is subject to the following Hong Kong laws and regulations which may be material to our operations in Hong Kong.

Registration of Pharmaceutical Products

The Department of Health in Hong Kong is responsible for overseeing the safety, efficacy and quality of all medicines and pharmaceutical products marketed in Hong Kong. Non-Chinese medicines such as ZEJULA are regulated under the Pharmacy and Poisons Ordinance (Chapter 138 of the Laws of Hong Kong) (the "Pharmacy and Poisons Ordinance"). Pursuant to the Pharmacy and Poisons Ordinance, all pharmaceutical products and medicine must be registered with the Pharmacy and Poisons Board of Hong Kong (the "Pharmacy and Poisons Board") before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use in Hong Kong. Any person who engages in the sale of unregistered pharmaceutical products commits an offense and is liable to a maximum fine of HK$100,000 and imprisonment for 2 years.

Under the Pharmacy and Poisons Ordinance, "pharmaceutical product" and "medicine" mean any substance or combination of substances:

- presented as having properties for treating or preventing disease in human beings or animals; or

- that may be used in, or administered to, human beings or animals, either with a view to (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or (ii) making a medical diagnosis.

A pharmaceutical product or medicine will only be approved for registration if it meets the criteria of safety, efficacy and quality relevant to it. The applicant has to provide a set of information including production formula, product specification, laboratory report and manufacturer licence in its application for registration for the approval of the Pharmacy and Poisons Board. Upon registration, the pharmaceutical product or medicine will be given a registration number by the Pharmacy and Poisons Board, which is required to be printed on the label of the pharmaceutical product or medicine.

ZEJULA is a registered pharmaceutical product in Hong Kong with registration number HK65945.

Poisons List

In Hong Kong, the Poisons List (the "Poisons List") under the Tenth Schedule of the Pharmacy and Poisons Regulations (Chapter 138A of the Laws of Hong Kong) (the "Pharmacy and Poisons Regulations") lists out certain ingredients classified as poisons. Some poisons are further categorized under different parts of the Poisons List and other different schedules under the Pharmacy and Poisons Regulations according to their potency, toxicity and potential side-effects. Such categorization determines the different levels of control over their sale. For instance, pharmaceutical products that do not contain any poisons or contain poisons listed under Part 2 of the Poisons List ("Part 2 poisons") are referred to as over-the-counter medicines. Pharmaceutical products that do not contain any poisons can be sold in any retail shops, while pharmaceutical products that contain Part 2 poisons can be sold in authorized sellers of poisons ("ASP," usually known as pharmacies or dispensaries) and listed sellers of poisons (usually known as medicine stores), both regulated by the Department of Health in Hong Kong. Pharmaceutical products containing poisons listed under Part 1 of the Poisons List ("Part 1 poisons") can only be sold in pharmacies (ASPs) in the presence and under the supervision of registered pharmacists.

Certain Part 1 poisons are further listed in the First Schedule and the Third Schedule of the Pharmacy and Poisons Regulations, which impose additional restrictions on the sale of pharmaceutical products containing such poisons at the retailers. For example, retailers of pharmaceutical products containing poisons listed in the First Schedule of the Pharmacy and Poisons Regulations are required to keep sales records which include the date of sale, the name, number of identity card, address and signature of the purchaser, the name and quantity of the medicine as well as the purpose for which it is required. The sale of pharmaceutical products containing poisons listed in the Third Schedule of the Pharmacy and Poisons Regulations must be authorized by a prescription from a registered medical practitioner, a registered dentist or a registered veterinary surgeon.

ZEJULA contains poisons that are listed under the First Schedule and the Third Schedule of the Pharmacy and Poisons Regulations. Therefore, ZEJULA can only be sold with prescription and the sales records of ZEJULA, which should include the required particulars as summarized above, must be kept in accordance with the Pharmacy and Poisons Regulations.

Emission of Radio Frequency

In Hong Kong, telecommunications equipment ("TE") and industrial, scientific and medical ("ISM") equipment emitting radio frequency energy intentionally are subject to requirements on technical specifications prescribed by the Communications Authority of Hong Kong. The technical specifications are mainly set for the purposes of electrical safety, prevention of interference, network compatibility and network interoperability.

Under the Hong Kong Telecommunications Equipment Evaluation and Certification Scheme (the "HKTEC Scheme") regulated by the Communications Authority of Hong Kong, certain TE and ISM equipment which falls under the "Compulsory Certification Scheme" must be certified by a local certification body accredited under section 32E of the Telecommunications Ordinance (Chapter 106 of the Laws of Hong Kong) (a "Certification Body") before it can be used or marketed in Hong Kong. Such TE or ISM equipment may be granted a certificate by a Certification Body once it has been evaluated to be in compliance with the relevant technical specification.

Given Optune, an ISM equipment which emits radio frequency, falls under the Compulsory Certification Scheme under the HKTEC Scheme, it must be approved by the Office of the Communications Authority ("OFCA"), the executive arm of the Communications Authority, and be granted a certificate by a Certification Body before it can be used or offered for sale in Hong Kong. With respect to Optune, we have obtained the approval from OFCA and a certificate from a Certification Body with certificate numbers HK0011801953 and HK0012002185.

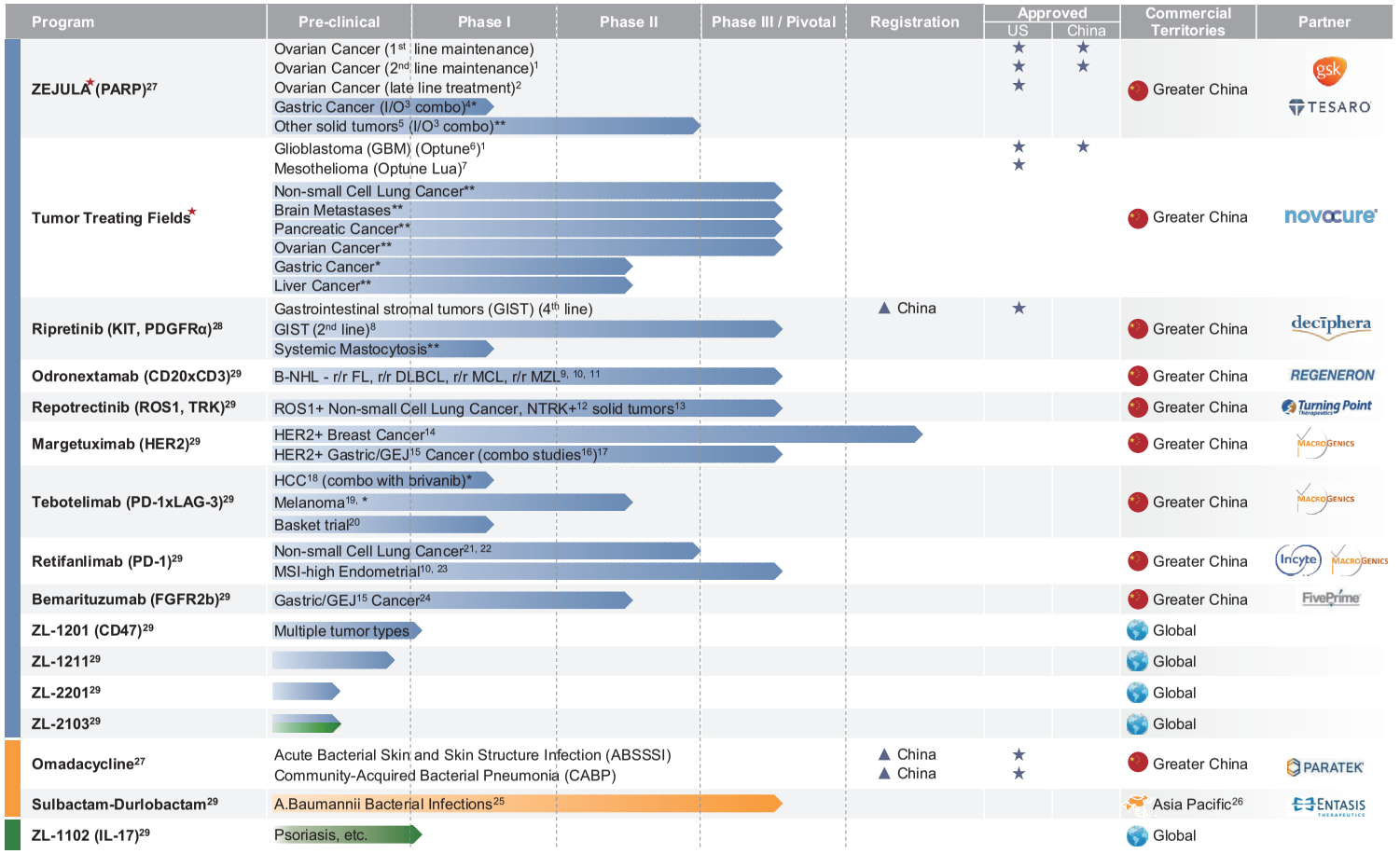
OVERVIEW

We are an innovative, research-based, commercial-stage biopharmaceutical company with a focus on discovering, licensing, developing and commercializing therapies that address areas of large unmet medical need in the China and global markets, including the fields of oncology, infectious and autoimmune diseases. By effectively executing our plan and closely following our strategy, we have built an integrated platform to bring both in-licensed and internally-discovered novel therapeutics to patients globally. We believe we are one of the first biopharmaceutical companies in China to scale, allowing us to further capitalize on the latest innovation and business opportunities globally.

Since our inception, we have executed our strategic approach of in-licensing promising biopharmaceutical products via global collaboration and investing in internal discovery and development efforts. Our robust portfolio consists of 16 products and drug candidates, including two commercialized products in China, Hong Kong and Macau and seven assets in pivotal or potentially registration-enabling trials in oncology and infectious diseases, which are therapeutic areas with large unmet needs and lack of innovative treatment options in Greater China. Although we have limited experience in manufacturing and commercializing our products and drug candidates, we are nevertheless at the inflection point of commercialization with recent launches of ZEJULA and Optune (Tumor Treating Fields) in multiple regions, empowered by our commercialization team with a proven track record and heritage from top-selling MNCs and innovative oncology brands. We believe that we remain the trusted partner in our areas of focus for the biopharmaceutical industry as we provide a differentiated approach for our collaborators to achieve success while also conducting timely trials and achieving eventual commercialization of promising therapies, accelerating access to the large patient population.

We founded Zai Lab with the intent to build a highly differentiated biopharmaceutical company delivering transformative therapies to patients. We have assembled a leadership team of industry veterans with global experience in the biopharmaceutical sector who have been at the frontier of framing the Chinese biopharma industry for more than two decades. Led by our experienced management team, we have developed into a leading biopharmaceutical company with products approved in Greater China, broad pipeline with differentiated innovative assets from collaboration and in-house development and state-of-art capabilities across research and development, clinical development, manufacturing and commercialization.

We have assembled a deep, clinically-validated and innovative portfolio through collaborations and partnerships with global biopharmaceutical companies as well as in-house discovery and development, targeting large markets and characterized by high unmet medical need. We believe our product portfolio is one of the most robust and differentiated portfolios in the biopharmaceutical sector, in China with therapeutics that aim to treat serious diseases such as gynecologic cancer, gastric cancer, brain cancer, lung cancer and multidrug-resistant bacterial infections. The following table summarizes the global development status of our portfolio of commercialized products and drug candidates and programs.



Note:*denotes our core product; * denotes China-only trials; ** Greater China trial in preparation or under planning

(1) Also launched in Hong Kong and Macau; (2) Bridging study initiated in China; (3) Immuno-oncology; (4) Phase Ib proof-of-concept combo trial with tebotelimab; (5) Including non-small cell lung cancer; (6) Class III medical device by NMPA; (7) Under preparation for MAA submission in China; (8) Bridging trial application approved in China; (9) B-NHL, B-cell non-Hodgkin lymphoma; r/r, relapsed or refractory; FL, follicular lymphoma; DLBCL, diffuse large B-cell lymphoma; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; (10) Global potentially registration-enabling trial; (11) Phase II pivotal trial application submitted in China; (12) Neurotrophic tropomyosin receptor kinase; (13) Phase II registrational trial application submitted in China; (14) Bridging study initiated in Greater China; (15) Gastroesophageal junction cancer; (16) Global Phase II/III study and registration path in first-line gastric & GEJ cancer; combo with retifanlimab and tebotelimab, respectively; (17) Phase II/III trial application approved in Greater China; (18) Hepatocellular Carcinoma; Phase I proof-of-concept trial; (19) Phase II proof-of-concept trial; (20) Phase I trial application approved in Greater China; (21) Global Phase III study in preparation; (22) Phase III trial application approved in China; (23) Phase II trial application accepted in China; (24) Phase II trial initiated in Greater China; (25) Phase III trial initiated in Greater China; (26) Including China, Hong Kong, Macau, Taiwan, South Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan; (27) Class 1 drug by NMPA; (28) Class 5.1 drug by NMPA; (29) The drug class will be designated upon the NDA submission.

Our team has successfully advanced each of the programs above on timelines that have met or exceeded our expectations. For example, it took us less than three years from ZEJULA's FDA approval to commercial launch in China. It took us less than three months from obtaining the exclusive license for Optune to commercial launch in Hong Kong, and an additional 20 months further to commercial launch in China, without the need of clinical trial. In less than six years since our founding, we have successfully transformed into a fully-integrated commercial enterprise. Beyond ZEJULA and Optune, we have submitted two NDAs which are under priority review. On September 8, 2020, the NMPA also approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

To implement our commercialization strategy, we have built our own commercial team to execute the successful launches of ZEJULA and Optune in China, Hong Kong and Macau. We launched ZEJULA in China in January 2020, and as of August 31, 2020, ZEJULA has been successfully enrolled into the regional reimbursement program that complements China's basic medical insurance scheme in one province and six cities. As of August 31, 2020, ZEJULA has also been listed in 17 commercial health insurances and 12 supplemental insurances guided by municipal governments (城市定制險); in addition, since we launched Optune in China in June 2020, Optune has been listed in four supplemental insurances guided by provincial or municipal governments, as of August 31, 2020, both of which underscores our execution capability in bringing important therapies to patients.

In addition to our development stage products, we have seen similar success in building comprehensive in-house research and development capabilities in China and the U.S. We have assembled an integrated drug discovery and development team with nearly 400 dedicated personnel who have extensive experience from discovery, translational medicine to late stage development and have been directly involved in the discovery and development of several innovative drug candidates. Through these efforts over the past few years, we have advanced two of our in-house discovery candidates with global intellectual property into global clinical development and we plan to have multiple innovative and differentiated assets move into clinical development over the next few years. We believe our discovery initiatives along with our collaborations with leading academic institutions will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new products and drug candidates for patients around the world.

To supplement our discovery, research and development and commercialization efforts, we have also efficiently established both large and small molecule drug manufacturing capabilities, capable of supporting clinical and commercial production of our drug candidates. These facilities would allow us to produce both large and small molecule therapeutics under global standards, such as current good manufacturing practices, or cGMP. Our small molecule manufacturing facility supports the commercial production of ZEJULA. The production capacity of our small molecule manufacturing facility is up to 50 million units per year for both commercial oral tablets and capsules. During the Track Record Period, less than 10 percent of the total production capacity of our small molecule manufacturing facility was utilized. Our

large molecule manufacturing facility supports the clinical production of ZL-1201. The annual production capacity of our large molecule manufacturing capacity is up to 12 to 18 200L or 1000L clinical batches, respectively. During the Track Record Period, approximately 40% of the production capacity of our large molecule manufacturing facility was utilized. We intend to expand our manufacturing capacity in a manner that will provide us with tangible and intangible benefits, including cost advantages, better control over quality and enhanced compliance capabilities and better ability to plan logistics for commercialization of drug candidates.

We aim to stay at the forefront of innovation in our industry by quickly and efficiently adopting technologies to further enhance our capabilities across research and development, manufacturing and commercialization. Together with our unique and strengthening platform and commitment to global standards, we believe we will contribute significantly to the improvement of the well-being of the patients globally.

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors:

Proprietary platform committed to bring innovative therapies to patients

Since our inception, we have been committed to pursuing global innovation through our proprietary, science-driven approach. Under the leadership of our management team led by Dr. Samantha Du, who has been pioneering China-based global biopharmaceutical innovation for over two decades, we have assembled an experienced execution team with in-depth knowledge and capabilities spanning research and development, regulatory approval process and commercialization. Our team is further supported by the expertise of our advisory board, academic collaborations and key opinion leader relationships. We believe that our disciplined approach in building a science-driven platform have allowed us to successfully identify and build strategic relationship to leverage the latest innovation with a truly global perspective, and to pursue a multi-source strategy for innovation. Through in-licensing, strategic co-development partnerships as well as our internal discovery efforts, we have assembled a robust portfolio of 16 potential best-in-class/first-in-class products and drug candidates, establishing a proven track record for open innovation while also gaining significant operational scale. Research and development of innovative therapies is high risk in nature, characterized by high failure rates, long timelines and increasingly high costs. By integrating both internal and external knowledge and technologies, our proprietary innovation model and expanding know-how enable us to source suitable potentially global best-in-class/first-in-class therapies and efficiently commercialize them for patient use with lowered development risk at reduced research and development costs. This model also shortens our in-house discovery and development cycle and improves overall success rates.

The recognition of our company as a preferred partner of choice in China is evidenced by our partnerships with leading global biopharmaceutical companies, including GSK, Novocure, Deciphera, Regeneron, Turning Point, MacroGenics, Incyte, Five Prime, Paratek, and Entasis, which have out-licensed select clinical products to us, many of which were their respective lead assets.

In addition to entrusting us with exclusive regional development and commercialization rights, some of our global partners have selected us to be their global co-development strategic partner in charge of managing the China portion of global trials and recruiting patients from China to these studies. Since 2018, we have successfully secured seven deals with six out of the seven being global co-development arrangements. Given the strategic importance of China to the development and commercialization of these drugs, we believe our strategic co-development model is sustainable and scalable. We believe our experienced leadership team with proven execution capabilities and our established expertise and network will facilitate China patient recruitment and clinical development, thereby accelerating development and approval of such drugs both in China and globally, while attracting more opportunities in the future.

To drive our long-term vision, we have also built a highly experienced in-house research and development team which was previously involved in the discovery and development of several innovative drug candidates at leading global biopharmaceutical companies. Our in-house research and development team focuses on the development of innovative therapeutics for the treatment of oncology, infectious diseases and autoimmune diseases. Our discovery efforts have resulted in the identification of a number of proprietary candidates against targets in our focus areas with high scientific validation including immuno-oncology, synthetic lethality and oncogenic signaling. As of the Latest Practicable Date, we have achieved FPIs for our internally generated drug candidates (ZL-1102 in autoimmune diseases and ZL-1201 in oncology) with multiple other compounds are in the candidate selection stage, in addition to other multiple discovery stage programs, which are synergistic with our clinical pipeline. We believe our internal research team and our in-house discovery and development capabilities will enable us to achieve our long-term goal of commercializing internally discovered innovative medicine with global rights for patients worldwide.

Highly differentiated and validated portfolio of assets with significant commercial opportunities

We are committed to bring in suitable potential best-in-class/first-in-class therapies and have assembled a broad and highly differentiated innovative portfolio of 16 products and drug candidates, with potentially global best-in-class/first-in-class potential, addressing huge unmet medical needs for oncology, autoimmune and infectious diseases to patients in China and around the world. Our innovative portfolio offers patients access to a novel and significantly improved treatment paradigm over existing standards of care for their targeted indications, especially for patients in China where there is a lack of innovative treatment options. We have

two approved, commercial stage products with significant market opportunity and seven assets in pivotal or potentially registration-enabling trials, two of which have had their NDA successfully submitted to China's NMPA.

We believe the success of our commercialised and late-stage oncology drug candidates with greater China rights will be driven by their differentiated clinical profiles, efficacy in patients and ability to provide clinical benefits over existing standards of care in a market where innovative therapies are often unavailable or less utilized relative to more developedmarkets. We have two approved and launched assets, and seven other assets in pivotal or potentially registration-enabling trials, two of which are already approved by the US FDA. We believe these assets represent a significant commercial opportunity.

- ***ZEJULA (Niraparib).*** ZEJULA is a potentially global best-in-class PARP inhibitor for ovarian cancer based on its clinical data to date, once-daily dosing and PK properties. ZEJULA is currently the only PARP inhibitor to have received a broad approval by FDA to treat all advanced ovarian cancer patients regardless of biomarker status as a monotherapy in both first-line and recurrent maintenance treatment settings. ZEJULA was also recommended in the NCCN Clinical Practice Guidelines in Oncology as monotherapy for first-line maintenance treatment for women with ovarian cancer.

  ZEJULA was the first and only approved Category 1 PARP inhibitor in China, supported by local patient data from the first fully-powered randomized, controlled Phase III trial ever done in ovarian cancer in China. Moreover, ZEJULA is recommended in the national treatment guideline in China.

  We licensed ZEJULA from Tesaro (now GSK) in September 2016 and successfully commercialized it in Hong Kong in October 2018, Macau in June 2019 and China in January 2020. On September 8, 2020, the NMPA also approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

- ***Optune (Tumor Treating Fields)*** is an only-in-class innovative cancer therapy which has demonstrated overall survival benefits in patients with newly diagnosed GBM. Tumor Treating Fields uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. Under this unique MoA, the anti-mitotic effect of Tumor Treating Fields has also demonstrated clinical proof of concept in multiple other tumor types and has ongoing global Phase III studies in brain metastases, non-small cell lung cancer (NSCLC), pancreatic cancer and ovarian cancer, which represent significant commercial opportunities in China. In addition, Optune (Tumor Treating Fields) was recommended with Level 1 evidence as a treatment for newly diagnosed GBM patients in the first Glioma Treatment Guideline in China and was included in the

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology with Category 1 recommendation, contributing to the establishment of a new and improved standard of care for newly diagnosed GBM patients in China.

Optune was granted "Innovative Medical Device Designation" from the NMPA in August 2019, and its Marketing Authorization Application (MAA) was approved by the NMPA in May 2020, making it the first innovative treatment approved for the treatment of GBM in China since 2007.

- ***Ripretinib*** is a potential best-in-class treatment for advanced GIST. It is the only drug approved by the FDA for the treatment of Fourth-Line GIST in the all-comer setting according to Frost & Sullivan. Although GIST patients may experience periods of disease control with approved first-to third-line treatments, due to the heterogeneous nature of the mutations that drive the disease, many patients continue to progress and ultimately fail all lines of treatment. Ripretinib was specifically designed to improve the treatment of GIST patients by inhibiting a broader spectrum of mutations in KIT and PDGFRα than approved first-to third-line treatments of GIST which inhibit only a limited subset of KIT and PDGFRα mutations known to occur in GIST patients.

- ***Odronextamab*** is an innovative, potential first-in-class CD20xCD3 bispecific antibody in Greater China. Odronextamab is the most advanced investigational fully human bispecific antibody invented by Regeneron's proprietary VelocImmune® technology and Veloci-Bi® bispecific platform and is designed to trigger tumor killing by binding to both a protein expressed on B-cell cancers (CD20) and a component of the T-cell receptor ("TCR") complex (CD3). Odronextamab was granted orphan drug designation by the FDA for the treatment of diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL), which have limited existing treatment options and relatively poor prognosis globally.

- ***Repotrectinib*** is an investigational next-generation TKI designed to effectively target ROS1 and TRK A/B/C with potential to treat TKI-naïve or-pretreated patients. ROS1 rearrangement is estimated to be an oncogenic driver in approximately 3 percent of patients with advanced NSCLC in China, and NTRK is estimated to be an oncogenic driver in approximately 0.5-1 percent of patients with other advanced solid tumors in China, according to Frost & Sullivan. Utilizing a July 22, 2019 data cut-off, data from the Phase 1 portion of TRIDENT-1 demonstrated the potential for repotrectinib to be best-in-class for the treatment of ROS1-positive advanced NSCLC in patients who were not previously treated with a TKI.

Other oncology drug candidates include retifanlimab, bemarituzumab, tebotelimab and margetuximab. In July 2019, we received the rights to develop and exclusively commercialize retifanlimab, an investigational monoclonal antibody that inhibits PD-1, in haematology and oncology in Greater China from Incyte. In May 2018, we received CTA approval from the NMPA to enroll Chinese patients in the bemarituzumab (a humanized monoclonal antibody,

IgG1 isotype, specific to FGFR2b) global registrational study, and we will manage the China portion of this global Phase III study and contribute patients from China. We obtained an exclusive license to develop and commercialize tebotelimab in Greater China from MacroGenics in November 2018. We also hold exclusive rights to develop and commercialize Margetuximab in Greater China.

In addition to these oncology-focused products, we believe that our two novel antibiotics, NUZYRA (omadacycline) and sulbactam-durlobactam, will address significant unmet patient and market needs. Over the past ten years, there were only eight novel antibiotics approved in China, according to Frost & Sullivan. The prevalent overuse of antibiotics, evolution of resistant bacteria and state of current treatment practices are expected to lead to an increase in drug-resistant infection rates.

- ***ZL-2401/NUZYRA (Omadacycline)*** is a novel tetracycline, specifically designed to overcome tetracycline resistance and improve activity across a broad spectrum of bacterial infections. NUZYRA is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. In April 2017, we licensed omadacycline from Paratek, which in October 2018 received FDA marketing approval and omadacycline was launched as NUZYRA in the United States in February 2019. There are limited treatment options against drug-resistant bacteria in China and NUZYRA is particularly well positioned for the China market due to its broad activity covering a wide spectrum of pathogens. In addition, drugs competing with omadacycline in the same class are only available in IV formulation. In contrast, omadacycline is available in both IV and oral once-daily formulations, which makes treatment more convenient for care givers and patients. In February 2020, the NMPA accepted our NDA with Category 1 new drug designation for NUZYRA for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infection (ABSSSI). The recent COVID-19 outbreak further evidenced the unmet medical demand for effective antibiotics such as NUZYRA as CABP is the most common secondary infection and respiratory complication resulting from the COVID-19 infection. We also believe that omadacycline has the potential to help physicians combat the growing antibiotic resistance problem in China.

- ***ZL-2402 (Sulbactam-Durlobactam)*** is a novel beta-lactamase inhibitor for the treatment of carbapenem-resistant Acinetobacter baumannii infections including penem-resistant A. baumannii. Acinetobacter infections occur predominantly in the hospital setting; the pathogen is often multi-drug resistant (MDR), and has become extremely difficult to treat. With over 200,000 occurrences estimated each year, China ranks among the countries with the highest incidence of A. baumannii infections in the world. We have licensed durlobactam from Entasis as part of a global strategic collaboration. The FDA has granted SUL-DUR Qualified Infectious Disease Product (QIDP) status, which is established by the FDA to incentivize the development of new antibiotics to treat serious or life-threatening infections caused by pathogens. Such QIDP status makes SUL-DUR eligible for the FDA's Fast Track

and Priority Review designations. Entasis has initiated a pivotal Phase III study in MDR Acinetobacter pneumonia and bloodstream infections in 2019, which will serve as a global registrational study. In May 2020, first Chinese patient was enrolled into the global Phase 3 ATTACK trial of durlobactam for Acinetobacter infections.

Established disease area strongholds within oncology driving scale and operational synergies

Through our consistent focus on world class innovation and global oncology partnerships, we have thoughtfully constructed our broad oncology portfolio targeting prevalent tumor disease areas in China, namely gynecologic cancer, breast cancer, gastro-intestinal cancer, brain cancer, lung cancer and hematological malignancies. Combining this focused oncology portfolio with dedicated expertise in each core business function across our fully-integrated platform, we are able to realize significant scientific, clinical development and commercial synergies in our operations. For example, through our continued efforts in advancing drug candidates within the same disease area into different stages of development, we are able to significantly enhance our understanding of disease biology. Such build-up in expertise and knowhow will allow us to more successfully identify attractive candidates that we would want to in-license and acquire the China or regional rights of in order to expand our portfolio and potential combination therapies between products. This expertise will also accelerate our internal discovery progress and enable us to prioritize resources on moving pre-clinical candidates into clinic. We also leverage the expertise of our scientific advisory board, academic collaborations and key opinion leader relationships to expand our insights.

From a clinical development perspective, as our pipeline expands, we accumulate increasing execution experience in each disease area and expect to benefit from significant synergies in clinical operations when conducting multiple trials with different lines and biomarkers in the same disease area. On the commercialization side, our dedicated oncology sales team will be able to promote multiple products to the same physician pool, while building stronger relationships with key opinion leaders. The combined impact of these synergies can bring significant efficiencies from an operating cost perspective, while allowing us to more rapidly scale our oncology business and effectively build our internal capabilities to support our global mission by leveraging China's large patient population. We believe we are well positioned to explore expansion of our disease strongholds to other indications.

We also believe that our rich oncology portfolio allows us to develop innovative combination-therapies and expand the commercial potential of our pipeline in each disease area. We managed to assemble innovative assets to treat cancers with diversified MoAs and modalities targeting key pathways and checkpoints of the tumor cell proliferation. Our various MoAs and modalities include, but are not limited to, synthetic lethality, Tumor Treating Fields, targeted therapy, immune-oncology therapy, small molecule, mAb and bispecific antibody. We also believe that our rich oncology portfolio has both the scale and mix to enable significant combination-therapy synergies and to develop innovative combination-therapies.

Distinguished world-class leadership team and deep talent pool

We have assembled a world-class leadership team with in-depth knowledge and extensive execution capabilities spanning pharmaceutical research, development and commercialization experience in both global and Chinese biopharmaceutical companies. Our leadership team led by Dr. Samantha Du has been pioneering China-based global biopharmaceutical innovation for decades, and we believe that we are leading the China biotech industry by successfully translating scientific visions into tangible drug candidates, solving complex issues in clinical development, progressing drug candidates through regulatory approval and commercializing innovative therapies.

Our Founder, Chairwoman and Chief Executive Officer, Samantha Du, Ph.D., is widely recognized as a leading figure in the China biopharmaceutical industry. Prior to founding our company, Dr. Du was Managing Director of healthcare investments at Sequoia Capital China, founder and CEO of Hutchison Medi-Pharma and co-founder and Chief Scientific Officer of Hutchison China MediTech Limited, where she pioneered China-based global biopharmaceutical innovation by bringing five internally-discovered innovative drug candidates into clinical trials, including two global Phase III ready drug candidates. Our other key management team members are also leaders in their respective areas globally or in China, heading clinical, medical, business development, commercial or corporate functions in globally renowned biopharmaceutical companies and MNCs before joining us.

Our visionary management team, together with the high-caliber talent pool we have established in both China and overseas, is key to propelling our company ahead of our peers in the Chinese biopharmaceutical industry. We have also assembled a scientific advisory board of respected academic leaders in their respective fields with a deep connection with scientific communities around the globe. Such a high-caliber talent pool has strengthened our capacity to discover potentially global best-in-class/first-in-class therapies through in-licensing and in-house discovery efforts, and these superior development opportunities in turn attract additional high-caliber talents to our platform, thereby forming a virtuous cycle. In particular, as a leading biotech company, attracting top talent globally has been, and will continue to be, an important driver of our organic growth. We have established and maintained a stable, growing team with 913 full-time employees as of the Latest Practicable Date, including nearly 400 employees in research and development.

We believe that the global academic resources and industry expertise of our leadership team, as well as our extensive and growing high-caliber talent pool will empower us to become a world-renowned biopharmaceutical company.

Proven institutionalized execution capabilities and track record of success

We believe that the execution capabilities of our management team, our scale of operation and unique resources, our commitment to excellence as well as our accumulated knowledge base and proprietary insights into the pharmaceutical industry, clinical development pathway and regulatory system in China have enabled us to institutionalize strong execution capabilities

across our organization. This has been proven by our extensive execution track records to identify and license in clinical assets with potential best-in-class/first-in-class potential, efficiently navigate through the clinical and regulatory approval process as well as quickly commercialize our products in Greater China.

- *Selectively screened and identified potentially global first- and/or best-in-class assets.* As a preferred partner of choice for global biopharma companies, we have accumulated proprietary know-how and insights, with extensive experience in selecting the clinical assets that are complementary to our existing portfolio. We managed to screen, identify and license in innovative and differentiated products in oncology, including DNA damage response (ZEJULA), targeted kinase inhibitors (ripretinib), novel HER-2 targeted antibody (margetuximab), fully human bispecifics antibody (odronextamab), investigational next-generation targeted kinase inhibitors (repotrectinib) and several immuno-oncology assets including retifanlimab, tebotelimab and ZL-1201.

- *Efficiently brought innovative clinical assets to the market.* Our experienced in-house clinical operations team has efficiently brought potential best-in-class/first-in-class assets to the China market, which is evidenced by the fact that it took us less than three years from ZEJULA's FDA approval to commercial launch in China. It took us less than three months from obtaining the exclusive license for Optune to commercial launch in Hong Kong, and an additional 20 months further to commercial launch in China, without the need of a clinical trial.

- *Successfully established commercialisation track record and manufacture infrastructure.* We have successfully brought two of our clinical assets to commercialization and quickly penetrated the market, as evidenced by ZEJULA's majority market share in Hong Kong. We have also commercially launched ZEJULA in China in January 2020, and ZEJULA has been successfully enrolled into the regional reimbursement program that complements China's basic medical insurance scheme in one province and six cities. As of August 31, 2020, ZEJULA has also been listed in 17 commercial health insurances and 12 supplemental insurances guided by municipal governments (城市定制險). We later built up our own commercialization team consisting of 401 employees as of the Latest Practicable Date to launch our drug products under global standards. In addition, we have efficiently established both small and large molecule drug manufacturing capabilities in 2017 and 2018.

Fully-integrated global biopharmaceutical platform with end-to-end capabilities

By focusing on developing, commercializing and manufacturing our late-stage in-licensed drug candidates and expanding our earlier-stage internal research and discovery capabilities, we have grown to a fully-integrated biopharmaceutical company with end-to-end capabilities and 913 employees encompassing all key disciplines including 377 and 401

employees in R&D and commercial. We have an established global operation with dual headquarters in China and the US, allowing us to capitalize on the latest innovation and business opportunities on a global scale.

- ***Research.*** With extensive research track records in both global and Chinese biopharmaceutical companies, our leadership team has assembled an in-house discovery team dedicated to the research and discovery of novel therapeutics in the areas of oncology and autoimmune diseases, with a focus on large market opportunities with unmet clinical needs. Our scientific advisory board is also comprised of world-renowned experts with valuable expertise in oncology and immunology. In addition, we have collaborations with academic institutions in China, including Tsinghua University, Shanghai Institute of Materia Medica and Shanghai Institute of Organic Chemistry, the Chinese Academy of Sciences, to expand our in-house research projects.

- ***Clinical development.*** We believe our experienced in-house clinical operations team with proven execution capabilities distinguishes us from other biopharmaceutical companies in China. As of the Latest Practicable Date, we had 244 clinical development staff. As of the same date, we had more than over 25 ongoing or planned clinical trials in China and Australia across over 20 indications. We believe our strong regulatory affairs team also enables us to keep up with the evolving regulatory environment for drug development and steer our drug registration practice towards the most efficient pathway to approval.

- ***Commercialization.*** To support our commercial launch of ZEJULA in Hong Kong, Macau and China, we have built and are expanding our nimble and science-driven commercialization team of 401 staff as of the Latest Practicable Date to cover major medical centers in Greater China. Our in-house sales and marketing team includes experienced personnel from MNCs such as AstraZeneca, Roche, Novartis and BMS. We have also established and continued to maintain strong working relationships with leading hospitals and medical professionals, including KOLs, in oncology and infectious diseases through our research and clinical development efforts. We believe we will continue to be well-positioned for the planned commercial launches of our late-stage products covering multiple therapeutic areas.

- ***Manufacturing.*** We currently operate two manufacturing facilities in Suzhou. In early 2017, we built a cGMP-compliant small molecule facility in Suzhou capable of supporting clinical and commercial production. In 2018, we completed construction of a large molecule facility in Suzhou capable of supporting the clinical production of our drug candidates. We believe that possessing manufacturing capabilities presents tangible benefits, which include maintaining better control over the quality and compliance of our operations given increasingly stringent industry regulations.

OUR STRATEGIES

Since our inception in 2013, our mission has been to leverage our expertise and insight to address the increasing needs of patients in China and to utilize our China-based competencies to improve the lives of patients worldwide. We believe that we have created substantial value for our shareholders and various other stakeholders through our proprietary and science-driven approach which has resulted in two successful commercial launches and multiple drug candidates advanced into late-stage clinical trials. With our proven track record and integrated capabilities, we believe we are uniquely positioned to take advantage of a once-in-a-generation opportunity to build a significant market leader on the back of China's rapid emergence and technological advances in the global biopharmaceutical space. We believe we are one of the first biotech companies in China to scale. We are committed to elevating Zai to the next level to become a leading global biopharmaceutical company, leveraging our capabilities and global network to help drive the next wave of innovation in the biopharmaceutical sector. Over the next three years, we expect to have a steady stream of approvals and commercial product launches in Greater China across multiple therapeutic areas, establish transformative partnerships, expand our global footprint, and advance our internally discovered global pipeline into the pivotal stage.

Rapidly ramp up the sales of our commercialized products and establish a strong commercial presence in Greater China

We plan to focus our resources on rapidly delivering ZEJULA and Optune to patients. We intend to leverage the momentum from the successful China launch of ZEJULA to penetrate more cities, leveraging our commercialization team dedicated to promoting ZEJULA. We will continue to leverage our strong momentum in commercial insurance coverage and aim for near-term NRDL so as to improve patient affordability, which drives the demand for healthcare products and services. With over 800 hospitals covered at the time of launch in China, we will strengthen commercialization efforts for ZEJULA through our established relationships with leading hospitals and medical professionals, including KOLs. We also plan to replicate the successful commercial launch of Optune in Hong Kong and rapidly drive the sales of Optune in China. We view our initial commercial success in Hong Kong as an encouraging sign for Optune and the unmet need Optune can address in China, based on its inclusion in the National Treatment Guidelines. We believe our experience successfully launching ZEJULA in China, as well as strong physician endorsement, will provide important lessons for the launch of Optune.

We also plan to expand our commercialization team in China in anticipation of the increased market demand for ZEJULA and the launch of Optune. We further aim to develop our commercialization team to be highly specialized and efficient through recruiting key talents in relevant indications to drive future product launch and bring innovative cancer therapies to our target markets. We believe our key commercialization leadership members, who have substantial experience and a strong track record relevant to our pipeline drug candidates, can leverage their experience launching innovative oncology products in China to strengthen our competitive position in the market.

Further expand our drug pipeline through our proprietary platform

We plan to further expand our drug pipeline through our proprietary platform to continue developing potentially global best-in-class/first-in-class assets around our disease strongholds within oncology, as well as in infectious and autoimmune diseases. We will further solidify our position as a partner of choice for global biopharmaceutical companies looking for access into China for either its vast commercial market potential or the opportunity to accelerate global development, while also developing our own pipeline candidates.

We will also seek bolt-on and transformational business development opportunities by leveraging our relationship with existing in-licensing partners and expertise in our focused therapeutic areas. In particular, we will focus on drug candidates complementary to our current drug pipeline with demonstrated promising data in early clinical studies and global market potential. We will also expand beyond existing areas leveraging our platform. We seek to utilize the advantages of drug development in China, including relatively fast patient enrollment and low clinical costs, to rapidly establish proof of concept for such candidates prior to pursuing further global multi-center trials for the global market with a focus on China-prevalent diseases, such as gastro-intestinal, brain and lung cancers. We believe that this unique approach, coupled with our global network and partnerships with major global biopharmaceutical companies, will make us an increasingly important contributor to the next wave of global innovation in biopharmaceuticals and allow us to access new areas of cutting-edge research for our future pipeline candidates, as well as to utilize our broad portfolio to identify unique combination therapies.

In addition, as part of our global development strategy, we continue to evaluate partnership opportunities and may invest in companies that offer a strategic or commercial fit with our current drug candidates and business.

Seek expedited approval on our late-stage clinical assets and advance other clinical or IND stage candidates through development stages

We plan to seek rapid indication expansion for our two commercialized products and to expedite approval of our other two NDA-stage clinical compounds to broaden our commercial portfolio and fully utilize our commercial infrastructure.

- ***ZEJULA.*** We intend to pursue expedited registration and expect to commercialize ZEJULA as a maintenance treatment of adult patients with ovarian cancer who are in a complete or partial response to first-line platinum-based chemotherapy, with our sNDA under priority review by the NMPA. Meanwhile, we will continue to explore the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the other clinically relevant indications.

- ***Tumor Treating Fields.*** We plan to submit MAA for MPM in China in the first half of 2021, and expect to leverage our experience in launching Optune in Hong Kong as well as China with a strong network of leading hospitals and medical professionals to explore incremental commercialization opportunities with additional coverage of MPM patients. In addition, we are conducting clinical trials of Tumor Treating Fields in Chinese patients with gastric cancer and plan to join global Phase III pivotal trials in non-small cell lung cancer, locally advanced pancreatic cancer and brain metastases in Greater China.

- ***Ripretinib.*** In July 2020, our NDA submission of ripretinib for advanced GIST was accepted by the NMPA. The NMPA granted priority review to our NDA for ripretinib for the treatment of adult patients with advanced GIST in August 2020. In July 2020, we also received the Clinical Trial Authorization (CTA) approval for the registrational bridging study of ripretinib in patients with second-line GIST. As the only product with all comer label in late lines, we believe Ripretinib will be able to address significant unmet medical needs in advanced GIST setting.

- ***Omadacycline.*** We received acceptance from the NMPA for our NDA for Omadacycline (ZL-2401) under priority review for CABP and ABSSSI in February 2020, and entered into a contract sales agreement with Hanhui, a local pharmaceutical company with a strong commercial presence in antibiotics. We plan to leverage Hanhui's existing infrastructure to optimize a potential future commercial launch of omadacycline in China given that omadacycline is a broad spectrum antibiotic in both the hospital and community settings.

We also plan to continue our efforts in rapidly developing other drug candidates in our pipeline.

- ***Odronextamab.*** We will continue to explore regulatory approval pathways for odronextamab in R/R B-NHL in China by joining the global Phase II program with multiple, potentially registrational cohorts of different subtypes of R/R B-NHL plan to enroll first Chinese patient into the potentially registrational global Phase 2 program by early 2021.

- ***Repotrectinib.*** We plan to open additional sites for the TRIDENT-1 Phase 2 registrational clinical study of repotrectinib. The ongoing study is currently active in 11 countries globally and enrolling patients with ROS1-positive advanced NSCLC and NTRK-positive solid tumors.

- ***Other Oncology Drug Candidates.*** We plan to participate in the upcoming global studies in the second half of 2020 of margetuximab (MAHOGANY) in combination with retifanlimab or tebotelimab in gastric cancer sponsored by MacroGenics in HER2+ first-line treatment of gastric cancer. In addition, with respect to retifanlimab, we plan to initiate pivotal trial in second-line MSI-high endometrial cancer in China in the second half of 2020 and enroll China patients to global Phase III study in first-line NSCLC in the second half of 2020. Furthermore, for tebotelimab, we intend to enroll the first Chinese patient in the second half of 2020 for this bispecific PD-1 x LAG-3 DART molecule in its global Phase I basket trial.

In addition to our oncology compounds, we also plan to rapidly advance the development of sulbactam-durlobactam so that we can introduce into China new and effective broad-spectrum antibiotics. Indeed, the first Chinese patient was enrolled into the global Phase III ATTACK trial of sulbactam-durlobactam for Acinetobacter infections.

With respect to the above late-stage clinical drug candidates with China rights, in addition to China, we intend to seek registration and commercialization in all geographies where we have applicable rights.

Enhance our internal research platform and discovery efforts

We believe internal research capabilities are a critical part of our platform. We have assembled an internal research and development team with extensive capabilities that we will leverage to discover, develop and commercialize innovative drug candidates that can address significant unmet medical needs globally. We have prioritized specific areas of cancer biology with clinical validation, synergistic with our clinical pipeline and aligned to our growing in-house expertise, including immune-oncology, DNA damage response and repair as well as oncogenic signaling.

Our discovery operations in Shanghai, China and San Francisco, California established in 2015 and 2018, respectively, have been focusing on generating small and large molecule therapeutics. We will continue to invest in and expand our internal research and discovery programs and expand our presence in both China and the United States to enhance internal drug discovery efforts. We continue to expand our U.S. presence to enhance internal drug discovery, clinical development and business development, with the opening of a new 20,000 sq.ft research facility in Menlo Park, California and the expansion of our Boston office.

We intend to continue to grow our internal pipeline and continue to progress assets with global rights into the clinic. We believe our discovery efforts will enable us to achieve our long-term goal of generating a sustainable, internally discovered pipeline of new products and drug candidates for patients around the world.

Efficiently grow our world-class organization and invest in our capabilities to support our global aspirations

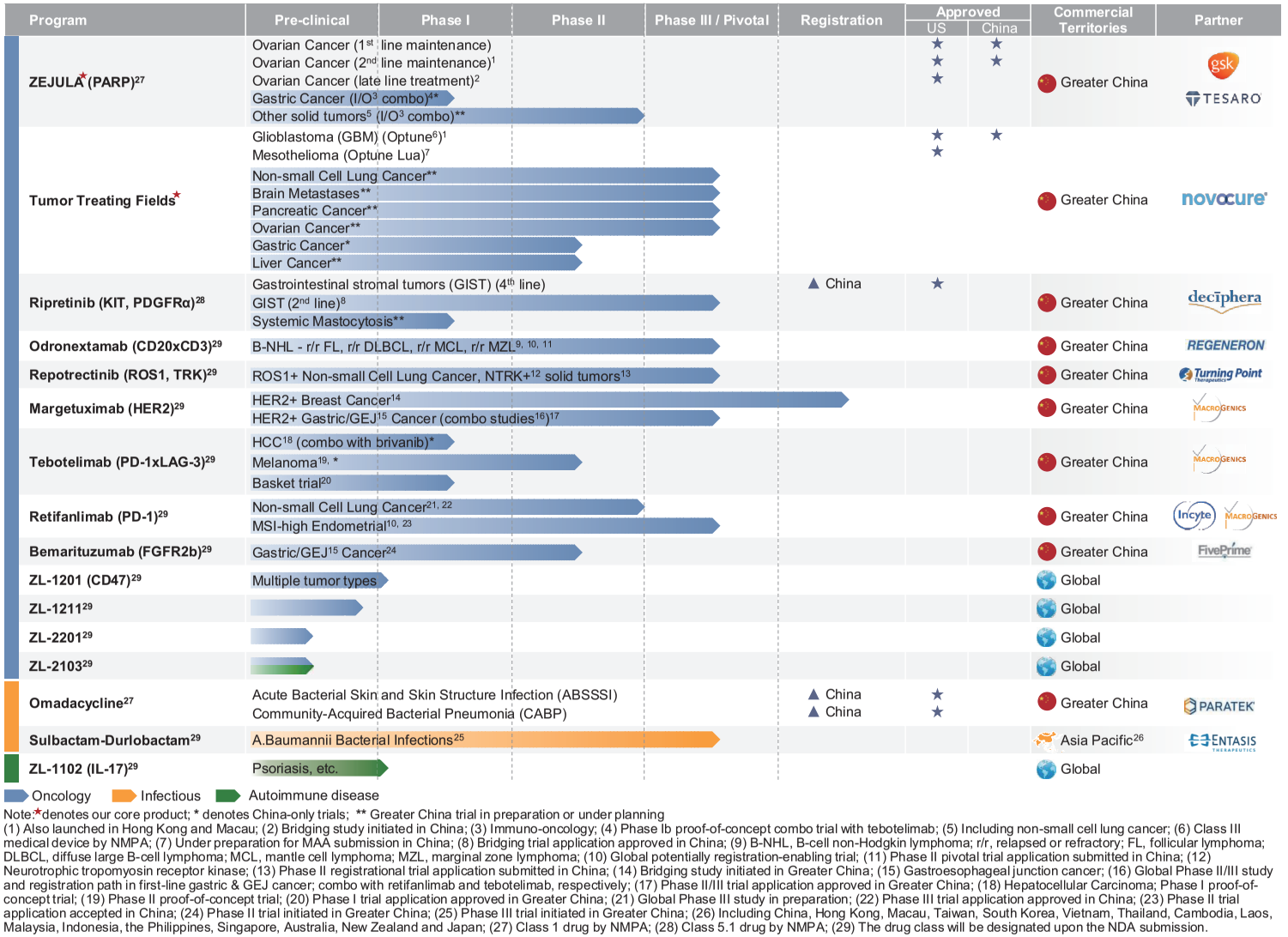
With our significant integrated capabilities in R&D, manufacturing and commercialization, we plan to strengthen and expand our platform and develop into a world-class organization with continued capital efficiency. In addition to expanding our product portfolio, we are committed to being innovative in our business model by identifying transformative deals and concepts globally, utilizing global clinical trial data, strengthening translational research and leveraging technologies. We also plan to expand the scale of our commercial organization and the breadth of our market coverage.

To support our efforts to grow our world-class organization, we will continue to recruit and train high-caliber talent globally to maintain our competitiveness in a rapidly evolving industry, in particular talent with expertise and experience in R&D and commercialization. By the end of 2020, we expect to have more than 1,000 employees. We expect vast majority of the new hires in the second half of 2020 will be for our sales and marketing team with our continued effort to expand our commercial capabilities in the preparation of launching of drug candidates and drugs with new indications, if approved. We expect by end of 2020, approximately 90% of our sales and marketing team will be based in municipalities (namely Beijing, Tianjin, Shanghai, and Chongqing) and provincial capitals to reinforce our commercial penetration primarily into Class III Hospitals in these regions. We are looking for talents with clinical medicine or life science background and business development, product management or portfolio management experience in a pharmaceutical or biotech/life science industry. We will strengthen our high-caliber and highly-skilled talent pool through the integration of external recruitment and internal training and enhance our incentive schemes to provide qualified employees with equity participation and promotion opportunities.

In addition, as our commercial-stage portfolio grows, we intend to expand our manufacturing capacity in-line with market demand for our products, whether by building new production facilities or expanding current production facilities, engaging contract manufacturing organizations (CMOs) and optimizing third-party manufacturer structure. Through both expanded in-house manufacturing capacities and diversified CMO cooperation, we believe our manufacturing capabilities will continue to support our validated portfolio in both clinical and commercial development.

OUR PRODUCTS AND DRUG CANDIDATES PIPELINE

We have a broad portfolio of proprietary products and drug candidates that range from discovery stage to late-stage clinical to commercial-stage programs. Our portfolio consists of 16 potential best-in-class/first-in-class products and drug candidates, including two commercialized products in China, Hong Kong and Macau and seven assets in pivotal or potentially registration-enabling trials in oncology, infectious and autoimmune diseases, which are therapeutic areas where there is a large unmet need and lack of innovative treatment options in China. The following table summarizes the global development status of our portfolio of commercialized products and drug candidates and programs.



Note:*denotes our core product; * denotes China-only trials; ** Greater China trial in preparation or under planning

(1) Also launched in Hong Kong and Macau; (2) Bridging study initiated in China; (3) Immuno-oncology; (4) Phase Ib proof-of-concept combo trial with tebotelimab; (5) Including non-small cell lung cancer; (6) Class III medical device by NMPA; (7) Under preparation for MAA submission in China; (8) Bridging trial application approved in China; (9) B-NHL, B-cell non-Hodgkin lymphoma; r/r, relapsed or refractory; FL, follicular lymphoma; DLBCL, diffuse large B-cell lymphoma; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; (10) Global potentially registration-enabling trial; (11) Phase II pivotal trial application submitted in China; (12) Neurotrophic tropomyosin receptor kinase; (13) Phase II registrational trial application submitted in China; (14) Bridging study initiated in Greater China; (15) Gastroesophageal junction cancer; (16) Global Phase II/III study and registration path in first-line gastric & GEJ cancer; combo with retifanlimab and tebotelimab, respectively; (17) Phase II/III trial application approved in Greater China; (18) Hepatocellular Carcinoma; Phase I proof-of-concept trial; (19) Phase II proof-of-concept trial; (20) Phase I trial application approved in Greater China; (21) Global Phase III study in preparation; (22) Phase III trial application approved in China; (23) Phase II trial application accepted in China; (24) Phase II trial initiated in Greater China; (25) Phase III trial initiated in Greater China; (26) Including China, Hong Kong, Macau, Taiwan, South Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan; (27) Class 1 drug by NMPA; (28) Class 5.1 drug by NMPA; (29) The drug class will be designated upon the NDA submission.

Our drug candidates are subject to approval by the relevant authorities, such as the FDA and the NMPA, before commercialization in each jurisdiction. See "Regulatory Environment" for details. As of the Latest Practicable Date, we had not received any material comments or concerns raised by the relevant authorities regarding, among others, our products, drug candidates or programs that we are not able to satisfactorily address in a timely manner.

Our Marketed Core Products

ZEJULA

Overview

ZEJULA (niraparib), one of our Core Products, is an once-daily small molecule poly (ADP-ribose) polymerase 1/2, or PARP 1/2, inhibitor approved by the NMPA as Category 1 drug for treatment across multiple solid tumor types in China. ZEJULA was approved in March 2017 by the FDA and in November 2017 by the EMA, as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer. Maintenance therapy is for those women who have had prior treatment but are expected to see their cancer return, with the purpose of avoiding or slowing a recurrence if the cancer is in remission after the prior treatment. A platinum-sensitive cancer is one that responded to initial platinum-based chemotherapy and remained in remission post-chemotherapy for more than six months.

ZEJULA is the first PARP inhibitor approved by the FDA for ovarian cancer that does not require BRCA mutation or other biomarker testing. This makes ZEJULA suitable for a wide patient population and significantly more accessible to patients in China where BRCA biomarker diagnostic tests are not widely accessible.

We obtained an exclusive license for the development and commercialization of ZEJULA in China, Hong Kong and Macau in 2016 from Tesaro (now GSK). For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements." In October 2018, the Hong Kong Department of Health approved our application for ZEJULA in Hong Kong for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy and we began commercializing ZEJULA in Hong Kong in the fourth quarter of 2018. In June 2019, we received the marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. In December 2019, ZEJULA was approved by the NMPA in China as a Category 1 maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. ZEJULA was the first and, as of the date of this prospectus, the only approved Category 1 PARP inhibitor in China, supported by local patient data from the first fully-powered randomized, controlled Phase III trial ever done in ovarian cancer in China. Moreover, ZEJULA is recommended in the national treatment guidelines in China. Since the commercial launch in China in January 2020, ZEJULA has been successfully

enrolled into the regional reimbursement program that complements China's basic medical insurance scheme in one province and six cities. It has also been listed in 17 commercial health insurances and 12 supplemental insurances guided by municipal governments (城市定制險) as of August 31, 2020.

In 2019, ZEJULA was designated as a "National Sciences and Technology Major Project" by the Chinese government as part of a key initiative to strengthen local innovation. On September 8, 2020, the NMPA also approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. Such sNDA was previously under the NMPA's priority review. Priority review was established in China to facilitate drug registration and accelerate the development of new drugs with clinical value under the guidance of the Opinions on Encouraging the Priority Review and Approval for Drug Innovations (《關於鼓勵藥品創新實行優先審評審批的意見》) issued by the former CFDA in December 2017. According to the guidelines, the regulatory authority will prioritize the review process and evaluation resources for applications under priority review, which should expect reduced review and approval timelines. Since the date of issue of the relevant regulatory approvals and as of the Latest Practicable Date, no material unexpected or adverse changes had occurred. We had not received any material comments or concerns raised by the relevant authorities regarding the completed or ongoing clinical trials of ZEJULA that we are not able to satisfactorily address in a timely manner as of the Latest Practicable Date.

We continue to explore ZEJULA in patients with breast cancer and non-small cell lung cancer in China. In February 2020, we dosed the first patient in the Phase Ib study of ZEJULA with tebotelimab, a potential first-in-class PD1/LAG-3 bispecific antibody, in advanced or metastatic gastric cancer. We are also exploring the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

Background on PARP Inhibitors

PARP inhibition has become an important part of cancer therapy, given its role in blocking DNA repair, which is a well-studied area of PARP activity. DNA contains genetic instructions used in the development and functioning of most known living organisms. DNA can be damaged by many types of mutagens, including oxidizing agents, alkylating agents, ultraviolet light and X-rays. An important property of DNA is that it can replicate, or make copies of itself. This is critical when cells divide because each new cell needs to have an exact copy of the DNA present in the old cell. It is also critical to the integrity and survival of cells that DNA damage can be repaired. Cells have evolved multiple mechanisms to enable such DNA repair, and these mechanisms are complementary to each other, each driving repair of specific types of DNA damage. If a cell's DNA damage repair system is overpowered, then the cell is programmed to die.

Radiation and certain chemotherapies such as alkylating agents and topoisomerase inhibitors induce significant damage to tumor cells, which results in programmed cell death. DNA repair mechanisms may reduce the activity of these anti-cancer therapies and, conversely, inhibition of DNA repair processes may enhance the effects of DNA-damaging anti-cancer therapy. For example, cancer cells can maintain viability despite disruption of the key DNA repair pathway known as the homologous recombination pathway, but they become particularly vulnerable to chemotherapy if an alternative DNA repair pathway is disrupted. This is known as "synthetic lethality"-a situation where the individual loss of either repair pathway is compatible with cell viability, but the simultaneous loss of both pathways results in cancer cell deaths.

Clinical studies have shown that PARP inhibitors are effective as a monotherapy in patients with certain types of cancer, including those with gene mutations as discussed below. PARP inhibitors have also been explored in numerous clinical trials to enhance chemotherapy treatments, including in combination with TMZ, cisplatin, carboplatin, gemcitabine and topotecan.

Mechanism of Action

Many DNA repair processes involve PARP-1 and PARP-2, which are zinc-finger DNA-binding enzymes that sense DNA damage and convert it into intracellular signals to promote DNA repair. PARP inhibitors block DNA repair by the base excision repair pathway. PARP inhibitors appear most effective when used to treat tumors with underlying defects in DNA repair or when combined with another DNA-damaging agent. This is because, in normal cells, the homologous recombination pathway compensates for PARP-mediated inhibition of the base excision repair pathway and maintains the fidelity of DNA repair. In cells with a deficiency in the homologous recombination pathway, such as those with BRCA-1 and BRCA-2 mutations, PARP inhibition leads to irreparable double-strand breaks, collapsed replication forks, and an increased use of the less effective nonhomologous end joining pathway. These disruptions ultimately result in synthetic lethality, and, in this manner, treatment with PARP inhibitors represents an opportunity to selectively kill cancer cells with deficiencies in homologous recombination and other DNA repair mechanisms. PARP inhibitors also have an additional mechanism of action known as "PARP trapping." The effect of PARP trapping is to poison DNA by stabilizing PARP-1 and PARP-2 at sites of DNA damage, generating complexes that may be even more toxic than the unrepaired single-strand breaks which result from PARP inhibition.

ZEJULA is designed to be a highly potent, selective inhibitor of PARP-1 and PARP-2. In an ovarian cancer patient-derived xenograft model, where tumor models are established from transplantation of a human tumor specimen from a cancer patient directly into a mouse, ZEJULA has been shown to have greater tumor concentration, allowing it to deliver sustained anti-tumor activity as compared to olaparib, an FDA-approved PARP inhibitor marketed by AstraZenaca for gBRCA+ ovarian cancer patients who have received at least three prior lines of chemotherapy.

Market Opportunity and Competition

We believe that ZEJULA represents a significant market opportunity in China, given its differentiated clinical profile, demonstrated clinical relevance to multiple solid tumor types, potential to provide a notable improvement to existing standards of care, and prospects to be utilized in multiple combination and monotherapy treatment options. We have the right to all indications in greater China (except prostate cancer), and we intend to pursue the approval and registration of ZEJULA as a Category 1 drug for treatment across multiple solid tumor types in China.

ZEJULA is the first PARP inhibitor approved by the FDA for all ovarian cancer patients regardless of biomarker status. With a potentially global best-in-class profile, it was approved by the FDA in both first-line and recurrent maintenance treatment settings. ZEJULA is recommended in national treatment guideline in the United States. ZEJULA has unique suitability for patients in China where biomarker diagnostic tests are still not widely accessible. As the first and only approved Category 1 PARP inhibitor in China, ZEJULA is supported by local patient data from the first fully-powered, randomized, controlled Phase III trial ever done in ovarian cancer in China. Similar to its status in the U.S., ZEJULA is also recommended in the national treatment guideline in China. In addition, ZEJULA obtained recognition and funding support from the Chinese government.

As of July 2020, there were only two marketed PARP inhibitors in China, one is LYNPARZA (olaparib) from AstraZeneca, which was approved in 2018; the other one is ZEJULA (niraparib), which was approved in 2019, according to the Frost & Sullivan Report.

The main competitive drug, LYNPARZA of AstraZeneca, was (i) approved by the FDA in December 2018 in first-line maintenance therapy but only for BReast CAncer gene ("BRCA")-positive patients, and (ii) approved by the FDA in May 2020 for patients whose cancer is associated with homologous recombination deficiency (HRD) positive status, which represent 50% of the advanced ovarian cancer patients, but only in combination with Avastin (bevacizumab). On the other hand, ZEJULA was approved (i) for all advanced ovarian cancer patients regardless of biomarker status, and (ii) as a monotherapy.

An additional four PARP inhibitors are in phase III clinical development or at NDA stage in China, comprising both China developed and global drug candidates. Three of these PARP inhibitors' lead indications focus on late-stage ovarian cancer while one focuses on metastatic prostate cancer. In the late stage ovarian cancer indications, one of the products is targeting BRCA+ patients only. We believe that, pending on the NMPA's approval of our supplemental new drug application (sNDA) for ZEJULA as a maintenance in first-line ovarian cancer, ZEJULA would target the broadest patient population.

ZEJULA is a potential best-in-class PARP inhibitor, given it is the only PARP inhibitor approved in the US as monotherapy for all-comer patients in the first-line and recurrent maintenance treatment settings, according to Frost & Sullivan. We believe that our early entrant status as one of the first PARP inhibitors in the China market, coupled with the global recognition, differentiated profile and availability of global and China clinical evidence for ZEJULA, position us favourably in China's PARP inhibitor market.

Our currently targeted indications for ZEJULA include the following:

Ovarian Cancer

Ovarian cancer had an estimated annual incidence of 53,900 patients in China in 2019, which is more than double that of the 22,500 patients in the United States, and has seen increasing mortality rates, according to NCCR and ACS. Since early symptoms of ovarian cancer are non-specific and difficult to detect, approximately 70% of women with ovarian cancer are diagnosed when the disease is at an advanced stage, when prognosis is poor. Finding effective therapeutic approaches for advanced ovarian cancer patients represents a large unmet medical need.

The previous standard of care in China consists of radical surgery and platinum-based chemotherapy. Although platinum-based chemotherapy is effective at inducing an initial response, ovarian cancer will recur in approximately 85% of patients. Many patients continue to respond to second-line platinum based chemotherapy, and following a response, the guideline-recommended approach for many patients is surveillance, monitoring patients for disease progression and managing their symptoms. However, during the surveillance period, ovarian cancer survivors report anxiety about cancer antigen testing and fear of recurrence, many experiencing symptoms associated with post-traumatic stress disorder. After relapse, patients respond moderately or poorly to subsequent chemotherapy, with later lines of therapy leading to progressively shorter treatment-free intervals. We believe effective maintenance therapies that address a broad patient population are needed to prolong the duration of response following platinum-based treatment. ZEJULA was recommended as a monotherapy first-line maintenance treatment for women with platinum-responsive advanced ovarian cancer in the Ovarian Cancer PARP Inhibitor Clinical Guidelines (卵巢癌PARP抑制劑臨床應用指南) published by Gynecological Oncology, Chinese Medical Association (中華醫學會婦科腫瘤學分會) in May 2020. This shows that ZEJULA is regarded as the standard of care in first-line maintenance treatment for women with advanced ovarian cancer in China.

Given the broad applicability of ZEJULA across all patient populations, regardless of gBRCA mutation status, we are currently targeting the entire platinum sensitive ovarian cancer patient population. This represents a significant advantage for patient convenience and access, given that there is no need for patients to utilize diagnostic tests to determine their gBRCA mutation status, particularly in China where such tests are not widely accessible.

Lung Cancer

Lung cancer has the highest total incidence as well as the highest mortality rate of any cancer in China. Annual incidence was estimated at 895.3 thousand patients in China in 2019, according to Frost & Sullivan.

Lung cancer can be categorized into non-small-cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC is any type of epithelial lung cancer other than (SCLC). The most common types of NSCLC are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. All types can occur in unusual histologic variants and developed as mixed cell-type combinations. NSCLC accounts for approximately 85% of total lung cancer patients in China. The incidence of NSCLC in China reached 761.0 thousands in 2019, with a CAGR of 3.3% between 2015 and 2019; in the future, the incidence is expected to reach 884.3 thousand in 2024 representing a CAGR of 3.0% from 2019 to 2024, and 1.0 million in 2030 with a CAGR of 2.8% from 2024 to 2030, according to the Frost & Sullivan Report. The 5-year survival rate of lung cancer in China is 19.7%, according to the Frost & Sullivan Report.

We intend to explore ZEJULA's efficacy in patients with NSCLC based on the large unmet need for effective treatment for such patients in China. The relatively limited therapy options for Chinese physicians and patients make us believe that a small molecule PARP inhibitor will offer an attractive addition to the standard of care.

Gastric Cancer

Cancer of the stomach, also called gastric cancer (GC), and cancer of the gastroesophageal junction (GEJ), which is where the esophagus joins the stomach, are collectively referred to as gastroesophageal adenocarcinoma, which is the third leading cause of cancer death worldwide according to the World Health Organization in 2018. Both GC and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a 5-year survival of 20-35%.

Gastric cancer is the second most common cancer in China and the third leading cause of death in China. The incidence of gastric cancer in China has reached 455.8 thousand in 2019, and it is expected to be 525.8 thousand in 2024, representing a CAGR of 2.9% from 2019 to 2024, and 613.8 thousand in 2030, with a CAGR of 2.6% from 2024 to 2030, according to the Frost & Sullivan Report. Current therapies of gastric cancer include surgery, chemotherapy, radiotherapy and targeted therapy. However, there are limited effective treatment options in China or globally for patients with advanced or metastatic gastric cancer who have failed prior treatment.

In February 2020, we initiated a Phase Ib study of ZEJULA in combination with tebotelimab in advanced or metastatic gastric cancer in China for the treatment of patients with advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma (collectively as gastric cancer) who failed prior treatment.

Clinical Development Plan and Strategy for ZEJULA in the China Market

Ovarian Cancer

In July 2018, we completed our open-label study evaluating the pharmacokinetic, or PK, profile of our China-produced formulation of ZEJULA in Chinese ovarian cancer patients. Results from the study show a comparable PK profile of the Chinese patients administered ZEJULA to that of patients evaluated in GSK's global PK study. The study demonstrated that the drug exposure increased proportionally from 100mg to 300mg, with a Tmax of approximately three hours. Systemic exposure to ZEJULA, as measured by Cmax and AUC, increased approximately proportionally with increased dose. There were no unexpected safety issues noted during the trial. All key PK and safety parameters were comparable to those in global studies. The study results and population PK data did not identify ethnicity differences between Chinese and non-Chinese patients.

In January 2019, we completed patient enrollment of our Phase III NORA trial evaluating ZEJULA as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. NORA is a Zai Lab self-sponsored Phase III randomized, double-blind, placebo-controlled, study of ZEJULA conducted by us as a second-line maintenance therapy in Chinese patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) who are in a complete or partial response to platinum-based chemotherapy. NORA randomized 265 patients at 2:1 to receive ZEJULA or placebo until disease progression. The study evaluated the efficacy of ZEJULA as a maintenance treatment, with the primary endpoint being progression-free survival (PFS) as assessed by blinded independent central review.

The starting dose was individualized at 200 mg except for those with a baseline body weight >77kg and a platelet count >150K/μL in which case the starting dose is 300 mg. Such individualized starting dose regimen was shown to be effective with improved safety profile in Chinese patients, with lower rates of anemia and thrombocytopenia. The study met its primary endpoint of a statistically significant improvement in progression free survival for patients with ovarian cancer regardless of their biomarker status. The safety profile was consistent with what was observed from the global NOVA study with lower rates of anemia and thrombocytopenia. NORA is a first fully powered, randomized, controlled (RCT) Phase III trial ever completed in ovarian cancer in China, excluding Chinese traditional medicines studies.

In November 2019, we completed patient enrollment of our Phase III PRIME trial evaluating ZEJULA as a first-line maintenance therapy in ovarian cancer patients who are in a complete or partial response to first-line platinum-based chemotherapy. PRIME is our self-sponsored Phase III randomized, double-blind, placebo-controlled study of ZEJULA as a maintenance therapy in Chinese patients with advanced ovarian cancer who are in a complete or partial response to first-line platinum-based chemotherapy. Advanced ovarian cancer patients were randomized 2:1 to receive ZEJULA or placebo as maintenance therapy. Randomization was stratified by use of neoadjuvant chemotherapy (yes or no), best response to platinum therapy (CR or PR), and homologous recombination deficiency (HRD) status

(positive or negative/not determined). The primary end point was progression-free survival (PFS) in patients who had tumors with HRD+ve and in those in the overall population, as determined on hierarchical testing.

In China, ZEJULA has been approved as a Category 1 drug by the NMPA in December 2019 as maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. The NMPA accepted and granted priority review to our sNDA for ZEJULA as a Category 2.4 first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy in March 2020 and April 2020, respectively.

In May 2020, we announced positive top-line results from the NORA Phase III study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer. In July 2020, we completed NORA Trial, at which time we completed the study report. The NORA trial met all primary and secondary endpoints with improved safety profile in Chinese patients. The full results from the NORA study will be presented at European Society for Medical Oncology (ESMO) 2020 Virtual Congress on September 19, 2020.

We dosed the first patient in registrational bridging trial for late-line ovarian cancer treatment in August 2020.

On September 8, 2020, the NMPA also approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

Lung Cancer

We initiated a Phase III study in patients with platinum responsive small cell lung cancer as maintenance therapy in August 2018. Given the rapidly changing landscape in the management of small cell lung cancer, particularly with the introduction of PD1/PD-L1 antibodies in the first-line treatment of small cell lung cancer, we terminated this study to prioritize our resources to other opportunities including exploring potential combination regimen for ZEJULA and immuno-oncology agents in the maintenance setting for non-small cell lung cancer.

Gastric Cancer

In February 2020, we dosed the first patient in the Phase Ib dose escalation and expansion clinical study of ZEJULA in China, in combination with tebotelimab, for the treatment of patients with advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma (collectively as gastric cancer) who failed prior treatment.

The primary endpoint of the study is assessing the safety of ZEJULA in combination with tebotelimab in patients with advanced gastric cancer and determining the recommended phase 2 dose. Secondary endpoints include objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS), and overall survival (OS).

We continue to explore the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the other clinically relevant indications.

Summary of Clinical Trial Results

The following clinical trials were conducted by our business partner, GSK.

NOVA, a Phase III maintenance study of ZEJULA versus placebo in patients with recurrent platinum-sensitive ovarian cancer

In March 2017, the FDA approved ZEJULA as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer, regardless of BRCA mutation or biomarker status, three months ahead of the FDA's scheduled decision date (PDUFA date). ZEJULA's FDA approval followed the release of successful results from GSK NOVA trial in which ZEJULA demonstrated a clinically meaningful increase in progression-free survival in women with recurrent ovarian cancer, regardless of gBRCA mutation or biomarker status. Treatment with ZEJULA reduced the risk of disease progression or death by 73% in gBRCA mutation positive patients (hazard ratio = 0.27) and by 55% in patients without gBRCA mutations (hazard ratio = 0.45). Hazard ratio is the probability of an event (such as disease progression or death) occurring in the treatment arm divided by the probability of the event occurring in the control arm of a study, with a ratio of less than one indicating a lower probability of an event occurring for patients in the treatment arm. P-value is a measure of the probability of obtaining the observed sample results, with a lower value indicating a higher degree of statistical confidence in these studies. The magnitude of benefit was similar for patients entering the trial with a partial response or a complete response to platinum treatment.

The NOVA trial was a Phase III randomized double-blind trial that assessed the effectiveness of ZEJULA compared with placebo to delay tumor progression following a platinum containing chemotherapy regimen. Patients enrolled into one of two independent cohorts based on gBRCA mutation status. A total of 553 patients were enrolled in the NOVA study at 107 centers worldwide. The study population has 203 patients assigned to the gBRCA mutation positive cohort and 350 patients assigned to the gBRCA mutation negative cohort. Among the patients in the gBRCA mutation negative cohort, 162 had tumors that were tumors deficient in homologous recombination, or HRDpos, and 134 had tumors did not have a homologous recombination deficiency, or HRDneg. The homologous recombination deficiency status was not determined for 54 patients. The gBRCA mutation negative cohort analyses included all patients randomized, regardless of homologous recombination deficiency status.

Within each cohort, patients were randomized 2:1 to receive ZEJULA or placebo, and were continuously treated with placebo or ZEJULA until progression. The primary endpoint of this study was progression free survival. Secondary endpoints included patient-reported outcomes, chemotherapy free interval length, and OS. This trial successfully achieved its primary endpoint in both cohorts, showing that ZEJULA treatment significantly prolonged progression free survival, compared to control in patients who were gBRCA mutation positive and in patients who were gBRCA mutation negative. In addition, within the gBRCA mutation negative cohort, ZEJULA treatment significantly prolonged progression free survival compared to placebo for the prospectively defined patient population with HRDpos tumors. A high proportion of patients in both treatment groups in both cohorts had received three or more prior lines of chemotherapy. The most common treatment-emergent grade 3/4 adverse events in the ZEJULA arm of the NOVA study, based on the National Cancer Institute's Common Terminology Criteria for Adverse Event, or CTC, which is a set of criteria for the standardized classification of adverse effects of drugs used in cancer therapy (with one and two being relatively mild and higher numbers up to five being more severe), were thrombocytopenia, anemia, and neutropenia.

The figures below present the results for the primary endpoint of progression free survival for the three primary efficacy populations.

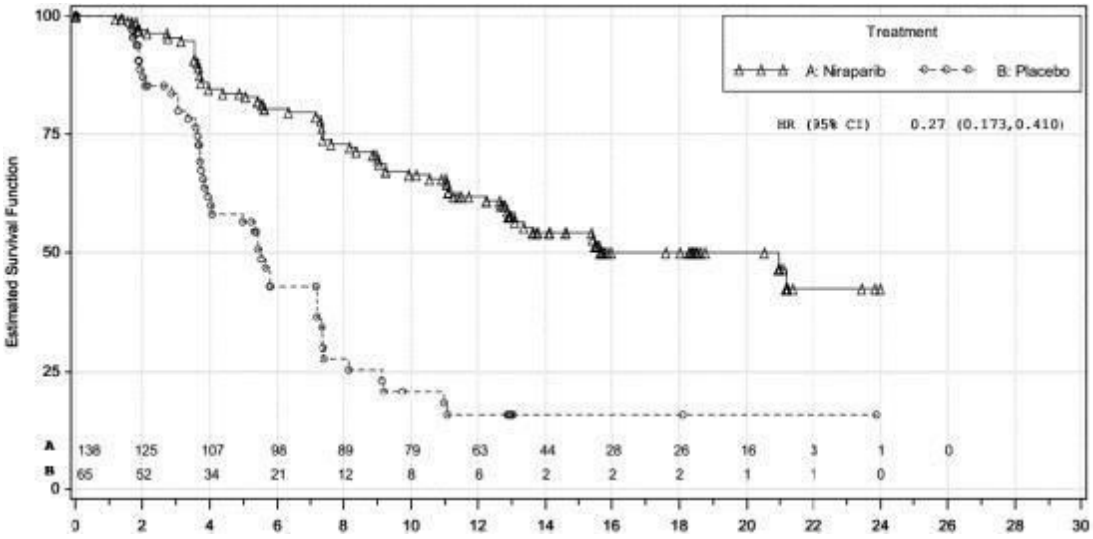
Figure 1: Progression free survival was significantly longer for patients who received ZEJULA compared to those who received placebo for all primary efficacy populations.

			Disease Progression Free (%)		
Treatment	**Median PFS (95% CI) (Months)**	**Hazard Ratio (95% CI) p Value**	**6 Months**	**12 Months**	**18 Months**
gBRCAmut Cohort					
ZEJULA (N = 138)	21.0 (12.9, NE)	0.27 (0.173, 0.410)	80%	62%	50%
Placebo (N = 65)	5.5 (3.8, 7.2)	p<0.0001	43%	16%	16%
HRDpos Subgroup					
ZEJULA (N = 106)	12.9 (8.1, 15.9)		69%	51%	37%
Placebo (N = 56)	3.8 (3.5, 5.7)		35%	13%	9%
Non-gBRCAmut Cohort					
ZEJULA (N = 234)	9.3 (7.2, 11.2)	0.45 (0.338, 0.607)	61%	41%	30%
Placebo (N = 116)	3.9 (3.7, 5.5)	p <0.0001	36%	14%	12%

Source: GSK.

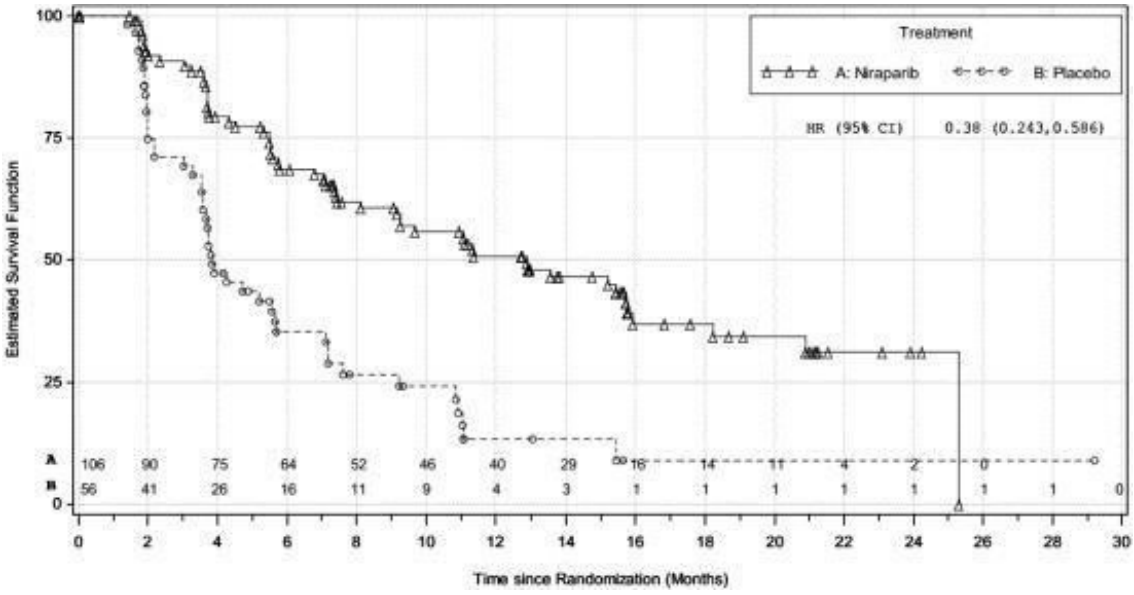
Notes: gBRCAmut = gBRCA mutation positive; non-gBRCAmut = gBRCA mutation negative

Figure 2: Progression free survival in the gBRCA mutation positive cohort of patients treated with ZEJULA versus placebo



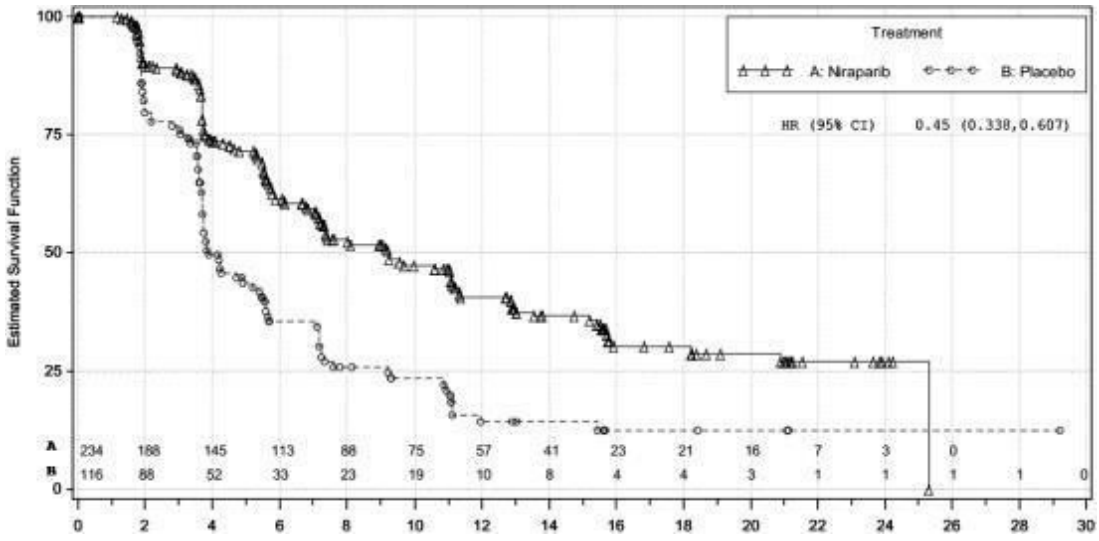
Source: GSK.

Figure 3: Progression free survival in the HRDpos group of the gBRCA mutation negative cohort of patients treated with ZEJULA versus placebo



Source: GSK.

Figure 4: Progression free survival in the overall gBRCA mutation negative cohort of patients treated with ZEJULA versus placebo



Source: GSK.

Within the gBRCA mutation positive cohort, the median progression free survival was 21.0 months on ZEJULA versus 5.5 months on placebo (hazard ratio=0.27; p<0.0001). As shown in the chart above, ZEJULA's treatment effect started very early during treatment as seen by the two curves being separated at first efficacy assessment. Progression free survival was also significantly longer with ZEJULA in the HRDpos group of the gBRCA mutation negative cohort (median, 12.9 months versus 3.8 months; hazard ratio=0.38; p<0.0001) and in the overall gBRCA mutation negative cohort (median, 9.3 months versus 3.9 months; hazard ratio = 0.45; p<0.0001). Additionally, in an exploratory pooled analysis that evaluated all patients in both cohorts combined, progression free survival was longer with ZEJULA (median 11.3 months versus 4.7 months, hazard ratio = 0.38, 95% confidence interval: 0.303, 0.488; p<0.0001).

As it is maintenance therapy, quality of life is important to patients receiving treatment. Patient-reported outcome data from validated survey tools indicated that ZEJULA-treated patients reported no significant difference from placebo in measures associated with symptom specific and general quality of life.

Furthermore, ZEJULA treatment did not reduce the effectiveness of subsequent therapies, and continued to show carry-over of the beneficial treatment effect in the secondary efficacy measure of second objective disease progression, which is time from randomization to objective tumor progression on next-line treatment or death from any cause. OS data, while immature, showed no negative impact of ZEJULA treatment.

The incidences of CTC grade 3/4 treatment-emergent adverse events (74% vs 23%), serious adverse events (30% vs 15%), treatment-emergent adverse events leading to treatment interruption (67% vs 15%), treatment-emergent adverse events leading to dose reduction (69% vs 5%), and treatment-emergent adverse events leading to treatment discontinuation (15% vs 2%) were higher for ZEJULA versus placebo. There were no on-treatment deaths reported.

The most commonly observed hematological treatment-emergent adverse events (all CTC grades) related to ZEJULA were thrombocytopenia (61%), anemia (50%) and neutropenia (30%). Although CTC grade 3/4 hematological laboratory events were common at the initiation of treatment, no severe clinical sequelae were observed and relatively few patients discontinued due to these adverse events. Dose adjustment based on individual tolerability during the first cycles substantially reduced the incidence of these events beyond the third 28-day treatment cycle, indicating the overall effectiveness of the approach to dose modification. Overall the treatment-emergent adverse events were manageable, with no negative impact on quality of life.

PRIMA, a Phase III maintenance study of ZEJULA versus placebo in patients with advanced ovarian cancer following response on front-line platinum-based chemotherapy

PRIMA is a randomized, double-blind, Phase III trial evaluating ZEJULA versus placebo as maintenance therapy in patients with advanced ovarian cancer following response on front-line platinum-based chemotherapy. The study was designed to enroll subjects with Stage III or IV ovarian cancer (including fallopian and peritoneal cancers) who had previously completed front-line platinum-based therapy with a physician-assessed response of CR or PR. Randomization was stratified by use of neoadjuvant chemotherapy (yes or no), best response to platinum therapy (CR or PR), and homologous recombination deficiency (HRD) status (positive or negative/not determined). The primary end point was progression-free survival (PFS) in patients who had tumors with HRD+ve and in those in the overall population, as determined on hierarchical testing.

From July 2016 through June 2018 and across 220 sites worldwide, a total of 733 patients were randomized at 2:1 to receive ZEJULA or placebo as maintenance therapy, of whom 373 (50.9%) had tumors with HRD. Among the patients in this category, the median PFS was significantly longer in the ZEJULA group than in the placebo group (21.9 months vs. 10.4 months; hazard ratio for disease progression or death, 0.43; 95% confidence interval [CI], 0.31 to 0.59; P<0.001). In the overall population, the corresponding progression-free survival was 13.8 months and 8.2 months (hazard ratio, 0.62; 95% CI, 0.50 to 0.76; P<0.001) (Table 1, Figure 5 and 6). At the 24-month interim analysis, the rate of overall survival was 84% in the ZEJULA group and 77% in the placebo group (hazard ratio, 0.70; 95% CI, 0.44 to 1.11).

The safety profile observed in the PRIMA study was consistent with the known safety profile of ZEJULA seen in previous clinical studies and other PARP inhibitors, including gastrointestinal and hematological events. In the safety population, for the ZEJULA versus placebo treatment arms, the incidences of CTCAE Grade ≥3 TEAEs (70.5% versus 18.9%), SAEs (32.2% versus 13.1%), TEAEs leading to treatment interruption (79.5% versus 18.0%), TEAEs leading to dose reduction (70.9% versus 8.2%), and of TEAEs leading to treatment

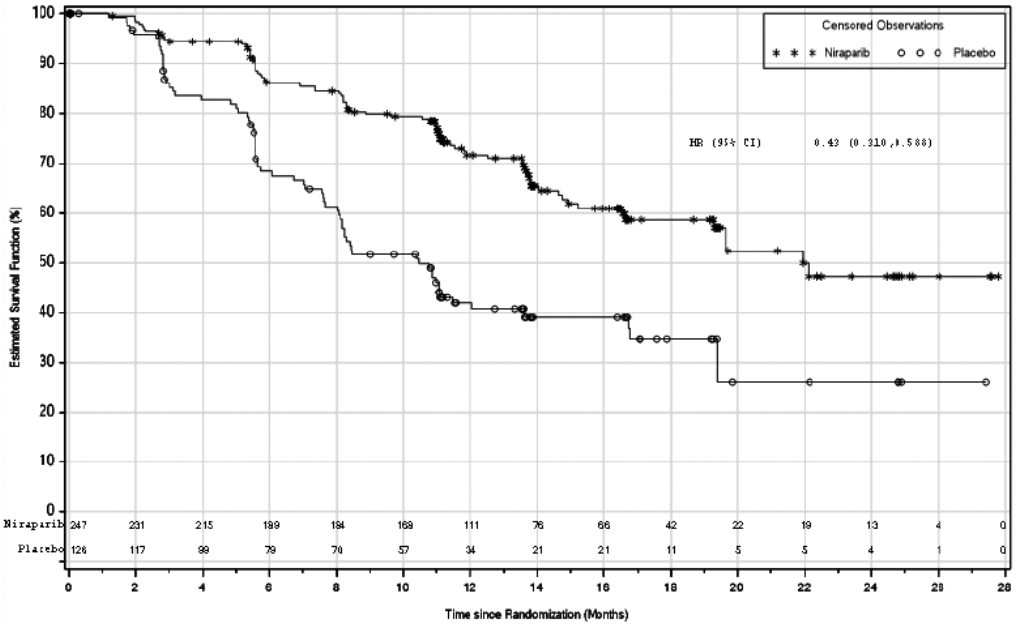
discontinuation (12.0% versus 2.5%) were higher for those receiving ZEJULA vs placebo. There were no on-treatment deaths reported during the study. The incidence of the most commonly reported events (overall and Grade ≥3) was higher for subjects who received a fixed starting dose of ZEJULA (300mg) compared with those who received an individualized starting dose based on baseline body weight and platelet count (300mg or 200mg).

Table 1: Primary efficacy endpoint of PFS based on blinded independent central review (BICR) (ITT Population)

	HRDpos		Overall	
Parameters	**ZEJULA (N=247)**	**placebo (N=126)**	**ZEJULA (N=487)**	**placebo (N=246)**
PFS (months)				
median (95%CI). .	21.9 (19.3, NE)	10.4 (8.1,12.1)	13.8 (11.5,14.9)	8.2 (7.3,8.5)
Survival distribution function (95% CI)				
6-month	0.86 (0.81,0.90)	0.68 (0.59,0.76)	0.73 (0.69,0.77)	0.60 (0.53,0.66)
12-month	0.72 (0.65,0.77)	0.42 (0.33,0.51)	0.53 (0.48,0.58)	0.35 (0.29,0.42)
18-month	0.59 (0.50,0.66)	0.35 (0.25,0.45)	0.42 (0.36,0.47)	0.28 (0.21,0.35)
24-month	0.47 (0.36,0.58)	0.26 (0.14,0.39)	0.32 (0.25,0.39)	0.23 (0.14,0.32)
30-month	0.47 (0.36,0.58)	0.26 (0.14,0.39)	0.32 (0.25,0.39)	0.23 (0.14,0.32)
P value.	<0.0001		<0.0001	
HR (95%CI) . . .	0.43 (0.310,0.588)		0.62 (0.502,0.755)	

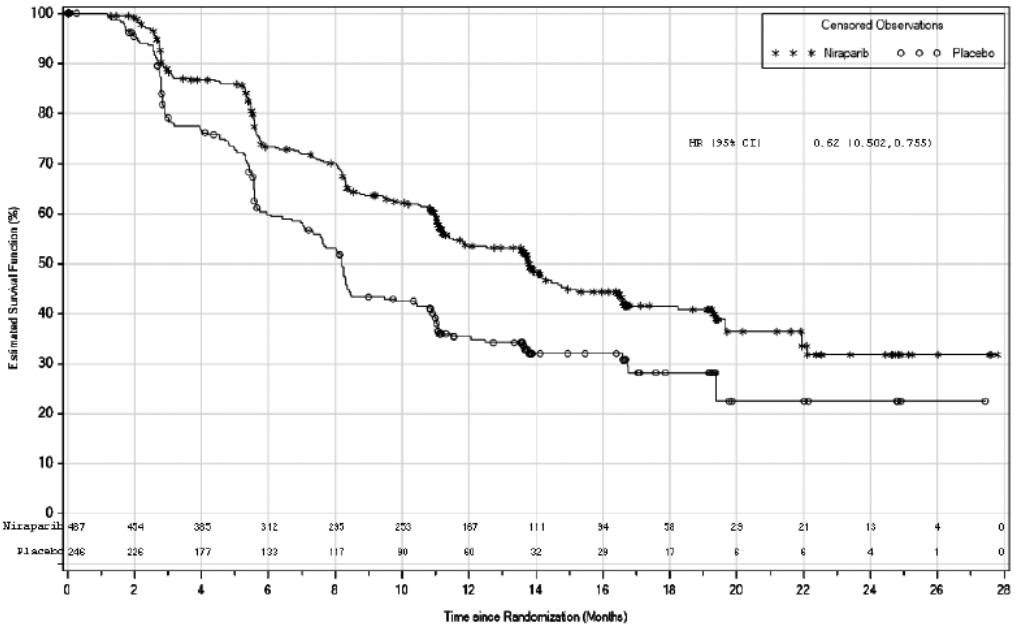
Source: GSK.

Figure 5: Kaplan-Meier plot of PFS by BICR assessment in subjects with HRD tumors (ITT Population)



Source: GSK.

Figure 6: Kaplan-Meier plot of PFS by BICR assessment in overall population (ITT Population)



Source: GSK.

Based on PRIMA results, sNDA application for ZEJULA for first-line maintenance treatment for women with platinum-responsive advanced ovarian cancer has been submitted to FDA. On April 29, 2020, the FDA approved ZEJULA for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

Licenses, Rights and Obligations

In September 2016, we entered into a collaboration, development and license agreement with Tesaro (now GSK) under which we obtained an exclusive sublicense under certain patents and know-how that Tesaro (now GSK) licensed from Merck Corp. and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize GSK's proprietary PARP inhibitor, ZEJULA, in China, Hong Kong and Macau, or licensed territory, in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). For more information, see "– Overview of Our License and Strategic Collaboration Agreements – GSK."

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ZEJULA IN OTHER CLINICALLY RELEVANT INDICATIONS SUCCESSFULLY.

Optune and Tumor Treating Fields

Optune (Tumor Treating Fields)

Optune (Tumor Treating Fields), one of our Core Products, is a portable battery or power supply operated device which act by delivering low intensity (1-3 V/cm), intermediate frequency (100-300 kHz), alternating Tumor Treating Fields to the patient's shaved head by means of electrically insulated surface transducer arrays. Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. Optune is approved by the FDA under the Premarket Approval ("PMA") pathway for the treatment of adult patients with newly diagnosed GBM in combination with TMZ, a chemotherapy drug, and for adult patients with GBM following confirmed recurrence after chemotherapy as monotherapy treatment. It also has approval or a CE certificate to market Optune for the treatment of GBM in the European Union, Japan and certain other countries.

In September 2018, we announced a global strategic development collaboration with Novocure, under which we obtained an exclusive license to develop and commercialize Optune (Tumor Treating Fields) in China, Hong Kong and Macau and will also support enrollment of Chinese patients to accelerate the development of Tumor Treating Fields in multiple solid tumor cancer indications. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements." In December 2018, within three months of signing the partnership deal with Novocure, we launched Optune in Hong Kong and treated its first patient with newly diagnosed GBM.

In May 2019, our partner Novocure received the U.S. FDA approval of a Humanitarian Use Device (HUD) for Optune Lua™ in combination with chemotherapy for the first-line treatment of adult patients with unresectable, locally advanced or metastatic malignant pleural mesothelioma (MPM), which is anticipated to be our next MAA filing with the NMPA. A device designated as a HUD is intended to benefit patients by treating or diagnosing a disease that affects, or is manifested in, not more than 8,000 individuals in the U.S. per year. The application submitted to the FDA for market approval of a HUD is an Humanitarian Device Exemption (HDE), that is similar in both form and content to a traditional premarket approval application (PMA) for non-HUD devices, in that the HDE applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement of demonstrating a reasonable assurance of effectiveness. The HDE pathway provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting smaller patient populations. Optune Lua™, the first treatment for MPM approved by the U.S. FDA since 2007, is a non-invasive, antimitotic cancer treatment that delivers Tumor Treating Fields within the torso.

In August 2019, the NMPA granted Innovative Medical Device Designation for Optune, which allowed us to take advantage of an expedited approval process for Optune that offered opportunities for pre-consultation with and input from the NMPA throughout the approval process. In May 2020, the NMPA approved the Marketing Authorization Application (MAA) for Optune without the need of a clinical trial in combination with TMZ for the treatment of patients with newly diagnosed GBM, and also as a monotherapy for the treatment of patients with recurrent GBM, which makes Optune the first treatment for glioblastoma approved in China since 2007. In August 2020, Optune Lua™ was launched for the treatment of MPM in Hong Kong. Since the date of issue of the relevant regulatory approvals and as of the Latest Practicable Date, no material unexpected or adverse changes had occurred.

Background of Tumor Treating Fields

Tumor Treating Fields were invented in 2000 by Professor Emeritus Yoram Palti of the Technion Institute of Technology in Israel, who founded Novocure (Israel) in 2000, conducted pre-clinical studies of Tumor Treating Fields, developed a medical device capable of delivering Tumor Treating Fields to patients, and finally brought Tumor Treating Fields into clinical use through clinical testing in patients with recurrent glioblastoma. Today, after more than 15 years of pre-clinical research, it is known that Tumor Treating Fields are an electric field based loco-regional, antimitotic treatment modality, which inhibits the growth of cancerous tumors *in vitro* and *in vivo*. As intermediate frequency (200 kHz) and low intensity (1-3 V/cm) alternating electric fields, Tumor Treating Fields act predominantly during two phases of mitosis: 1) during metaphase, by disrupting the formation of the mitotic spindle, and 2) during cytokinesis, by dielectrophoretic dislocation of intracellular constituents resulting in apoptosis. Tumor Treating Fields cannot stimulate nerves or muscles, nor do they lead to heating of the tumor or surrounding tissues. Since Tumor Treating Fields are generated using electrically insulated electrodes (transducer arrays), there is no direct current flow into the tissue so that electrolysis and tissue damage do not occur over time. Since most normal adult brain cells proliferate very slowly, if at all, they are minimally affected by the Tumor Treating Fields.

The efficacy of Tumor Treating Fields is frequency dependent on specific cell types. The anti-mitotic effect of Tumor Treating Fields has been shown in multiple cell lines when the appropriate frequency was utilized. This includes but not limited to the following tumor models: glioblastoma at 200 kHz, NSCLC at 150kHz; breast carcinoma at 120kHz; mouse melanoma at 100kHz.

Four Phase III trials of Tumor Treating Fields in a variety of solid tumors are ongoing. PANOVA-3 is Tumor Treating Fields combined with chemotherapy for newly-diagnosed pancreatic cancer. LUNAR is targeting advanced NSCLC with disease progression on or after prior platinum-based treatment, to evaluate Tumor Treating Fields combined with chemotherapy versus chemotherapy alone, METIS trial is intended for patients who have recently been diagnosed with brain metastases from NSCLC, and ENGOT-ov50/INNOVATE-3 trial is intended for patients who have recently been diagnosed with ovarian cancer that progressed and became resistant to chemotherapy containing platinum (platinum resistant ovarian cancer).

Market Opportunity and Competition

Novocure currently has global Phase III studies evaluating the safety and efficacy of Tumor Treating Fields in brain metastases, non-small cell lung cancer, or NSCLC, pancreatic cancer and ovarian cancer, which are large commercial opportunities in China.

Glioblastoma Multiforme (GBM)

GBM, a malignant form of astrocytoma, is the most common primary intracranial neoplasm. Incidence of GBM represents 46.6% of all brain cancer incidence in China, according to the Frost & Sullivan Report, and in 2019, GBM had 53.6 thousand incidences in China. GBM is treated mainly by surgery, radiotherapy combined with TMZ chemotherapy and other methods. However, as a primary malignant central nervous system tumor, despite numerous attempts to improve the outcome of patients with GBM, long-term survival remains poor. The global five-year survival rate of GBM patients is still at a mid-single digits, ranging from 5% to 6%, and in China, the rate is less than 5%, according to Frost & Sullivan. Optune (Tumor Treating Fields) was approved in 2020 in China as a new treatment for glioblastoma.

- Optune is indicated for the treatment of adult patients (22 years of age or older) with histologically-confirmed recurrence in the supra-tentorial region of GBM. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

- Optune with TMZ is indicated for the treatment of adult patients with newly diagnosed, supratentorial GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

As of July 2020, there are two main treatment choices in China – one is TMZ, a chemotherapy drug which was approved in 2007 (original version was approved in 2007, whereas the generic was approved in 2004); and the other one is Optune (Tumor Treating Fields) from Zai Lab, a novel cancer therapy that uses electric fields to inhibit tumor growth, which was approved in May 2020. Tumor Treating Fields was recommended with Level 1 evidence as a treatment for newly diagnosed GBM patients in the first Glioma Treatment Guideline (2018 Version) (腦膠質瘤診療規範(2018年版) published by the National Health Commission of China.

Optune has an "only-in-class" profile which more than doubles survival benefit in GBM patients. It is recommended in the national treatment guideline in the U.S. with category 1 recommendation for newly diagnosed GBM. In China, Optune is the first innovative treatment approved for GBM treatment since 2007.

Mesothelioma

The incidence of mesothelioma in China reached 3.1 thousand in 2019, with a CAGR of 2.7% from the year of 2015, according to Frost & Sullivan.

Gastric Cancer

For market opportunity and competition information with respect to gastric cancer, please see "– ZEJULA – Market Opportunity and Competition – Gastric Cancer."

Lung Cancer

For market opportunity and competition information with respect to lung cancer, please see "– ZEJULA – Market Opportunity and Competition – Lung Cancer."

Pancreatic Cancer

The incidence of pancreatic cancer in China has grown rapidly in recent years. From 2015 to 2019, the incidence of pancreatic cancer in China has increased from 95.0 thousand to 108.4 thousand, representing a CAGR of 3.3%. The incidence is estimated to reach 127.1 thousand by 2024, representing a CAGR of 3.2% from 2019 to 2024. By 2030, it is anticipated to reach 152.2 thousand.

The treatment of pancreatic cancer mainly includes surgical treatment, radiotherapy, chemotherapy, interventional therapy, ERCP related treatment and TCM treatment. Currently, the option of targeted therapies is quite limited. Several targeted therapies besides erlotinib have been assessed in combination with emcitabine, but none has been shown to significantly impact outcomes.

Ovarian Cancer

For market opportunity and competition information with respect to ovarian cancer, please see "– ZEJULA – Market Opportunity and Competition – Ovarian Cancer."

Liver Cancer

Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, accounting for approximately 90% of all liver cancer, and is the most common cause of death in people with cirrhosis. HCC incidence increased to 369.4 thousand in 2019 at a CAGR of 2.6% from 2015 to 2019, and is expected to reach 473.4 thousand in 2030, representing a CAGR of 2.2%. The 5-year survival rate of HCC in China is 12.1%, according to the Frost & Sullivan Report. Current treatment of HCC include surgery, localized treatments, hepatic artery chemoembolization, radiation therapy and drug therapy. Overall, chemotherapy remains the main drug treatment method for HCC in China. There is only a low level of usage of targeted therapy with agents such as sorafenib. There is, therefore, a large unmet medical need to

develop new treatments for advanced HCC treatment in China which presents better efficacy and tolerability for Chinese patients. This is especially relevant since chemotherapy drugs are generally less effective in HCC, compared to other cancers.

Summary of Clinical Trial Results

The following clinical trials were conducted by our business partner, Novocure.

Pivotal Study of Tumor Treating Fields for Recurrent GBM Subjects

In a prospective, randomized, open label, active parallel control trial (EF-11) was conducted to compare the effectiveness and safety. A total of 237 patients (120 Tumor Treating Fields; 117 best supportive care, BSC) with progressive or recurrent GBM were enrolled in the study. Baseline characteristics were similar between treatment groups. In the ITT population which included all randomized subjects, overall survival in subjects treated with Tumor Treating Fields was comparable to that observed in subjects treated with BSC (median OS=6.3 vs. 6.4 months; p=0.98). The pivotal study data establish that Tumor Treating Fields therapy is comparable to BSC therapy in extending OS.

The one-year survival is similar in the Tumor Treating Fields and BSC groups in the ITT population (21.9% vs. 22.1%). Progression free survival at 6 months (PFS6) is the same in the ITT population (21.4% vs. 15.2%). Radiological response rates from the subset of patients evaluated were reported as 14% for the Tumor Treating Fields group compared to 9.6% for the BSC group in the ITT population. Median time to progression, or TTP, was 9.3 weeks for Tumor Treating Fields vs. 9.6 weeks for BSC.

Tumor Treating Fields subjects experienced fewer adverse events in general, significantly fewer treatment related adverse events, and significantly lower gastrointestinal, hematological and infectious adverse events compared to BSC controls. The only device-related adverse event seen was a mild to moderate skin irritation beneath the device transducer arrays, which was easily treated with topical ointments. Finally, certain quality of life measures were better in Tumor Treating Fields subjects as a group when compared to subjects receiving effective BSC chemotherapy.

Pivotal Study of Tumor Treating Fields for Newly Diagnosed GBM

An international Phase III trial (EF-14) in newly diagnosed GBM, evaluating the role of Tumor Treating Fields in combination with TMZ maintenance after surgery and chemoradiation versus TMZ alone was conducted between July 2009 and September 2014 to evaluate efficacy and safety.

A total of 695 patients were randomized, the median number of maintenance TMZ cycles was 6 and 5 cycles, for Tumor Treating Fields/TMZ and TMZ alone, respectively. The median progression-free survival was 6.7 months for the patients treated with Tumor Treating Fields/TMZ versus 4.0 months for TMZ alone (HR 0.63;95% CI 0.52-0.76; p<0.001). Median

overall survival from randomization was 20.9 months versus 16 months for the Tumor Treating Fields/TMZ and TMZ alone, respectively, with a hazard ratio of 0.63 (95% CI 0.53-0.76), p<0.001. The most common adverse events in the Tumor Treating Fields/TMZ arm, defined as occurring in ≥10% of patients, were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression. Grade 3 to 4 adverse events were well balanced between the 2 treatment arms. None of the systemic grade 3 to 4 adverse events were considered related to Tumor Treating Fields by any of theinvestigators. Mild to moderate skin toxicity underneath the transducer arrays occurred in 52% of patients who received Tumor Treating Fields-TMZ vs no patients who received TMZ alone.

Based on the data, FDA expanded approval of Optune in combination with TMZ for the treatment of adult patients with newly diagnosed GBM.

Our Clinical Trial Designs and Strategy for Tumor Treating Fields in the China Market

In August 2019, the NMPA granted Innovative Medical Device Designation for Optune, which allowed us to take advantage of an expedited approval process for Optune that offered opportunities for pre-consultation with and input from the NMPA throughout the approval process. In May 2020, the NMPA approved the Marketing Authorization Application (MAA) for Optune without the need of a clinical trial in combination with TMZ for the treatment of patients with newly diagnosed GBM, and also as a monotherapy for the treatment of patients with recurrent GBM, which makes Optune the first treatment for glioblastoma approved in China since 2007. As recommended by the NMPA, we are currently collecting efficacy and safety data from GBM patients treated with Optune. We believe that the collection of data in Chinese patients will facilitate our registration certificate renewal for Optune in five years as well as market promotion.

In January 2020, we began patient enrollment for a Phase II pilot trial of Tumor Treating Fields in gastric cancer in Greater China. The First-Patient-In (FPI) occurred in January 2020 in Hong Kong and as of the Latest Practicable Date, four patients had been enrolled. The initiation of enrollment in China is expected by the end of 2020. The National Institutes for Food and Drug Control under the NMPA is currently conducting a technical testing on Tumor Treating Fields. We must pass the technical testing prior to the ethics committee approval and the initiation of patient enrollment in China. This trial is single arm, open-label, multi-center study designed to investigate the safety and efficacy of Tumor Treating Fields in combination with chemotherapy as the first-line treatment of unresectable gastric adenocarcinoma, or gastroesophageal junction adenocarcinoma. If the results of such ongoing Phase II pilot trials are positive, we contemplate to participate in the larger-in-scale pivotal or potentially registration-enabling trials that will be initiated by Novocure.

We are preparing to join global Phase III pivotal trials in non-small cell lung cancer, locally advanced pancreatic cancer and brain metastases in Greater China by early 2021.

We are in the planning phase for clinical trials in liver cancer and ovarian cancer in Greater China.

Licenses, Rights and Obligations

In September 2018, we entered into a license and collaboration agreement with Novocure. Under the terms of the agreement, Novocure exclusively licensed to us the rights to perform clinical studies, sublicensable to affiliates and third parties (subject to Novocure's consent), sell, offer for sale and import Tumor Treating Fields products in the field of oncology, each, a licensed product and collectively, the licensed products, in China, Hong Kong, Macau and Taiwan, or the territory. For more information, see "– Overview of Our License and Strategic Collaboration Agreements – Novocure."

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TUMOR TREATING FIELDS IN OTHER CLINICALLY RELEVANT INDICATIONS SUCCESSFULLY.

Our Oncology Pipeline

Ripretinib

Overview

Ripretinib is an investigational KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including GIST, systemic mastocytosis, or SM, and other cancers. Ripretinib was specifically designed to improve the treatment of GIST patients by inhibiting a broad spectrum of mutations in KIT and PDGFRα. Ripretinib is a KIT and PDGFRα inhibitor that blocks initiating and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST as well as the primary D816V exon 17 mutation involved in SM. Ripretinib also inhibits primary PDGFRα mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

We obtained an exclusive license to develop and commercialize ripretinib in China, Hong Kong, Macau and Taiwan in June 2019 from Deciphera. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Deciphera."

In December 2019, an NDA was submitted to the FDA for ripretinib in the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. The NDA submission is based on positive results from first Phase III study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies other than avapritinib in the U.S. which is approved for GIST patients with PDGFRα exon 18 mutations only (estimated approximately 6% of all patients with newly-diagnosed GIST). In August 2019, the top-line results from INVICTUS was published, including that the study achieved its primary endpoint of improved PFS compared to placebo as determined by blinded independent central radiologic review using modified RECIST. In

February 2020, the FDA accepted the NDA for ripretinib for the treatment of patients with fourth-line and fourth-line plus GIST, granted priority review and set an action date of August 13, 2020 under the PDUFA. On May 15, 2020, the FDA approved ripretinib for adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In July 2020, we received the CTA approval for the registrational bridging study of ripretinib in patients with second-line GIST. The NMPA accepted and granted priority review to our NDA for ripretinib for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib in July 2020 and August 2020, respectively. Ripretinib has been approved by Health Commission and Medical Products Administration of Hainan Province as the first Urgently Needed Drug that can be taken out from the Boao Pilot Zone by a designated patient, which is also known as the special Named Patient Program (NPP). Under the NPP, patients may apply for taking away a small amount of the legally imported drugs that is not yet registered domestically (neither inside or outside the Boao Pilot Zone) but is on urgent medical need from the Boao Pilot Zone following his therapeutic schedule. See "Regulatory Environment – PRC Regulations of Pharmaceutical Product Development and Approval – Import of Urgently Needed Drug in Boao Pilot Zone."

Mechanism of Action

KIT and PDGFRα are dual switch kinases, each containing i) an auxiliary inhibitory switch encoded by KIT exon 11 or PDGFRα exon 12 and ii) a main activation loop switch within the kinase domain encoded by KIT exons 17 and 18 or PDGFRα exons 18 and 19. This dual switch mechanism carefully regulates cellular kinase activity by controlling kinase conformation in either an "on" or "off" position. Oncogenic kinase mutations predominantly function by disrupting one or more regulatory switch mechanisms, leading to dysregulated switch function and loss of normal, physiologic conformational control. Ripretinib is a novel switch-control tyrosine kinase inhibitor (TKI) specifically designed to broadly inhibit KIT and PDGFRα kinase signaling through a dual mechanism of action that locks the kinase into an inactive conformation, resulting in inhibition of downstream signaling and cell proliferation.

Ripretinib precisely and durably binds to both the switch pocket region and the activation loop to lock the kinase in the inactive "off" state. Portions of ripretinib mimic the inhibitory loop and occupy the switch pocket, thereby preventing the activation loop's entry. Other residues on ripretinib bind to the activation loop, stabilizing it out of the switch pocket and covering the adenosine triphosphate (ATP) binding site, so kinase activation cannot occur.

This dual mechanism of action secures KIT and PDGFRα kinases in their inactive conformations providing broad *in vitro* inhibition of KIT and PDGFRα kinase activity, including wild type and multiple primary and secondary mutations. Ripretinib also inhibits other kinases *in vitro*, such as PDGFRβ, TIE2, VEGFR2, and BRAF.

The dual MoA of ripretinib provided broad-spectrum inhibition of KIT and PDGFRα kinase signaling *in vitro*, including multiple primary and secondary mutations and wild type GIST.

Market Opportunity and Competition

Gastrointestinal Stromal Tumor (GIST)

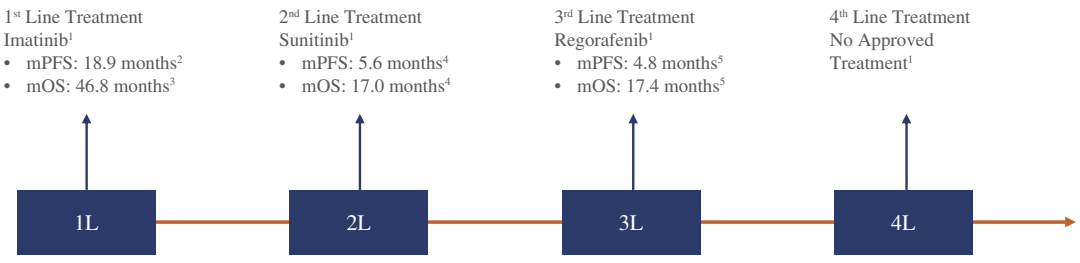
GIST are the most common sarcoma of the gastrointestinal tract and present most often in the stomach or small intestine. The typical patient is over 50 years old. Estimates for 5-year survival range from 48% to 90% depending upon the stage of the disease at diagnosis. GIST has 31.9 thousand incidences in China in 2019, according to the Frost & Sullivan Report.

GIST is a disease driven initially by primary mutations in KIT kinase in approximately 75% to 80% of cases or in PDGFRα kinase in approximately 5% to 10% of cases. In approximately 12% of all GIST patients, the disease is not driven by KIT or PDGFRα but by other genetic mutations or alterations.

Metastatic KIT-driven GIST is a disease characterized by many mutations in KIT, with over 90% of individual KIT-driven GIST patients harboring multiple mutations that drive progression of their disease. Multiple secondary mutations can arise within an individual patient and/or tumor in different areas or sites of tumor growth.

The complex heterogeneity of KIT mutations within individual tumors and individual patients is a major cause of resistance to existing therapies, which individually only address a subset of the mutations driving disease progression. A kinase inhibitor that could inhibit a broad spectrum of clinically relevant KIT mutations could be of high therapeutic value in the treatment of KIT-driven GIST in patients who are unresponsive to treatment or have grown resistant to treatment. In PDGFRα-driven GIST, there are no approved therapies other than avapritinib. The primary PDGFRα mutations are mostly insensitive to imatinib and other drugs approved for GIST. The design of ripretinib as a PDGFRα switch control inhibitor may make the appearance of secondary mutations less likely after treatment than with a traditional kinase inhibitor.

The following table shows reported PFS or TTP (as applicable), ORR, overall survival, all as per RECIST, for imatinib, sunitinib, and regorafenib in first-line, second-line, and third-line GIST, respectively, based upon the published results of registrational trials that were presented to the FDA for approval of these drugs. This treatment paradigm is also applicable in China.



Notes: mPFS=median progression free survival; mOS=median overall survival.

1. As of January 9, 2020, avapritinib is approved in the U.S. for GIST patients with PDGFRα exon 18 mutations only, which mutations are harbored by an estimated ~6% of patients with newly diagnosed GIST;

2. Gleevec. Stein, Switzerland: Novartis; 2008;

3. Casali PG, et al. *J Clin Oncol.* 2017;35:1713-1720;

4. Sutent. New York, NY: Pfizer; 2011, mPFS and mOS converted from weeks to months;

5. Stivarga. Germany: Bayer Healthcare; 2013.

While imatinib, sunitinib, and regorafenib inhibit certain clinically relevant initiating and drug resistance-causing mutations in KIT, these approved drugs, in addition to avapritinib, each inhibit only a limited subset of KIT and PDGFRα mutations known to occur in GIST patients. Although GIST patients may experience periods of disease control with these treatments, due to the heterogeneous nature of the mutations that drive the disease, many patients continue to progress and ultimately fail all lines of treatment.

According to Frost & Sullivan, only three TKI therapies have been approved for treating GIST currently, namely Glivec (imatinib) from Novartis, Sutent (sunitinib) from Pfizer and Stivarga (regorafenib) from Bayer, and a vast majority of advanced and metastatic GIST patients will eventually relapse after first-line and subsequent lines of treatment. This creates a significant opportunity for new drugs that can help overcome the problem of patient lack of responsiveness or who have developed resistance to existing treatments.

Summary of Clinical Trial Results

INVICTUS: Completed Phase III Study in Fourth-Line and Fourth-Line Plus GIST

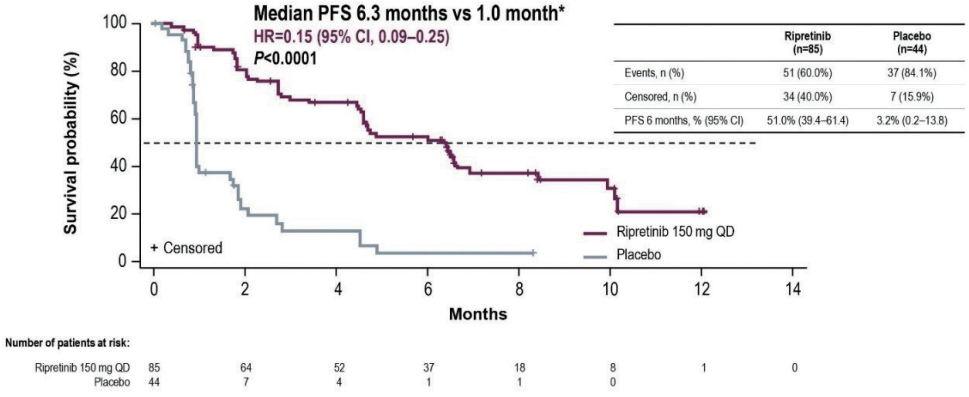
The INVICTUS Phase III study was a randomized, double-blind, placebo-controlled, global, multicenter trial conducted by Deciphera to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The trial enrolled 129 patients who had a confirmed diagnosis of GIST and had previously received at least three different kinase inhibitors including imatinib, sunitinib, and regorafenib. Patients were treated with ripretinib or placebo, in accordance with their randomization, until they developed disease progression, experienced unacceptable toxicity, or withdrew consent. Placebo patients had the opportunity to cross over to ripretinib treatment upon disease progression with placebo. Patients on ripretinib had the opportunity to remain on their current dose or escalate to 150 mg twice daily (BID) upon disease progression.

Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily (QD) in repeated 28-day cycles with best supportive care. Patients were evaluated for PFS based upon independent radiologic review of CT scans, as assessed by modified RECIST. Tumor response assessments per modified RECIST were conducted every cycle for the first three cycles and then every two cycles thereafter beginning with the fourth cycle. The primary efficacy endpoint was PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST included ORR, overall survival (OS), and TTP.

In 2019, the top-line results from INVICTUS is published, including that the study achieved its primary endpoint of improved PFS compared to placebo.

In the INVICTUS study, ripretinib demonstrated a median PFS of 6.3 months (27.6 weeks) compared to 1.0 month (4.1 weeks) in the placebo arm and significantly reduced the risk of disease progression or death by 85% (Hazard Ratio (HR) of 0.15, 95% Confidence Interval (0.09,0.25), p-value <0.0001) compared to placebo. This PFS benefit was consistent across all assessed patient subgroups. The following graph shows the estimated PFS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated PFS Probability for Ripretinib and Placebo Arms



	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	51 (60.0%)	37 (84.1%)
Censored, n (%)	34 (40.0%)	7 (15.9%)
PFS 6 months, % (95% CI)	51.0% (39.4–61.4)	3.2% (0.2–13.8)

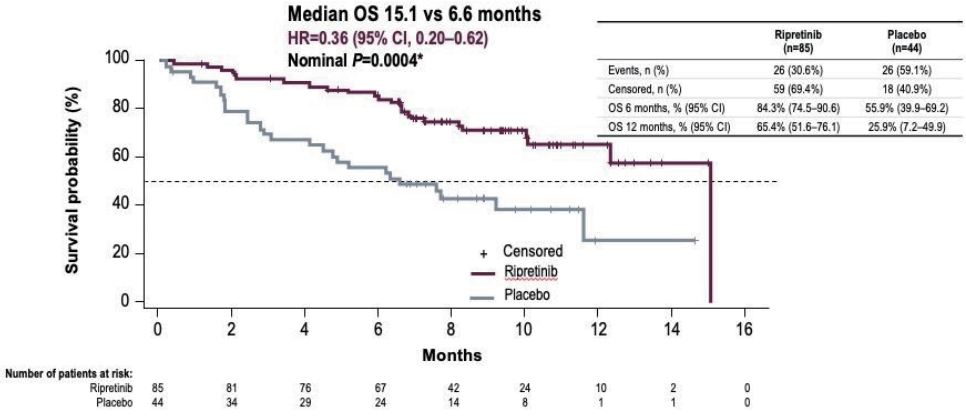
** Double-blind period*

Source: Deciphera

For the key secondary endpoint of ORR as determined by blinded independent radiologic review using modified RECIST, ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p-value=0.0504), which was not statistically significant. As of the cutoff date of May 31, 2019, the median duration of response had not been reached with seven of the eight patients still responding to treatment. All responders had partial responses.

Ripretinib also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint of OS (median OS 15.1 months with ripretinib compared to 6.6 months with placebo, HR = 0.36, 95% Confidence Interval (0.20, 0.62), nominal p-value=0.0004). The OS data for the placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment. The following graph shows the estimated OS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated OS Probability for Ripretinib and Placebo Arms



	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	26 (30.6%)	26 (59.1%)
Censored, n (%)	59 (69.4%)	18 (40.9%)
OS 6 months, % (95% CI)	84.3% (74.5–90.6)	55.9% (39.9–69.2)
OS 12 months, % (95% CI)	65.4% (51.6–76.1)	25.9% (7.2–49.9)

* Due to hierarchical testing procedures of the endpoints, the OS endpoint could not be formally tested because the ORR was not statistically significant.Data includes all time periods, including dose escalations. Placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment.

Source: Deciphera

Ripretinib was generally well tolerated and the adverse events reported in the INVICTUS study were consistent with data from previously presented Phase I study results. Grade 3 or 4 treatment-emergent adverse events (TEAEs) occurred in 42 patients (49%) on the ripretinib arm compared to 19 patients (44%) on the placebo arm. Grade 3 or 4 TEAEs in greater than 5% of patients in the ripretinib arm were anemia (9%; n=8), abdominal pain (7%; n=6), and hypertension (7%; n=6). Grade 3 or 4 TEAEs in greater than 5% of patients in the placebo arm were anemia (14%; n=6).

The below table lists all TEAEs (and corresponding grade 3 and 4 TEAEs) in greater than 10% of patients in the ripretinib arm compared to the placebo arm in INVICTUS.

INVICTUS: TEAEs in >10% of Patients (and Corresponding Grade 3 and 4 TEAEs)

Treatment Emergent Adverse Event	Ripretinib any grade (n=85)	Ripretinib grade 3 and 4 (n=85))1	Placebo any grade (n=43))2	Placebo grade 3 and 4 (n=43))1,2
Any TEAE or grade 3/4 TEAE	**84 (98.8%)**	**42 (49.4%)**	**42 (97.7%)**	**19 (44.2%)**
Alopecia	44 (51.8%)	0	2 (4.7%)	0
Fatigue	36 (42.4%)	3 (3.5%)	10 (23.3%)	1 (2.3%)
Nausea	33 (38.8%)	3 (3.5%)	5 (11.6%)	0
Abdominal pain	31 (36.5%)	6 (7.1%)	13 (30.2%)	2 (4.7%)
Constipation	29 (34.1%)	1 (1.2%)	8 (18.6%)	0
Myalgia	27 (31.8%)	1 (1.2%)	5 (11.6%)	0
Diarrhea	24 (28.2%)	1 (1.2%)	6 (14%)	1 (2.3%)
Decreased appetite	23 (27.1%)	1 (1.2%)	9 (20.9%)	1 (2.3%)
Palmar-plantar erythrodysesthesia syndrome	18 (21.2%)	0	0	0
Vomiting	18 (21.2%)	3 (3.5%)	3 (7%)	0
Headache	16 (18.8%)	0	2 (4.7%)	0
Weight decreased	16 (18.8%)	0	5 (11.6%)	0
Arthralgia	15 (17.6%)	0	2 (4.7%)	0
Blood bilirubin increased	14 (16.5%)	1 (1.2%)	0	0
Edema peripheral	14 (16.5%)	1 (1.2%)	3 (7%)	0
Muscle spasms	13 (15.3%)	0	2 (4.7%)	0
Anemia	12 (14.1%)	8 (9.4%)	8 (18.6%)	6 (14%)
Hypertension	12 (14.1%)	6 (7.1%)	2 (4.7%)	0
Asthenia	11 (12.9%)	1 (1.2%)	6 (14%)	2 (4.7%)
Dry skin	11 (12.9%)	0	3 (7%)	0
Dyspnea	11 (12.9%)	0	0	0
Hypophosphatemia	9 (10.6%)	4 (4.7%)	0	0
Lipase increased	9 (10.6%)	4 (4.7%)	0	0
Pruritus	9 (10.6%)	0	2 (4.7%)	0
Stomatitis	9 (10.6%)	0	0	0

Notes:

1 Corresponding grade 3 and 4 TEAEs to TEAEs in >10% of patients receiving ripretinib

2 44 patients were randomized to placebo, but 1 did not receive treatment

3 Regardless of causality

Source: Deciphera

TEAEs leading to dose reduction occurred in 7% of patients on the ripretinib arm compared to 2% on the placebo arm. TEAEs leading to dose interruption occurred in 24% of patients on the ripretinib arm compared to 21% on the placebo arm. TEAEs leading to study treatment discontinuation occurred in 8% of patients on the ripretinib arm compared to 12% of patients on the placebo arm. TEAEs leading to death occurred in 6% of patients on the ripretinib arm compared to 23% on the placebo arm.

INTRIGUE: Ongoing Phase III Study in Second-Line GIST

The INTRIGUE Phase III study is an interventional, randomized, global, multicenter, open-label study conducted by Deciphera to evaluate the safety, tolerability, and efficacy of ripretinib compared to sunitinib in approximately 358 patients with GIST previously treated with imatinib. Patients are randomized 1:1 to either 150 mg of ripretinib once daily or 50 mg of sunitinib once daily for four weeks followed by two weeks without sunitinib. The primary efficacy endpoint is PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST include ORR and OS.

Our Clinical Trial Designs and Strategy for Ripretinib in the China Market

We will seek regulatory approval for ripretinib in China using data from global studies and China bridging studies. In November 2019, we received the NMPA approval to conduct the bridging study in fourth-line GIST. In July 2020, we received the CTA approval for the registrational bridging study of ripretinib in patients with second-line GIST. The NMPA accepted and granted priority review to our NDA for ripretinib for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib in July 2020 and August 2020, respectively.

We are in the planning phase for clinical trials in systemic mastocytosis in China.

Odronextamab

Overview

Odronextamab is an investigational bispecific monoclonal antibody that is designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20). Odronextamab is currently being evaluated as a treatment for late stages of follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) and other lymphomas in a Phase I trial as well as a potentially registrational Phase II trial odronextamab was granted orphan drug designation by the FDA for the treatment of FL and DLBCL and was invented by Regeneron using the company's proprietary *VelocImmune*® technology and proprietary *Veloci-Bi*® bispecific platform. *Veloci-Bi*® allows for the generation of full-length bispecific antibodies similar to native antibodies that are amenable to production by standard antibody manufacturing techniques, and likely to have favorable antibody-like pharmaco-kinetic properties.

Odronextamab has demonstrated clinical activity in heavily pre-treated patients with Relapsed/Refractory (R/R) B-NHL in a Phase I trial and is currently being investigated in a potentially registrational Phase II program.

In April 2020, we entered into a strategic collaboration with Regeneron for the development and exclusive commercialization of odronextamab in oncology in mainland China, Hong Kong, Taiwan and Macau. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Regeneron."

Mechanism of Action

Bispecific antibodies are an emerging class of therapeutic molecules which have been engineered to engage more than one target. When targeted to CD3, a component of the T-cell receptor (TCR), and a tumor target antigen, these molecules can direct cytotoxic effector T-cells to kill tumor cells in an antigen-specific manner that is independent of the specificity of the TCR. In the case of odronextamab, that binds to CD3 and CD20 (a B-cell surface antigen present on normal B cells and several B-cell lineage malignancies), this binding directs T-cells to specifically kill CD20 expressing target cells.

Market Opportunity and Competition

Non-Hodgkin lymphomas (NHL) is the most common hematological malignancy in the world. It comprises a heterogeneous group of malignancies with lymphoid characteristics that arise from hematopoietic progenitor cells. In China, there were an estimated 90,300 new cases and 52,900 deaths due to NHL in 2019.

Among the heterogeneous group of NHLs, 85% are of B-cell origin (B-NHL), which includes FL, DLBCL, mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), and several other subtypes of B-NHLs. DLBCL and MZL are the two most common subtypes of B-NHL, accounting for approximately 41.0% and 8.0% of NHL in China. Anti-CD20 antibodies in combination with chemotherapy (or R-CHOP) are the standard of care for the treatment of B-NHLs; however, despite initial responses, about 50% of NHL patients will eventually experience disease progression due to drug resistance, indicating a need for new treatment options. In particular, around 15% of DLBCL (the most common subtype of NHL) patients are characterized as primary refractory towards first-line R-CHOP therapy. For these refractory patients, treatments options with new modalities are highly necessary. According to the Frost & Sullivan Report, there are currently no marketed bispecific antibody drugs for hematological malignancy in China as of July 2020.

Preclinical and Clinical Development

Pre-clinical Pharmacology

In vitro assays were performed to examine the ability of odronextamab to bind to target cells and to activate T-cells to specifically kill CD20-expressing target cells. Odronextamab was shown to bind to both Raji cells, a CD20+ B-cell lymphoma line, and Jurkat cells, an immortalized CD3+ T-cell line, as well as to primary human B and T-cells. In cellular cytotoxicity assays, odronextamab was able to engage T-cells to kill CD20-expressing cells in a target dependent manner. In these cytotoxicity assays, odronextamab also induced the expression of T-cell activation markers, T-cell proliferation, and cytokine release.

In vivo experiments utilizing murine tumor models were performed to evaluate the anti-tumor efficacy of odronextamab. In a model where Raji (B) lymphoma cells were grown in mice and human PBMC were added as effector cells, odronextamab treatment resulted in significant tumor growth suppression.

Nonclinical pharmacokinetics

The PK profile of odronextamab was evaluated in cynomolgus monkeys during a single-dose PK study. In general, the PK of total odronextamab in the monkey is described by non-linear, target-mediated elimination. Following a single IV infusion, mean total odronextamab serum maximum concentration (Cmax) values in monkeys increased in an approximately dose-proportional manner. The concentration-time profile of total odronextamab was characterized by a short distribution phase, followed by a saturating beta elimination phase at higher doses and an accelerated target mediated elimination phase at low doses (and corresponding low serum concentrations). Target mediated elimination (presumably due to binding of odronextamab to the CD20 target on B cells) was observed in the distribution phase and correlated with the nearly complete depletion of B cells observed 24 hours post infusion. The duration of peripheral B cell depletion increased with the odronextamab dose and in general, the rate of B cell repletion was positively correlated with the rate of clearance of total odronextamab.

Nonclinical Toxicology

The toxicity profile of odronextamab was evaluated in an exploratory, non-GLP, single-dose intravenous (IV) infusion toxicology study (dose level 1mg/kg) and a 4-week repeat dose GLP-toxicology study (dose levels 0.01, 0.1, and 1 mg/kg). The no-observed-adverse-effect-level (NOAEL) for each of the toxicology studies conducted is considered to be 1.0 mg/kg, the highest dosage administered. Odronextamab resulted in B cell depletion at all doses tested, with earlier recovery at the lower doses. This depletion extended into deep tissues including lymph nodes and spleen. A transient release of cytokines was observed whose magnitude correlated with the strength of the dose, and at the highest dose several animals also displayed some vomiting with the first dose. Neither cytokine release nor symptoms occurred upon second or subsequent dosing. An ex vivo tissue cross-reactivity study also was conducted

to assess the binding specificity of odronextamab in a panel of human and cynomolgus monkey tissues. All staining in this study was consistent with expected reactivity with the target antigens, and no unanticipated cross-reactivity of odronextamab was observed.

Clinical Background

In an ongoing Phase I study (NCT02290951) of odronextamab in patients with B-cell malignancies, a total of 110 patients (61 with DLBCL; 31 with grade 1 to 3a FL; 9 with MCL; 6 with MZL; and 3 with other B-cell malignancies) were treated with odronextamab ranging from 0.03-320 mg as of 3rd September 2019. Patients had a median of 3 prior lines of therapy (range 1-11).

Among the 22 patients with R/R FL who were treated with ≥5 mg of odronextamab, the overall response rate (ORR) was 95.5% and the complete response (CR) rate was 77.3%. Patients with R/R FL who were treated with ≥80 mg of odronextamab had an ORR of 100%. The median progression-free survival for R/R FL patients treated with ≥5mg of odronextamab was 11.4 months (95% CI, 6.7-not evaluable). In the DLBCL cohort, the objective response rate (ORR) was 57.9% (11/19), and the CR rate was 42.1% (8/19) with treatment at ≥80 mg of odronextamab. At this dosage, the ORR was 71.4% in those patients not treated with prior chimeric antigen receptor (CAR) T-cell therapy (n = 7), which included all CRs. In those who received prior CAR T-cell therapy, the ORR and CR rate were 50% and 25%, respectively. The response rate was higher in patients who had not previously received CAR T-cell therapy (Figure 7). Survival rates and ongoing response rates are shown in Figure 8 by diagnosis, dose of odronextamab, and prior CAR T therapy.

Figure 7. Efficacy results by diagnosis and dose of odronextamab

Diagnosis	**FL, n (%)**	**DLBCL, n (%)**	**DLBCL with prior CAR T therapy, n (%)**	**DLBCL without prior CAR T therapy, n (%)**
Dose of odronextamab	≥5mg	≥80mg	≥80mg	≥80mg
N	22	19	12	7
ORR	21 (95.5)	11 (57.9)	6 (50.0)	5 (71.4)
CR	17 (77.3)	8 (42.1)	3 (25.0)	5 (71.4)
PR	4 (18.2)	3 (15.8)	3 (25.0)	0
SD	1 (4.5)	2 (10.5)	1 (8.3)	1 (14.3)
PD	0	3 (15.8)	2 (16.7)	1 (14.3)
Not available	0	3 (15.8)	3 (25.0)	0

Source: Regeneron

CAR, chimeric antigen receptor; CR, complete response; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease

Figure 8. Median survival and responses by diagnosis, prior CAR T therapy and odronextamab dosing

	Patients with FL	**DLBCL with prior CAR T therapy**	**DLBCL without prior CAR T therapy**
Dose of odronextamab	≥5mg	≥80mg	≥80mg
N	22	12	7
Median PFS, months (95% CI)	11.4 (6.7 – not evaluable)	NR	NR
Median duration of follow-up, months (range)	6.8 (1.0-22.1)	2.6 (0.4-9.9)	5.3 (1.2-11.8)
Number of patients with ongoing response at last assessment	14/21	4/6	5/5
Number of patients with ongoing CRs at last tumor assessment	12/17	3/3	5/5

Source: Regeneron

CAR, chimeric antigen receptor; CR, complete response; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; NR, not reported; PFS, progression-free survival

No dose limiting toxicities (DLTs) were observed during dose escalation. The most common treatment-emergent adverse events (TEAEs) of any grade were pyrexia (80%) and cytokine release syndrome (CRS, 59.1%). Grade 3-4 TEAEs that occurred in 10% or more of patients are anemia (21.8%), hypophosphatemia (19.1%), neutropenia (19.1%), lymphopenia (19.1%), thrombocytopenia (13.6%), and leukopenia (10.0%). CRS grade ≥3 occurred in 6.4% of patients and no seizures or grade 4-5 neurologic events were observed.

Preliminary data from the Phase I study showed broad antitumor activity with odronextamab in heavily pretreated R/R B-NHL patients, including some with progression after prior chimeric antigen receptor T (CAR T)-cell therapy. Odronextamab has been tolerated at doses up to 320 mg weekly, with no observed dose limiting toxicities.

Odronextamab is currently evaluated in a potentially pivotal Phase II program. This open-label, multi-center, Phase II program (NCT03888105) is evaluating the efficacy and safety of odronextamab in different disease-specific cohorts, including patients with R/R FL, DLBCL, MCL, MZL and other B-NHL subtypes. Recruitment of this study is ongoing.

Our Clinical Trial Designs and Strategy for Odronextamab in the China Market

We are exploring regulatory approval pathways for odronextamab in R/R B-NHL in China by joining the global Phase II program with multiple, potentially registrational cohorts of different subtypes of R/R B-NHL. We have submitted Phase II pivotal CTA to the NMPA and plan to enroll the first Chinese patient into the potentially registrational global Phase II study by early 2021.

Repotrectinib

Overview

Repotrectinib is an investigational next-generation tyrosine kinase inhibitor (TKI) designed to effectively target ROS1 and TRK A/B/C with potential to treat TKI-naïve or-pretreated cancer patients. Repotrectinib is currently being evaluated in an ongoing Phase I/II trial called TRIDENT-1 for the treatment of patients with *ROS1*+ advanced NSCLC and patients with *NTRK*+ advanced solid tumors.

Turning Point Therapeutics ("Turning Point") initiated the multi-cohort Phase II registrational portion of TRIDENT-1 in June 2019 and plans to conduct the Phase II portion of the trial in approximately 120 sites in North America, Europe and Asia-Pacific regions, and to enroll a total of approximately 320 patients. The Phase II portion of TRIDENT-1 is a registrational trial for potential approval in *ROS1*+ advanced NSCLC and *NTRK*+ advanced solid tumors. The FDA has granted orphan drug designations for the development of repotrectinib in NSCLC with adenocarcinoma histology and fast track designations for the treatment of *ROS1*+ advanced NSCLC patients who have been previously treated with one prior line of platinum-based chemotherapy and one prior line of a ROS1 TKI, and for the treatment of *ROS1*+ advanced NSCLC patients who have not been previously treated with a ROS1 TKI.

We obtained an exclusive license from Turning Point to develop and commercialize repotrectinib in China, Hong Kong, Macau and Taiwan in July 2020. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Turning Point."

Mechanism of Action

Repotrectinib is a small (low molecular weight), macrocyclic TKI of ROS1, TRK, and ALK. Repotrectinib was designed to efficiently bind with the active kinase conformation and avoid steric interference from a variety of clinically resistant mutations, especially the solvent front and gatekeeper mutations of the ROS1 and TRK kinases. Repotrectinib has a rigid, three-dimensional structure and is smaller than currently approved or investigational ROS1, TRK and ALK inhibitors. The rigid, three-dimensional structure enables repotrectinib to precisely and efficiently bind to its oncogenic targets with a desirable selectivity profile.

Turning Point has screened repotrectinib against approximately 400 kinases which indicated repotrectinib is a selective multi-targeted kinase inhibitor that is highly potent against ROS1, TRK, and ALK, and inhibits JAK2, SRC and FAK.

The selectivity index (SI) is defined as the kinase IC50 value divided by the lowest IC50 value (0.071 nM) from the inhibition against the ROS1 kinase. SI for ROS1 is 1, followed by kinases with 1< SI <10 (TRKA, TRKB and TRKC), 10< SI <20 (ALK, JAK2, and SRC family member FYN), and 20< SI <250 (SRC family members LYN, YES1, FGR and SRC; TXK, ARK5, DDR1 and FAK). Based on the selectivity profile, Turning Point believes repotrectinib will be able to target ROS1 and TRK family members with high potency, and target JAK2, some SRC family members and FAK with moderate potency. According to a 2015 review article, selective multi-targeted kinase inhibitors with a favorable safety profile may be more suitable for cancer treatment, which Turning Point believes is due to their activity against redundant signaling pathways mediated by different kinases. Repotrectinib inhibits JAK2, SRC and FAK leading to the modulation of STAT3 signaling, one of the major signaling pathways that is common for both intrinsic and acquired resistance. Turning Point believes the inhibition of JAK2, SRC and FAK may lead to a longer duration of response for patients treated with repotrectinib.

Market Opportunity and Competition

For market opportunity and competition information with respect to lung cancer, please see "– ZEJULA – Market Opportunity and Competition – Lung Cancer."

Specifically in relation to repotrectinib, ROS1 rearrangement is estimated to be an oncogenic driver in approximately 3 percent of patients with advanced NSCLC in China, while NTRK is estimated to be an oncogenic driver in approximately 0.5-1 percent of patients with wide range of solid tumors in China, according to the Frost & Sullivan Report. As of July 2020, there were three ROS1/NTRK/ALK targeted drugs marketed in China, of which there is only one approved targeted therapy for patients with advanced ROS1-positive lung cancer and despite its efficacy, most patients eventually acquire resistance. The unmet need in the ROS1-positive lung cancer patient population is significant. The preliminary clinical activity and safety data generated to date for repotrectinib represent a promising clinical profile.

Clinical Development by Turning Point

In the Phase I portion of TRIDENT-1, as of the July 22, 2019 data cut-off, a total of 93 patients had been dosed, 23 patients were still on treatment, and the MTD had not been reached. Of the 93 patients, 40 of 52 with *ROS1*+ advanced NSCLC and five of 10 with *NTRK*+ advanced solid tumors were evaluable by blinded independent central review (BICR). All patients received at least one dose of repotrectinib across nine dose cohorts ranging from 40 mg QD to 200 mg BID.

Utilizing the July 22, 2019 data cut-off, with a median follow-up of 20.1 months (range: 5.3 to 24.9+), repotrectinib demonstrated a confirmed overall response rate (ORR) by BICR of 91 percent (N=11, 95% CI: 59-100) in patients with *ROS1*+ advanced NSCLC who are ROS1 TKI-naïve and repotrectinib demonstrated a median duration of response (DOR) of 23.1 months (95% CI: 5.6-NR) (based on Kaplan-Meier estimation). The probability of patients with a DOR $\geq$ 9 months, $\geq$ 12 months and $\geq$ 18 months was 78%, 65%, and 65%, respectively. Also, repotrectinib showed a median progression-free survival (PFS) of 24.6 months (95% CI: 7.2-NR). With an additional 8.5 months of follow-up as of April 6, 2020, 4 of the 5 responding patients remained in a PR (partial response) per physician assessment data since the July 22, 2019 data cutoff and the duration of treatment ranged from 9.2 to 34.2+ months with 7 of the total 11 (64%) patients remaining on repotrectinib. All 7 (64%) remained on treatment for more than 17 months, 6 (55%) on treatment for more than 24 months, and 3 (27%) on treatment for more than 30 months at the time of the analysis. Repotrectinib has demonstrated CNS activity among patients with *ROS1*+ advanced NSCLC who are ROS1 TKI-naïve, with an intracranial objective response rate (IC-ORR) of 100% (3 of 3 patients, 95% CI: 29-100) with durations of response, as of the July 22, 2019 data cut-off, of 14.8+, 17.6+ and 23.1 months. All three of these patients remained on treatment, as of April 6, 2020, for 26.0+, 28.5+ and 34.2+ months.

In the *ROS1*+ advanced NSCLC patients who had received one prior TKI, the confirmed ORR by BICR was 39 percent (N=18, 95% CI: 17-64). Repotrectinib has demonstrated CNS activity among patients with *ROS1*+ advanced NSCLC who have received one prior TKI, with an intracranial objective response rate (IC-ORR) of 75% (N=4, 95% CI: 19-99). As of April 6, 2020, 6 of 29 (21%) TKI pre-treated *ROS1*+ advanced NSCLC patients remained on repotrectinib. All 6 patients remained on treatment for more than 12 months, 2 on treatment for more than 24 months and 1 patient on treatment for more than 30 months.

Turning Point anticipates reporting preliminary physician assessed safety and efficacy data from approximately 30 to 40 patients across multiple Phase II cohorts of TRIDENT-1, including both registrational and exploratory cohorts, in the third quarter of 2020. Turning Point also commenced a Phase I/II study of repotrectinib in pediatric and young adult patients with ALK+, *ROS1*+ or TRK+ advanced solid tumors in November 2019.

Turning Point is currently evaluating potential combination regimens for repotrectinib based on preclinical data Turning Point presented at the 2020 AACR virtual Annual Meeting in late June. In preclinical models, repotrectinib synergized with a proxy molecule for the KRAS G12C inhibitor AMG510 and inhibited KRAS G12C tumor cell proliferation, increased apoptosis, and reduced KRAS G12C tumor cell cytokine release. Repotrectinib also enhanced the efficacy of AMG510 in KRAS G12C xenograft models. Turning Point's preclinical studies also showed that repotrectinib, in combination with the MEK inhibitor trametinib, was synergistic in KRAS mutant NSCLC, colorectal cancer, and pancreatic cancer tumor cell lines and enhanced efficacy in mutant KRAS xenograft models *in vivo*, highlighting the potential for repotrectinib to enhance the effectiveness of MEK inhibitors targeting KRAS mutant cancer when used in combination.

Our Clinical Trial Designs and Strategy for Repotrectinib in the China Market

We have submitted Phase II registrational CTA and anticipate opening additional sites for the TRIDENT-1 Phase II registrational clinical study of repotrectinib in China.

Margetuximab

Overview

Margetuximab is a human/mouse chimeric IgG1 anti-HER2 antibody with an optimized Fc domain designed to outperform trastuzumab whose mechanism of action involves not only the inhibition of the signal transduction pathway from HER2, but also the antibody-dependent cytotoxicity (ADCC) mediated by the binding of the Fc domain of the antibody with CD16A (Fcg receptor IIIA or FcgRIIIA) expressed on the surface of the natural killer (NK) cells andmacrophages. Both 158V and 131H variants bind the Fc of IgG1 with higher affinity than their respective allelic counterparts. With optimized Fc domain, margetuximab binds different CD16 variants with similar affinity, leading to stronger ADCC than trastuzumab. A Phase III trial known as SOPHIA compared margetuximab in combination with chemotherapy with trastuzumab in combination with chemotherapy in HER2+ breast cancer after 2 or more lines of treatment with other HER2-targeting agents including trastuzumab and pertuzumab. The study reported positive outcome indicating that margetuximab is superior to trastuzumab in a heavily pretreated HER2+ metastatic breast cancer. Additional clinical trials are being planned to evaluate margetuximab in HER2+ breast and gastric cancer.

We obtained an exclusive license to develop and commercialize margetuximab in China, Hong Kong, Macau and Taiwan from MacroGenics in November 2018. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – MacroGenics."

Mechanism of Action

HER2 oncoprotein drive the aggressive behavior of HER2+ breast and other cancer and it proves to be a good target for cancer therapeutics exemplified by the clinical success of the monoclonal antibody trastuzumab. Margetuximab is believed to mediate its therapeutic activity against HER2+ tumors by a combination of mechanisms that are initiated by binding of margetuximab to HER2 expressed on the cell surface, including the following:

- Direct impact on HER2 receptor leading to reduced HER receptor dimerization and subsequent activation, induction of endocytosis of the HER2 receptor, and prevention of shedding of the extracellular domain of the HER2 receptor (thereby preventing formation of a constitutively active truncated intracellular receptor);

- Induction of apoptosis; and

- Antibody-mediated cellular cytotoxicity, or ADCC, and presentation of the antigenic determinants of opsonized cells to antigen-presenting cells.

Fcγ-receptor (FcγR)-mediated mechanisms, such as ADCC, play a critical part in the action of many antibodies including trastuzumab. Optimization of the Fc component of margetuximab enhances binding to the V/F heterozygous subtype and the F/F homozygous subtype of FcγR compared to trastuzumab, potentially leading to enhanced ADCC activity in a broader patient population. Margetuximab significantly increased the level of ADCC activity mediated by Fc domain optimization, and the enhanced ADCC was observed in a range of breast, gastric, bladder and colorectal cancer cell lines. Margetuximab maintains the same direct anti-proliferative activity as trastuzumab, but, in contrast to trastuzumab, margetuximab interacts efficiently with both 158F and 158V allotypes of CD16A due to specific mutations introduced into its Fc region. Consistent with its enhanced binding to CD16A, margetuximab exhibits enhanced *in vitro* antitumor activity against HER2-expressing tumor cell lines, including against lines expressing low HER2 levels, and in xenograft models in human CD16A+ transgenic mice. The data from the nonclinical pharmacology studies support the hypothesis that margetuximab can be active against HER2-expressing tumors.

Market Opportunity

HER2-expressing tumors

HER2 is a protein found on the surface of some cancer cells that promotes growth and is associated with aggressive disease and poor prognosis. HER2-expressing tumors represent approximately 25% of breast cancer and approximately 20% of gastric cancer. The HER2 positive rate may be lower for gastric cancer in China. HER2-targeting agents have had significant impact on the behavior of HER2+ breast and gastric cancers. Monoclonal antibody-based therapies targeting HER2 have greatly improved outcomes of patients with HER2+ breast cancer and are now standard of care in both early-and late-stage disease. Ongoing HER2 blockade is recommended for patients who have relapsed or refractory HER2+ disease; after progression occurs during treatment with other HER2-directed therapies, the need for additional agents in later lines remains. In the metastatic setting, trastuzumab in combination with pertuzumab and chemotherapy has become the standard of care (SOC) in the first line treatment of HER2+ breast cancer, while trastuzumab in combination with chemotherapy is the SOC in the first line treatment of HER2+ gastric cancer. Trastuzumab has been demonstrated to improve PFS of patients with gastric and GEJ tumors that overexpress HER-2 from 5.5 months to 6.7 months and OS from 11.1 months to 13.8 months when added to chemotherapy compared to chemotherapy alone. The addition of a targeted mAb to chemotherapy has also demonstrated improved PFS and OS in the second line setting. Ramucirumab (a mAb targeting the vascular endothelial growth factor pathway) improved median OS to 9.6 months when added to paclitaxel chemotherapy compared to 7.4 months with paclitaxel chemotherapy alone.

Breast cancer

Approximately 25% of breast tumors overexpress the HER2 protein which is a member of the ErbB receptor tyrosine kinase family and plays an important role in the growth and proliferation of HER2-expressing cancer cells. HER2 expression is associated with aggressive metastatic cancers with a poor prognosis. The incidence of breast cancer in China grew from 304.0 thousand in 2015 to 326.2 thousand in 2019 with a CAGR of 1.8% from 2015 to 2019, according to the Frost & Sullivan Report. Many HER2-targeting agents have been developed and marketed with trastuzumab (Herceptin) as one of the most important treatments for HER2+ breast cancer.

There are different types of treatment for patients with breast cancer. Six types of standard treatment are used, including surgery, radiation therapy, chemotherapy, hormone therapy, targeted therapy and immunotherapy. As of July 2020, there were three HER2-targeted mAbs marketed in China. However, after treatment failure or disease progression after second-line anti-HER2 treatment, there is no approved effective treatment in late-stage setting in China and globally. There would be a significant need for new and effective HER2 targeted therapies that can be administered to patients with HER2+ metastatic breast cancer who have previously been treated with other anti-HER2-targeted therapies. Zai Lab's margetuximab is at Phase I clinical trial stage.

Gastric cancer

For market opportunity and competition information with respect to gastric cancer, please see "– ZEJULA – Market Opportunity and Competition – Gastric Cancer."

For patients with advanced metastatic gastric cancer, systemic treatment has been adopted clinically at present. Chemotherapy and targeted therapy are the main treatments for advanced metastatic gastric cancer. For HER2+ advanced gastric cancer, trastuzumab is the only HER2-targeted antibody, according to Frost & Sullivan; thus, there has been a strong demand for reliable and affordable treatment options for advanced gastric cancer.

Preclinical and Clinical Development

Nonclinical Pharmacology

In ligand binding studies, compared to the wild-type Fc domain, margetuximab imparts enhanced binding to both the CD16A-158F and CD16A-158V alleles. Binding to human CD32A is unchanged (131H allele) or decreased (131R allele), and there is a substantial decrease in binding to the human inhibitory receptor, CD32B. In the monkey, the optimized Fc domain of margetuximab imparts increased binding to all three cynomolgus FcγRs (CD16A, CD32A and CD32B) compared to the wild type Fc domain.

Consistent with its enhanced binding to CD16A, margetuximab exhibits enhanced anti-tumor activity against HER2-expressing tumor cell lines *in vitro* and in xenograft models in human CD16A-transgenic mice. Margetuximab, as a single agent, is active against HER2-expressing breast, ovarian or pancreatic tumors in a manner consistent with that of trastuzumab. In general, HER2 3+ tumors (breast BT474 and ovarian SKOV3 cell lines) were highly sensitive to treatment with either margetuximab or a trastuzumab analogue, RES120, with maximal effects observed at the lowest dose tested. Margetuximab showed enhanced activity against JIMT-1 xenografts compared to RES120 in mCD16-/-hCD16A+ transgenic mouse lines. JIMT-1 is a HER2+ (2+ by HercepTest) cell line derived from a metastatic breast cancer patient that progressed on trastuzumab therapy and is insensitive to trastuzumab anti-proliferative activity. Margetuximab was also active as a single agent against HER2-expressing gastric cancer xenografts and when combined with a chemotherapy agent (taxane or irinotecan). The anti-tumor effects of the combinations were enhanced compared to that of the individual agents.

Based on *in vitro* secondary pharmacology studies conducted with human PBMC and anti-HER2 monoclonal antibodies in the absence or presence of immobilized HER2 antigen, the optimized Fc domain of margetuximab does not contribute to enhanced cytokine release *in vitro*. These data suggest that margetuximab is not likely to induce cytokine release in human patients to levels any higher than those induced by trastuzumab.

Margetuximab exhibited anti-tumor activity equal to or better than that of RES120, its WT Fc domain counterpart, in all models tested and increased potency compared with RES120 in a selected system where the contribution of the optimized Fc domain can be ascertained. These data support the hypothesis that margetuximab is more potent than trastuzumab. In addition, margetuximab exhibited enhanced tumor activity when combined with chemotherapy agents. For patients with HER2-expressing tumors, margetuximab has the potential to expand the benefit to the whole patient population, irrespective of the CD16A genotype. Thus, these data support the use of margetuximab, in combination with chemotherapy, to treat HER2+ breast cancer.

Nonclinical pharmacokinetics

In the single dose toxicology study, intravenous infusion of margetuximab at 50 mg/kg led to a mean Cmax of 1.62 mg/mL for males and 1.70 mg/mL for females. The terminal phase half-life was estimated to be 223.9 hours in males and 233.9 hours in females, while serum clearance was 0.434 mL/hr and 0.400 mL/hr in males and females, respectively. The volume of distribution at steady state (Vss) was estimated to be 132.4 mL in males and 127.2 mL in females, which is similar to the plasma volume. No gender related differences were apparent in the pharmacokinetic profile. The pharmacokinetic properties for RES120, an antibody identical to margetuximab except for the presence of a wild type human IgG1 Fc domain, were similar to those for margetuximab. In the multi-dose toxicology study, margetuximab was administered weekly for 6 weeks at doses of 15, 50 or 150 mg/kg. Toxicokinetic measurements showed an increase in exposure to margetuximab with increasing dose. Cmax appeared to increase linearly with dose following the first dose on Day 1; however, increases in Cmax were

not dose proportional following the sixth dose on Day 36. Similar trends were observed with respect to AUC0-∞. Terminal serum half-life ranged from 133 to 189 hours on Day 1 and 176 to 222 hours on Day 36. Serum clearance ranged from 0.55 to 1.09 mL/hr on Day 1 and 0.20 to 0.36 mL/hr on Day 36. The volume of distribution approximated to the blood volume. No substantial gender differences were observed. The more rapid clearance following the first dose on Day 1 as compared to Day 36 was probably due to binding to the target receptor and saturation of this binding following multiple doses. Taken together, these data indicate that the pharmacokinetic profile of margetuximab in monkeys is comparable to that of other anti-HER2 IgG1 monoclonal antibodies.

Nonclinical Toxicology

Margetuximab has been investigated in single and repeat dose toxicity studies in the cynomolgus monkey and in a battery of *in vitro* tissue cross-reactivity studies in human and cynomolgus monkey tissues. Cynomolgus monkeys (Macaca fascicularis) express both the target antigen and FcγRs that are relevant for modeling margetuximab. A direct comparison of margetuximab and trastuzumab revealed similar staining patterns in human and cynomolgus monkey tissues. A second (rodent) species was not used in repeat dose toxicity studies because margetuximab, which retains the HER2-binding properties of 4D5, the original precursor to the trastuzumab antibody, does not cross react with rodent HER2/neu.

In a pilot toxicology study in cynomolgus monkeys margetuximab or RES120 was well tolerated when administered by IV infusion at a single dose of 50 mg/kg. There were no test article-related mortalities and no test article-related changes with regard to clinical signs, food consumption, body weights, haematology, coagulation, or urinalysis parameters. There were also no macroscopic, organ weight or microscopic findings related to the administration of RES120 or margetuximab. Mild increases in alanine aminotransferase (ALT), aspartate aminotransferase (AST), and lactate dehydrogenase (LD), with both margetuximab and RES120, were consistent with a nonhepatic source and can be observed following 1-hour infusions and frequent blood sampling for toxicokinetic analysis. In the repeat dose study, margetuximab, administered weekly via 1-hour intravenous infusion for six weeks at 15, 50 and 150 mg/kg, was well tolerated in male and female cynomolgus monkeys. There were no margetuximab-related mortalities or clinical signs and no test article-related changes in food consumption, body weights, ECG, troponin I or ophthalmic examinations, physical examinations, blood pressure or heart rate, haematology, coagulation, or urinalysis parameters. No margetuximab-related changes were observed in natural killer (NK) cell cytolytic activity during the dosing or recovery intervals. There were no gross findings observed at necropsy, no organ weight or organ weight ratio alterations, and no microscopic findings attributed to the administration of margetuximab (including no findings in heart tissue).

Clinical Development – Breast Cancer

In December 2019, MacroGenics submitted a Biologics License Application (BLA) to the FDA for margetuximab for the treatment of patients with metastatic HER2+ breast cancer in combination with chemotherapy. The BLA submission was based primarily on data from

SOPHIA, the Phase III clinical trial comparing margetuximab plus chemotherapy versus trastuzumab plus chemotherapy in patients with HER2+ metastatic breast cancer who have previously been treated with anti-HER2-targeted therapies. In February 2020, the BLA was accepted for review by the FDA.

The SOPHIA study enrolled 536 patients at approximately 200 trial sites across North America, Europe and Asia. Patients were treated with either margetuximab or trastuzumab in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine). All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine. Primary endpoints are sequentially-assessed progression-free survival (PFS), determined by centrally-blinded radiological review, and overall survival (OS). A pre-specified exploratory objective of the study was to evaluate the effect of CD16A (Fcγ receptor) allelic variation on margetuximab activity; approximately 85% of the overall human population, as well as patients enrolled in the SOPHIA study, carry the CD16A 158F allele, which has been previously associated with diminished clinical response to trastuzumab and other antibodies.

In June 2019, at a medical conference, the data from SOPHIA as of the aforementioned October 2018 data cut-off that showed a statistically significant improvement in PFS in patients treated with margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in the intention-to-treat (ITT) population after 265 PFS events (median PFS=5.8 months versus 4.9 months; hazard ratio [HR]=0.76; 95% confidence interval [CI]: 0.59-0.98; P=0.033). In the pre-specified, exploratory subpopulation of patients carrying the CD16A 158F allele, PFS was prolonged by 1.8 months in the margetuximab arm compared to the trastuzumab arm (median PFS=6.9 months versus 5.1 months; HR=0.68; 95% CI: 0.52-0.90; P=0.005). The data from the planned first interim analysis of OS based on 158 OS events. This interim analysis was not expected to and did not reach statistical significance. In the ITT population, median OS was 18.9 months in the margetuximab arm versus 17.2 months in the trastuzumab arm (HR=0.95; 95% CI: 0.69-1.31). In the pre-specified, exploratory subpopulation of patients carrying the CD16A 158F allele, median OS was 23.6 months in the margetuximab arm versus 16.9 months in the trastuzumab arm (HR=0.82; 95% CI: 0.58-1.17). As a secondary outcome measure in the SOPHIA study, the objective response rate (ORR) in the ITT population was 22% in the margetuximab arm (95% CI: 17.3-27.7%) compared to 16% in the trastuzumab arm (95% CI: 11.8-21.0%).

At a medical conference in December 2019, the data from the planned second interim analysis of OS as of a September 2019 cut-off after 270 OS events showed that, OS favored margetuximab plus chemotherapy compared with trastuzumab plus chemotherapy in the ITT population; however, these data were not expected to and did not reach statistical significance (median OS=21.6 months versus 19.8 months; HR=0.89; 95% CI: 0.69-1.13; nominal P=0.326). The final pre-specified OS analysis is planned after 385 OS events have accrued, which is projected to occur in the second half of 2020, at which point the results may or may not reach statistical significance. Among the genetically defined exploratory subpopulation of patients carrying a CD16A 158F allele, the median OS at the second interim analysis was prolonged by 4.3 months in the margetuximab arm compared to the trastuzumab arm (23.7

months versus 19.4 months; HR=0.79; 95% CI: 0.61-1.04; nominal P=0.087). Among the approximately 15% of patients who were homozygous for the CD16A 158V allele, the trastuzumab arm performed better than the margetuximab arm.

As of the April 2019 data cut-off for safety, Grade 3 or greater adverse events occurred in 142 (54%) patients on the margetuximab arm compared to 140 (53%) patients on the trastuzumab arm. Serious adverse events occurred in 43 (16%) patients on the margetuximab arm compared to 49 (18%) patients on the trastuzumab arm. Infusion-related reactions (IRR) were more common with margetuximab treatment than with trastuzumab (13% versus 3%) and were mostly Grade 1 or 2 and associated with the first dose. A substudy evaluating shorter, 30-minute infusions of margetuximab in Cycle 2 and beyond showed no effect on safety outcomes, including risk or severity of IRR.

Clinical Development – Gastric Cancer

In September 2019, an ongoing Phase II, open-label, dose escalation and expansion study of margetuximab plus pembrolizumab, an anti-PD-1 monoclonal antibody, in patients with advanced HER2+ GC or GEJ cancer who have previously been treated with chemotherapy and trastuzumab in the metastatic setting were presented. In this study, 92 patients, including 61 patients with GC and 31 patients with GEJ, who had HER2+ disease, were treated at the recommended Phase II dose of 15 mg/kg margetuximab and 200 mg pembrolizumab, both administered every three weeks, and were included in the analysis. HER2 positivity was characterized by a score of 3+ by immunohistochemistry (IHC), or IHC3-positve, or a score of 2+ by IHC and detection by fluorescence in situ hybridization (FISH), or IHC2-positive/FISH-positive. Patients in the study were enrolled irrespective of programmed death-ligand 1 (PD-L1) expression status. MacroGenics reported data as of July 10, 2019. As of this data cut-off date, the study was ongoing with eight patients remaining on therapy. Acceptable tolerability was observed in this study in patients treated with margetuximab and pembrolizumab. Grade 3 or higher treatment-related adverse events (TRAE) occurred in 19.6% of patients. Response rates, median PFS and OS observed in the ongoing study are summarized in the following table:

	Gastroesophageal Adenocarcinoma (GEA = GC + GEJ)				**Gastric Cancer (GC)**			
	ORR	**DCR**	**Median PFS (months)**	**Median OS (months)**	**ORR**	**DCR**	**Median PFS (months)**	**Median OS (months)**
All Patients	20*/92 (21.7%)	50/92 (54.4%)	2.7	12.5	18*/61 (29.5%)	40/61 (65.6%)	4.1	13.9
HER2 IHC3+	20*/71 (28.2%)	45/71 (63.4%)	4.3	13.9	18*/55 (32.7%)	38/55 (69.1%)	4.7	14.6
HER2 IHC3+/PD-L1+	12/25 (48.0%)	19/25 (76.0%)	4.8	20.5	12/23 (52.2%)	19/23 (82.6%)	5.5	20.5

* Three unconfirmed responses; ORR includes complete responses (CR) and partial responses (PR); DCR=disease control rate and includes CR, PR and stable disease (SD).

Source: MacroGenics

Based on these results, in September 2019, MacroGenics initiated the MAHOGANY study, a Phase II/III registration-directed clinical trial to evaluate, in Module A, margetuximab in combination with MGA012, an anti-PD-1 monoclonal antibody, in patients with tumors that are both HER2+ and PD-L1 positive. This approach is designed as a chemotherapy-free regimen that engages both innate and adaptive immunity for the treatment of patients with GC or GEJ cancer in the first-line setting. The primary outcome measure for efficacy in Module A is ORR per Response Evaluation Criteria in Solid Tumors (RECIST) v 1.1. In Module B, is to evaluate margetuximab with chemotherapy and tebotelimab, a PD-1 x LAG-3 bispecific DART molecule, compared to standard of care therapy of trastuzumab with chemotherapy in MAHOGANY study. In this portion of the randomized, controlled study, patients are planned to be enrolled irrespective of PD-L1 expression. The primary outcome measure for efficacy in Module B is planned to be OS.

Our Clinical Trial Designs and Strategy for Margetuximab in the China Market

We are exploring regulatory approval pathways for margetuximab in HER2+ breast cancer in China using a bridging approach which may require a PK study and a bridging trial. In February 2020, the first patient was dosed in the registrational bridging study of margetuximab in combination with chemotherapy for the treatment of patients with metastatic HER2+ breast cancer. Data from the positive SOPHIA study and the bridging study data will be used to support potential regulatory filing and approval in China. In addition, we plan to enroll the first Chinese patient in second half of 2020 in MacroGenics sponsored Phase II/III global studies of margetuximab (MAHOGANY) in combination with a PD-1 antibody or a PD-1 x LAG-3 bispecific DART molecule in the first line treatment of HER2+ gastric cancer.

Retifanlimab

Overview

Retifanlimab (PD-1) is an investigational monoclonal antibody that inhibits PD-1. retifanlimab (PD-1) is currently being evaluated as monotherapy in registration-directed trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer. Incyte is currently developing retifanlimab (PD-1) in Phase II/III clinical trials for the gastric cancer and oesophageal cancer; Phase II clinical trials for anal cancer; endometrial cancer; merkel cell carcinoma; solid tumors; Phase I/II clinical trials for colorectal cancer; and Phase I clinical trials for acute myeloid leukaemia, among other indications.

We obtained an exclusive license from Incyte to develop and commercialize retifanlimab (PD-1) in haematology and oncology in China, Hong Kong, Macau and Taiwan in July 2019. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Incyte."

Mechanism of Action

PD-1 is expressed on T-cells (CD4+ and CD8+), B-cells, NK cells, and myeloid-derived cells. The interaction of PD-1 with its ligands, PD-L1 and PD-L2, forms a negative signaling axis in T-cells to suppress T-cell function which is the mechanism utilized by the immune system to help maintain self-tolerance and modulate the duration and amplitude of physiological immune responses.

PD-L1 and PD-L2 have also been found to be abnormally expressed by tumor cells in the tumor microenvironment. Extensive research has shown that cancer cells co-opt certain immune checkpoint pathways, including the PD-1 pathway, as a major mechanism of immune evasion/resistance, particularly against T-cells that are specific for tumor antigens. Disruptors of this pathway using antibodies that inhibit PD-1 receptor-ligand interactions have been shown to inhibit tumor growth in murine models through enhancing T-cell proliferation and restore immune responses. Moreover, blocking the PD-1-PD-L1/L2 pathway has been clinically validated as an effective cancer treatment in multiple clinical settings.

Clinical Development

Pharmacology

Preliminary PK data from the 167 participants in the dose expansion cohorts receiving weight-based or flat doses of retifanlimab suggested that first dose retifanlimab exposure increased in a dose-proportional manner, consistent with the observations in participants receiving weight-based doses. A population PK analysis demonstrated that the concentrations of retifanlimab can be adequately described by a 2-compartment model, and body weight dependence of clearance was characterized by a power relationship with an exponent of 0.911.

Simulations demonstrated that the median steady-state concentration of retifanlimab 500 mg Q4W was approximately 21.1 μg/mL, which is the median trough concentration for pembrolizumab 200 mg Q3W.

Safety

Adverse events in participants treated with retifanlimab monotherapy included fatigue, diarrhea, nausea, and pyrexia (very common), ALT increased, colitis, dysgeusia, hyperthyroidism, hypothyroidism, influenza-like illness, infusion-related reaction, lipase increased, myalgia, pruritus, and rash (includes terms of rash, maculopapular rash, and macular rash) (common), and pneumonitis (uncommon). These AEs are similar to those observed with other anti-PD-1 antibodies.

The 375 mg Q3W and 500 mg Q4W doses were selected for further development based on favorable safety and PK profiles.

Efficacy

Preliminary efficacy data demonstrate clinical activity of retifanlimab based on durable RECIST responses in multiple tumor types. Preliminary efficacy in terms of RECIST response has been shown in previously treated NSCLC, cervical, and endometrial cancers. Based on the available data, the preliminary efficacy profile of retifanlimab is consistent with that of other anti-PD-1 antibodies.

Retifanlimab is currently in development as a single agent or in combinations in multiple tumor types including endometrial cancer, anal cancer, NSCLC, and others.

Our Clinical Trial Designs and Strategy for Retifanlimab in the China Market

Our CTA application for Phase II confirmatory study has been accepted for second-line MSI-high endometrial cancer. We plan to enroll the first Chinese patient into the Incyte-sponsored global Phase I/II potentially registration-enabling study in second half of 2020. In addition, we have obtained Phase III CTA approval and plan to enroll the first Chinese patient into the Incyte-sponsored global Phase 3 study of retifanlimab with platinum-based chemotherapy in first-line metastatic squamous and non-squamous non-small cell lung cancer in second half of 2020.

Tebotelimab

Overview

Tebotelimab is a bispecific monoclonal antibody designed to block the interaction of PD-1 or LAG-3 with their respective ligands, thereby contributing to sustain or restore the function of exhausted T-cells. Tebotelimab is an Fc-bearing bispecific tetravalent (bivalent for each antigen) DART protein engineered as a hinge stabilized IgG4 molecule designed to concomitantly bind PD-1 and LAG-3, 2 checkpoint molecules expressed by T lymphocytes following antigen-induced activation. Tebotelimab is under development as a therapeuticcandidate for the treatment of cancer.We obtained an exclusive license to develop and commercialize Tebotelimab in China, Hong Kong, Macau and Taiwan from MacroGenics in November 2018. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – MacroGenics."

Mechanism of Action

PD-1 and LAG-3 protein play an important role in immune response regulation. PD-1 is expressed on T (CD4+ and CD8+) cells, B cells, natural killer cells, and myeloid-derived cells. LAG-3 is a membrane protein that belongs to the Ig superfamily and binds to MHC-II. It enhances T regulatory cell activity and negatively regulates T-cell proliferation and differentiation. LAG-3 has been shown to be expressed on dysfunctional T-cells and is a marker for T regulatory cells. Upon interaction with their respective ligands, PD-1 and LAG-3 act as negative regulators of T-cell function. The combined PD-1 and LAG-3 expression on

tumor-infiltrating lymphocytes (TILs) or chronically viral-infected T-cells have been correlated with immune dysfunction, also known as "T-cell exhaustion." LAG-3 appears to negatively regulate CD4+ and CD8+ T-cell proliferation, function, and homeostasis in a manner that is distinct from that of PD-1.

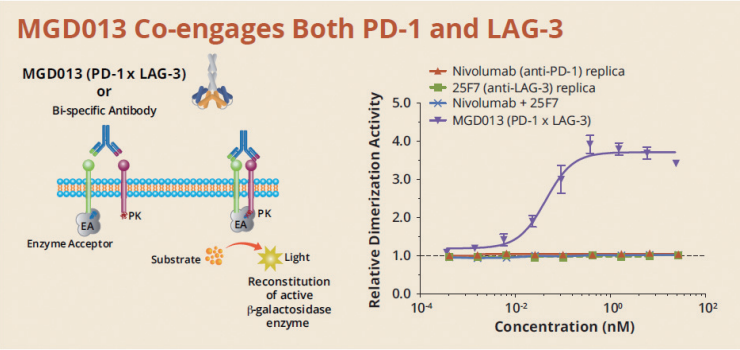
Cancer cells can co-opt certain immune-checkpoint pathways, including the PD-1 pathway, as a major mechanism of immune evasion/resistance, particularly against T-cells that are specific for tumor antigens (seen in the figure below). Blockade of PD-1 provides clinical benefit in patients with certain advanced tumors. Furthermore, combined blockade of 2 inhibitory receptors on T-cells may exert greater efficacy than monotherapy. Studies in mouse tumor models have indicated that PD-1 and LAG-3 blockade can synergize to generate potent tumor eradicating immunity. Furthermore, translational studies using TILs from patients with ovarian cancer showed that NY-ESO-1 antigen-specific LAG-3+/PD-1+ CD8+ T-cells were impaired in their ability to respond to antigen stimulation, but following combined LAG-3 and PD-1 blockade, T-cell responsiveness could be restored to a greater extent than a single-agent blockade. Together, these data suggest that, in tumors in which PD-1 and/or LAG-3 are expressed on TILs, dual therapy may increase response rates and/or effectiveness of immunotherapy. Currently, several anti-LAG-3 mAbs are under investigation in clinical trials, either as a monotherapy or in combination with anti-PD-1.

Competition

There is no marketed PD-(L)1-based bispecific monoclonal antibody in China, according to the Frost & Sullivan Report.

Pre-Clinical and Clinical Background

In vitro studies were performed to evaluate the ability of tebotelimab to co-engage PD-1 and LAG-3 receptors within an enzyme dimerization assay. Briefly, serial equal molar dilutions of tebotelimab, nivolumab replica, and/or relatlimab replica (negative control antibodies) were incubated with the DiscoverX PathHunter® U2OS PD1/LAG-3 dimerization cell line. PathHunter cells are genetically engineered to over-express the two proteins, whereby one protein is fused to Prolink and the second protein is fused to the enzyme acceptor (EA) of the β-galactosidase enzyme. As shown in the figure below, co-engagement of two proteins by tebotelimab, but not anti-PD-1 and/or anti-LAG-3 mAbs, drives complementation between PK and EA, resulting in the reconstitution of an active β-galactosidase enzyme that cleaves a substrate to generate chemiluminescent signal.



Sadhna Shankar, et al. Abstract No. P244, SITC 2017

Tebotelimab is currently in Phase I development in a basket trial of multiple tumor types. The specific indication for tebotelimab has not been defined and data from the basket trial may inform on the selection of specific indications for further development.

Our Clinical Trial Designs and Strategy for Tebotelimab in the China Market

Our global partner, MacroGenics, is conducting a Phase I, open-label, dose escalation and cohort expansion study designed to characterize the safety, tolerability, PK, pharmacodynamics, immunogenicity, and preliminary antitumor activity of tebotelimab administered by IV infusion on a Q2W or Q3W schedule. The study consists of a Dose Escalation Phase to determine the MTD or MAD (if no MTD is defined) of tebotelimab, followed by a Cohort Expansion Phase to further define the safety and initial antitumor activity of tebotelimab with the dose established in the Dose Escalation Phase. To date, the RP2D of tebotelimab on a Q2W or Q3W had been selected and the Cohort Expansion is ongoing in multiple tumor types.

In February 2020, we dosed the first patient in an open-label, single-arm, multicenter, Phase Ib dose escalation and expansion clinical study to assess the safety and antitumor activity of ZEJULA, in combination with tebotelimab, in patients with advanced or metastatic gastric cancer who failed prior treatment. In April 2020, we initiated a tebotelimab monotherapy and in combination with brivanib dose escalation and expansion study in advanced liver cancer patients. The study consists of a dose escalation phase to determine the Recommended Phase II Dose (RP2D) of tebotelimab monotherapy and that of tebotelimab when in combination with brivanib in subjects with advanced liver cancer, followed by a dose expansion phase. The part 1 of the dose expansion study is to assess the safety and efficacy of tebotelimab monotherapy and tebotelimab in combination with brivanib in subjects with advanced hepatocellular carcinoma (HCC). In the part 2 of the dose expansion study, a therapeutic method (tebotelimab monotherapy or tebotelimab in combination with brivanib, determined by the sponsor according to the obtained data) will be selected for dose expansion study in HCC subjects who have previously failed immune checkpoint inhibitor treatment, to further evaluate the safety and efficacy of the study treatments in the specific group of subjects.

In addition, we plan to enroll Chinese patients in Phase II/III global MAHOGANY study of margetuximab in combination with retifanlimab or tebotelimab in gastric cancer sponsored by MacroGenics in HER2+ first line treatment of gastric cancer and to initiate MAHOGANY Cohort B in China, Hong Kong, Macau and Taiwan in the second half of 2020. We also have obtained Phase I CTA approval in January 2020 and intend to enroll the first Chinese patient in the second half of 2020 for tebotelimab into its global Phase I basket trial sponsored by MacroGenics. Further, we have obtained CTA approval in June 2020 and are conducting a Phase I (proof of concept) clinical trial for second-line melanoma in Greater China.

Bemarituzumab

Overview

Bemarituzumab is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastroesophageal cancer. Gastric cancer, including gastroesophageal junction (GEJ) cancer, carries a poor prognosis, with five year overall survival (OS) rates below 30% for advanced stage disease (Stage III and IV) in the United States. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually.

We obtained an exclusive license from Five Prime to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan in December 2017. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Five Prime."

In December 2017, Five Prime initiated dosing in a Phase I safety lead-in portion of its Phase I/III clinical trial of bemarituzumab in combination with the mFOLFOX6 chemotherapy regimen in patients with previously untreated, advanced gastric or gastroesophageal cancer. The randomized, controlled Phase III portion of the trial evaluating bemarituzumab plus chemotherapy, the FIGHT trial, was initiated in the second half of 2018 and we enrolled the 1st patient in September 2018 in this global registrational study for the treatment of front-line gastric and gastroesophageal cancers. We and Five Prime intend to use the proposed global pivotal Phase III study and additional supportive data from clinical and nonclinical development to form the basis of an eventual marketing application for bemarituzumab both within and outside of China.

Five Prime has paused enrollment in the FIGHT trial pending the occurrence of a sufficient number of events to trigger a futility analysis that is expected to occur in mid-2020. Approximately 150 patients with newly diagnosed advanced stage gastric cancer were enrolled into the FIGHT trial before Five Prime paused enrollment in the fourth quarter of 2019. Five Prime expects that it will only resume enrollment in the FIGHT trial if the trial passes the futility analysis and Five Prime will look to enter into a collaboration or license agreement that will pay for all or substantially all of any future development and commercialization costs for bemarituzumab.

In March 2020, Five Prime announced the publication of results from the Phase I escalation and expansion study of bemarituzumab in patients with advanced solid tumors and FGFR2b-selected gastroesophageal adenocarcinoma in the digital edition of the Journal of Clinical Oncology. The purpose of the Phase I trial was to evaluate the safety, pharmacokinetics, and preliminary activity of single-agent bemarituzumab in patients with FGFR2b-overexpressing GEA. Seventy-nine patients were enrolled in the trial and no dose-limiting toxicities were reported. Bemarituzumab was well tolerated and the most frequent treatment-related adverse events (TRAEs) were fatigue, nausea, and dry eye. The overall response rate observed in this study of advanced-stage patients with high FGFR2b-overexpressing GEA was 17.9% (95% CI 6.1% to 36.9%) with five of 28 patients achieving a confirmed partial response.

In May 2020, Five Prime announced that the FIGHT trial is being converted from a Phase III to a randomized, double-blind, Phase II trial based on the approximately 150 patients enrolled. The Phase II FIGHT study is expected to have a sufficient number of progression-free survival (PFS) and overall survival (OS) events to generate clinically meaningful data by the end of 2020 or early 2021. Five Prime believes that converting to a Phase II trial is the fastest path to generating informative data about bemarituzumab: the first agent to target FGFR2b overexpressing gastric and gastroesophageal junction cancer (GEJ).

Mechanism of Action

Bemarituzumab is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor (National Center for Biotechnology Information; NCBI; reference sequence ID NP_001138385.1) that blocks FGF ligand binding to the receptor. Bemarituzumab is directed against the third Ig region of the FGFR2b receptor isoform, the region that is alternatively spliced and regulates ligand specificity. This antibody is glycosylated, but is produced in a Chinese hamster ovary (CHO) cell line that lacks the *FUT8* gene (α1,6-Fucosyltransferase) and therefore lacks a core fucose in the polysaccharide portion of the antibody. The absence of the core fucose results in higher affinity for the Fc receptor FcγRIIIa compared to the fucosylated molecule and potentially enhances immune cell-mediated tumor cell killing. The antibody has thus been glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). Bemarituzumab inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation in cell culture in FGFR2b overexpressing gastric and breast cancer cell lines. Bemarituzumab also inhibits tumor growth in FGFR2b overexpressing gastric and breast xenograft models. The 3 potential mechanisms of action of bemarituzumab thus include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and enhancing ADCC.

Bemarituzumab can produce complete and durable tumor growth inhibition in FGFR2b-overexpressing and FGFR2 gene-amplified gastric cancer xenografts in immune-compromised mice where FGFR2b is considered a driver of tumor growth. In addition, bemarituzumab demonstrates recruitment of natural killer (NK) cells and concomitant tumor growth inhibition

in the 4T1 syngeneic tumor model with modest expression of FGFR2b. These data suggest that ADCC may be efficacious in patients without FGFR2 gene amplification with moderate FGFR2b overexpression, and that ADCC activity may be a major contributor to the mechanism of action in these patients.

Additionally, since bemarituzumab is specific for the FGFR2b receptor, it does not interfere with signaling of the other FGFs/FGFRs, including FGFR2c. In contrast to the FGFR tyrosine kinase inhibitors (TKIs), bemarituzumab does not inhibit FGF23 signaling. FGF23 is a ligand involved in calcium/phosphate metabolism. Thus, treatment with bemarituzumab is not expected to cause the dose-limiting hyperphosphatemia associated with the FGFR TKIs.

Market Opportunity

Gastric cancer, including a portion of gastroesophageal junction (GEJ) cancer, carries a poor prognosis, with five year OS rates below 30% for advanced stage disease (Stage III and IV) in the United States and China. Intensive multimodal therapy fails to cure the majority of patients with locoregional disease and for advanced stage disease, standard chemotherapy provides only short-term benefits. First-line chemotherapy used in metastatic or recurrent disease consists of a fluoropyrimidine (5FU, capecitabine, or S-1) with a platinum agent (usually oxaliplatin or cisplatin). This combination chemotherapy treatment prolongs survival by 6 months compared to best supportive care but still only provides short-term benefit, with a progression free survival (PFS) of five to six months and a median OS of nine to 10 months.

FGFR2 amplification in gastric cancer results in high levels of FGFR2b expression, which is correlated with poor prognosis for OS when compared to patients without FGFR2b overexpression. FGFR2 is amplified in approximately 3% to 9% of tumors from patients with gastric cancer, with similar rates being observed across Japan, Korea, China, and the United Kingdom, and across platforms used to assess gene amplification (including reverse transcription polymerase chain reaction; RT-PCR; fluorescence in situ hybridization; FISH; and single nucleotide polymorphism; SNP; arrays). Using a validated immunohistochemistry (IHC) assay to specifically detect FGFR2b expression in solid tumors, approximately 12% of gastric cancers from China express a range of FGFR2b protein. To date, no drug has been approved for the FGFR2b-overexpressing molecular subset of patients with gastric cancer including cancer of the GEJ.

Bemarituzumab is a recombinant, afucosylated, humanized immunoglobulin G1 (IgG1) kappa monoclonal antibody directed against FGFR2b. Bemarituzumab is glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). Pre-clinically, bemarituzumab blocks ligand binding and acts as a targeted immunotherapy that drives NK cells and recruits T-cells into targeted tumors. As well as driving NK cells into tumors, *in vivo* pre-clinical studies have shown that bemarituzumab creates an "inflamed" tumor microenvironment consisting of recruited T-cells and elevated levels of programmed death-ligand 1 (PD-L1). The three potential mechanisms of action of bemarituzumab include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and ADCC.

There is currently no marketed FGFR2-targeted drug for gastric cancer in China, according to the Frost & Sullivan Report. Among the pipelines in this category, bemarituzumab, anlotinib and erdafitinib are in late clinical stage for gastric cancer.

Clinical Background

Bemarituzumab (FPA144) is being developed in combination with chemotherapy for the treatment of patients with unresectable, locally advanced, or metastatic gastric cancer including cancer of the GEJ whose tumors overexpress FGFR2b, as determined by an investigational device(s) being developed as a companion diagnostic test(s). Evaluation of this agent in patients with gastric cancer whose tumors have alterations of FGFR2 is an important strategy to improve the outcome for these patients.

A Phase I study, bemarituzumab-001, entitled "A Phase I Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of bemarituzumab in Patients with Advanced Solid Tumors" is ongoing in the United States, South Korea, and Taiwan. Safety and efficacy data in 74 patients, including preliminary data from an expansion cohort of 24 gastric cancer patients with high FGFR2b overexpression (IHC 3+ intensity in $\geq$ 10% of tumor cells as determined in a laboratory developed test), support further clinical investigation of bemarituzumab in patients with FGFR2b-selected tumors. Based on an August 7, 2017 data cut, treatment with bemarituzumab resulted in no dose-limiting toxicities (DLTs) reported at doses up to 15 mg/kg administered every two weeks. Of the 74 patients who have received at least one dose of bemarituzumab, 50 patients had gastric cancer, of whom 24 had gastric cancer with high FGFR2b overexpression and were evaluable for response. Of these 24 patients, four, or 16.7% (95% CI 4.7-37.4%), reported a radiographically confirmed partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) criteria (version 1.1). The median duration of response (DoR) in these four patients was 15.4 weeks (95% CI 9.1 to 19.1 weeks). Conversely, no responses were reported in the 25 patients with gastric cancer who either had low or moderate FGFR2b overexpression, were IHC negative, or who had unknown FGFR2b status. One patient with gastric cancer did not have measurable disease and was inevaluable for response.

To address the unmet medical need of patients with unresectable, locally advanced, or metastatic gastric cancers and based on the preliminary Phase I data, Five Prime is proposing bemarituzumab-004 (FIGHT), a double-blind, randomized, controlled, global Phase III study of bemarituzumab in combination with modified FOLFOX6 (mFOLFOX6) chemotherapy, preceded by a Phase I safety run-in. The Phase I safety run-in will be conducted in the United States and will assess safety and tolerability and identify the recommended dose (RD) of bemarituzumab as an add-on therapy to fluorouracil, leucovorin, and oxaliplatin (mFOLFOX6, a combination that is used globally) for patients with gastrointestinal (GI) tumors.

The global Phase III portion of the study will evaluate the efficacy and safety of bemarituzumab in combination with mFOLFOX6 versus placebo in combination with mFOLFOX6 in patients with unresectable, locally advanced, or metastatic gastric cancers whose tumors have FGFR2b overexpression, as determined by an IHC assay, and/or *FGFR2* amplification, as determined by a circulating tumor DNA (ctDNA) assay. The proposed Phase III study will enroll a majority of Asian patients, from countries including Japan, South Korea, Taiwan, Thailand, and China. The primary endpoint for the proposed Phase III study will be OS, supported by a principle secondary endpoint of investigator-assessed PFS. Other secondary and exploratory endpoints include overall response rate (ORR), DoR, and physical function, as measured by EQ-5D-5L and EORTC QLQ-C30. Additional development of bemarituzumab for the treatment of gastric cancer includes bemarituzumab-002, a Phase I pharmacokinetic (PK) safety study in Japan. This dose escalation study is designed to assess the PK and safety of single agent bemarituzumab and will identify the RD for single agent bemarituzumab in Japanese patients. The first cohort of three patients treated on bemarituzumab-002 had no DLTs reported at doses of 10 mg/kg administered every two weeks.

Our Clinical Trial Designs and Strategy for Bemarituzumab in the China Market

As bemarituzumab is a targeted biologic, the clinical development of bemarituzumab will ultimately be in selected patients with alterations in the fibroblast growth factor receptor 2, or FGFR2, pathway that are most likely to respond to this novel agent. The tumor types most relevant to date include gastric, bladder, and possibly cholangiocarcinoma. Each of these cancers needs new therapeutic options. The FIGHT (bemarituzumab-004) study is designed to evaluate the efficacy, safety, and PK of bemarituzumab in combination with modified FOLFOX (infusional 5-FU, leucovorin, and oxaliplatin) (mFOLFOX6) chemotherapy treatment. Patients with gastrointestinal (GI) tumors will be enrolled in a Phase I safety run in. The primary endpoint for Phase I part is the incidence of Grade 2 or higher AEs assessed as related to bemarituzumab by the Investigator and the incidence of clinical laboratory abnormalities defined as DLTs.

Our partner, Five Prime, announced the FIGHT trial has been converted to a Phase II randomized, double-blind trial, based on the approximately 150 patients enrolled. The Phase II FIGHT study is expected to generate clinical data to inform the further development strategy of bemarituzumab by the end of the year or early 2021. We have halted the enrollment in China, and will wait for our partner to provide further guidance.

Our Infectious Disease Pipeline

Omadacycline

Overview

Omadacycline (ZL-2401) is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. Omadacycline is primarily being developed for ABSSSI, CABP and UTI in both the hospital and community settings and is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. Omadacycline has been granted QIDP and Fast Track status by the FDA. The drug has been administered to over 1,500 patients and has an established safety and tolerability profile. In October 2018, following priority review, Omadacycline was approved by FDA for both indications and for both the IV and oral once-daily formulations.

In June 2016, Paratek announced positive top-line efficacy data in a Phase III registration study in ABSSSI which demonstrated the efficacy and safety of IV to oral once-daily omadacycline compared to linezolid. In April 2017, Paratek announced positive top-line results from a global, pivotal Phase III clinical study in CABP which demonstrated the efficacy, general safety and tolerability of IV to oral omadacycline compared to moxifloxacin. In July 2017, Paratek also announced positive top-line results from a Phase III study comparing oral-only administration of omadacycline in ABSSSI compared to oral-only linezolid, which met all of its primary endpoints.

Omadacycline was approved by the FDA in October 2018 for both indications. It was launched as NUZYRA in the United States in February 2019. It is labeled for once-daily oral or intravenous administration for the treatment of adults with CABP and ABSSSI. The European Marketing Authorization Application for oral and IV omadacycline was submitted in October 2018.

In October 2019, Paratek announced that it is withdrawing its application in Europe for Nuzyra for business reasons. While approvable by EMA for skin infections, EMA requested a second study in CABP to meet current European regulatory standards of two Phase III studies in the indication. Paratek plans to re-submit application to EMA following completion of the planned Post-Marketing Approval CABP study already agreed with the FDA. Paratek conducted two exploratory studies in UTI for dose-finding purposes, one in women with acute cystitis (cUTI) and another in patients with pyelonephritis (cUTI). As per a press release in October 2019, Paratek plans to conduct additional analyses and investigations for these UTI indications.

We obtained the exclusive license from Paratek to develop, manufacture and commercialize omadacycline in the field of all human therapeutic and preventative uses (other than biodefense) in China, Hong Kong, Macau and Taiwan in April 2017. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Paratek." In March 2020, we entered into a contract sales agreement with

Hanhui, a local pharmaceutical company with a strong commercial presence in antibiotics. The agreement allows us to leverage Hanhui's existing infrastructure to optimize a potential future commercial launch of omadacycline in China given that omadacycline is a broad spectrum antibiotic in both the hospital and community setting.

Competition

In China, there is currently only one marketed tetracycline derivative antibiotic, which was approved in 2010. Omadacycline is expected to be the second approved drug in this category.

Summary of Clinical Results

Background on Tetracycline Antibiotics

The tetracycline class of antibiotics was introduced into the clinic in the 1960s and found considerable use in the treatment of respiratory and gastrointestinal infections. They are mostly bacteriostatic drugs interfering with protein synthesis by binding selectively to the bacterial 30S ribosomal subunit.

Tetracyclines provide excellent broad-spectrum coverage of Gram-positive, Gram-negative, anaerobes and special pathogens (e.g., malaria, anthrax, Lyme borrelia, nocardia). Resistance is due to efflux mechanisms and ribosomal mutations, but despite the gradual and inevitable increase in resistance over many decades of continued use, doxycycline is still an effective and commonly used drug today.

Omadacycline – Pharmacokinetics

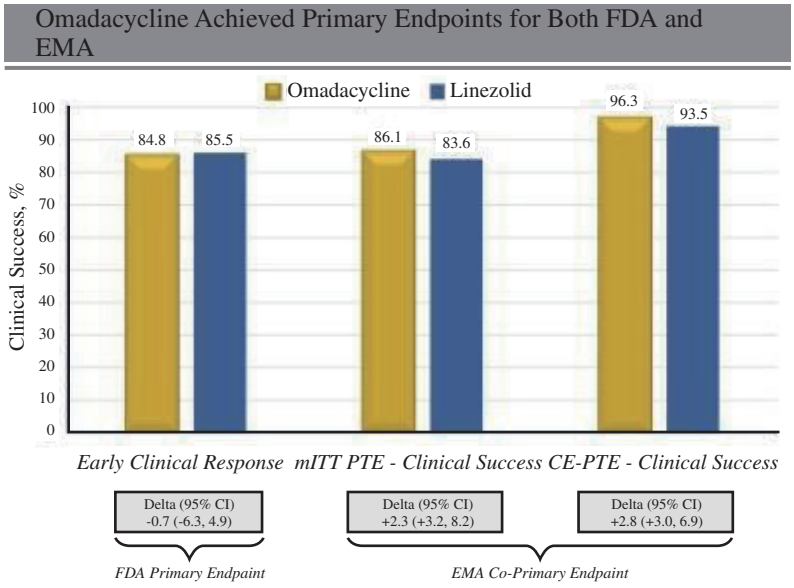
Studies showed that oral doses of 300 mg provide bioequivalent exposure with the therapeutic IV dose of 100 mg. Like with other tetracyclines, absorption is affected by food and divalent cations. The drug has a long half-life (approximately 17 hours) and excellent penetration into tissues, including alveolar and epithelial lining fluid. In contrast to other tetracyclines, plasma protein binding is low (20%) and not dose-related. The drug is not metabolized and excretion is predominantly via the biliary route. There is no need for dose adjustment in hepatic or renal impairment.

Phase III Pivotal Trial-ABSSSI/OASIS-ABSI 1108

Omadacycline was statistically non-inferior to linezolid IV/PO in a direct comparison study following a protocol established under an SPA agreed to with the FDA as well as the criteria outlined by the EMA. In this trial, patients with wound infections, major abscesses, and erysipelas/cellulitis were enrolled in equal numbers. On average, patients received IV omadacycline for 4.4 days, and oral omadacycline for 5.5 days.

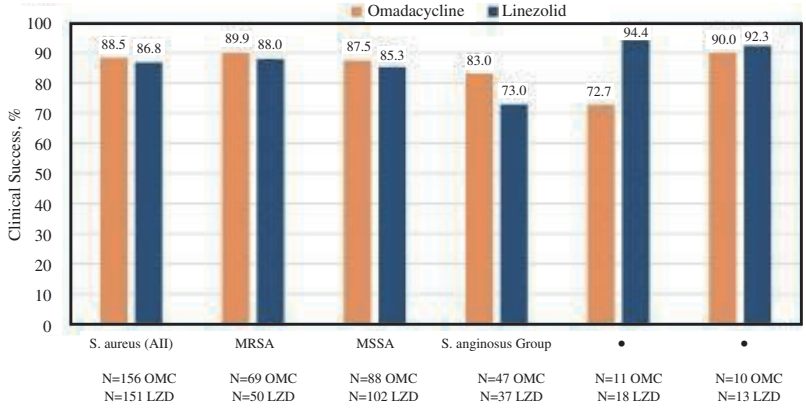
S. aureus (both MSSA and MRSA) was the predominant pathogen isolated from patients followed by streptococci. Clinical response and bacterial eradication rates showed the high efficacy of omadacycline against skin pathogens including MRSA.

Figure 9: Omadacycline vs Linezolid-ABSSSI Trial-Primary Efficacy Outcomes



Source: Rodrigo, Keith. Infection and Drug Resistance; 2019:12 1895-1915

Figure 10: Early Clinical Success by Pathogen-micro-mITT Population



Source: Omadacycline - Antimicrobial Drugs Advisory Committee (AMDAC) Briefing Book. Paratek Pharmaceuticals; 2018

The safety/tolerability profile was very similar between the treatment arms with only a slightly higher rate of gastrointestinal side effects and infusion site reactions in omadacycline recipients. There was no significant imbalance in treatment emergent adverse events, or TEAEs, serious TEAEs, premature discontinuations or deaths.

This study was recently published in the New England Journal of Medicine (W O'Riordan et al. Omadacycline for Acute Bacterial Skin and Skin-Structure Infections, N Engl J Med 2019; 380:528-538).

Figure 11: Study ABSI-1108: Most Frequent TEAEs (> 3%)-Safety Population

	Omadacycline N = 323	**Linezolid N = 322**
	%	%
Subjects with Any TEAE	48.3	45.7
Nausea	12.4	9.9
Infusion Site Extravasation	8.7	5.9
Subcutaneous Abscess	5.3	5.9
Vomiting	5.3	5.0
Cellulitis	4.6	4.7
Headache	3.1	4.0
ALT Increased	2.8	4.3
AST Increased	2.5	3.7
Diarrhea	2.2	3.1

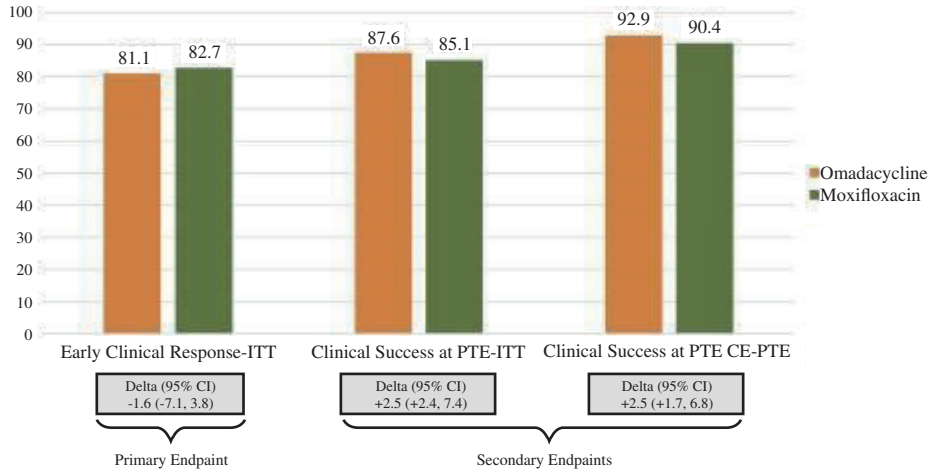
Source: William O'Riordan, et al. The New England Journal of Medicine; 2019

Phase III Pivotal Trial-CABP/OPTIC-CABP1200

Omadacycline was non-inferior to moxifloxacin IV/oral in this direct comparison study following a protocol established under an SPA agreed with the FDA as well as the criteria outlined by the EMA. In this trial, patients with PORT Class II-IV were recruited; less than 25% of patients had received non-study antibiotics before enrollment.

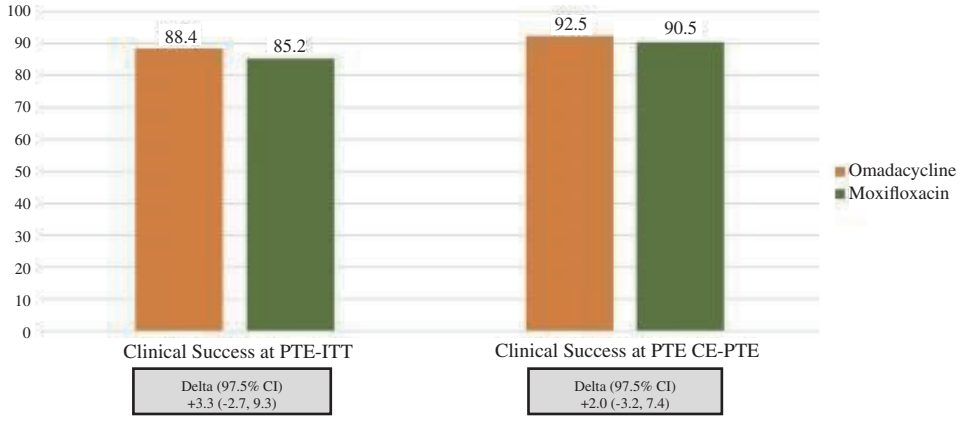
Streptococcus pneumoniae and Mycoplasma pneumoniae were the predominant pathogens isolated, followed by H. influenzae, H. parainfluenzae, Legionella and Chlamydophila. The clinical response rates were high for all respiratory pathogens isolated at entry and very similar between omadacycline and moxifloxacin, a powerful respiratory fluoroquinolone.

Figure 12: CABP Study – OPTIC: Primary Efficacy Results – FDA Analysis



Source: Roman Stets et al. The New England Journal of Medicine; 2019

Figure 13: CABP Study – OPTIC: Primary Efficacy Results – EMA Analysis



Source: EMA assessment report

Figure 14: CABP Study-OPTIC: Clinical Success at PTE by Baseline Pathogen

	Omadacycline (N = 204)		Moxifloxacin (N = 182)	
Baseline Pathogen	**N**	**Clinical Success n (%)**	**N1**	**Clinical Success n (%)**
Atypical Pathogens	118	109 (92.4)	106	97 (91.5)
Mycoplasma Pneumoniae . . .	70	66 (94.3)	57	50 (87.7)
Chlamydophila Pneumoniae .	28	25 (89.3)	28	25 (89.3)
Legionella Pneumophila	37	35 (94.6)	37	36 (97.3)
Gram-Negative Bacteria (aerobes)	79	67 (84.8)	68	55 (80.9)
Haemophilus Influenzae	32	26 (81.3)	16	16 (100.0)
Haemophilus Parainfluenzae .	18	15 (83.3)	17	13 (76.5)
Klebsiella Pneumoniae	13	10 (76.9)	13	11 (84.6)
Gram-Positive Bacteria (aerobes)	61	52 (85.2)	56	49 (87.5)
Steptococcus Pneumoniae . . .	43	37 (86.0)	34	31 (91.2)
PSSP	26	23 (88.5)	22	21 (95.5)
Macrolide Resistant	10	10 (100.0)	5	5 (100.0)
Stephylococcus Aereus	11	8 (72.7)	11	9 (81.8)

* 10 or More Isolates for Omadacycline

Source: Roman Stets et al. The New England Journal of Medicine; 2019

Neither gastrointestinal side effects nor IV infusion reactions occurred more frequently in the omadacycline arm than in the comparator arm. Cardiovascular signs and symptoms and liver function test abnormalities occurred in both study arms with similar frequency.

This study was recently published in the New England Journal of Medicine (R Stets et al.. Omadacycline for Community-Acquired Bacterial Pneumonia, N Engl J Med 2019; 380:517-527).

Figure 15: TEAEs in CABP Trial

	Omadacycline (N = 382) N (%)	**Moxifloxacin (N = 388) n (%)**
Subjects with at Least One TEAE	157 (41.1)	188 (48.5)
ALT Increased	14 (3.7)	18 (4.6)
Hypertension	13 (3.4)	11 (2.8)
GGT Increased	10 (2.6)	8 (2.1)
Insomnia	10 (2.6)	8 (2.1)
Vomiting	10 (2.6)	6 (1.5)
Constipation	9 (2.4)	6 (1.5)
Nausea	9 (2.4)	21 (5.4)
AST Increased	8 (2.1)	14 (3.6)
Headache	8 (2.1)	5 (1.3)

Source: Roman Stets et al. The New England Journal of Medicine; 2019

Phase III trial – ABSSSI/OASIS-2

Paratek's third Phase III clinical study (OASIS-2) was an oral-only administration of omadacycline in ABSSSI compared to oral-only linezolid. Oral, once daily omadacycline met the FDA-specified primary efficacy endpoint of statistical non-inferiority in the modified intent-to-treat, or mITT, population (10% non-inferiority margin, 95% confidence interval) compared to oral, twice daily linezolid at the early clinical response, or ECR, 48-72 hours after initiation of therapy. The ECR rates for the omadacycline and linezolid treatment arms were 87.5% and 82.5%, respectively. In addition, omadacycline met specified co-primary endpoints for the EMA, which are key secondary endpoints for the FDA. For these endpoints, non-inferiority in the mITT and clinically evaluable populations in at the post treatment evaluation, seven to 14 days after end of treatment, omadacycline demonstrated a high response rate and met statistical non-inferiority to linezolid for both populations using a pre-specified 95% confidence interval. High success rates were observed with response rates of 84.2% (omadacycline) vs. 80.8% (linezolid) and 97.9% (omadacycline) vs. 95.5% (linezolid), respectively.

The most common TEAEs in omadacycline-treated patients (occurring in ≥ 3% of patients) were gastrointestinal adverse events of omadacycline vs. linezolid included: vomiting (16.8% vs. 3.0%), nausea (30.2% vs. 7.6%), diarrhea (4.1% vs. 2.7%). In addition, alanine aminotransferase, or ALT, increase (5.2% with omadacycline vs. 3.0% with linezolid), aspartate aminotransferase increases (4.6% with omadacycline vs. 3.3% for linezolid) and headache (3.5% with omadacycline vs. 2.2% with linezolid). Drug-related TEAEs were 37.8%

for omadacycline vs. 14.2% for linezolid (including gastrointestinal events). Discontinuation for TEAEs was uncommon, 1.6% for omadacycline vs. 0.8% for linezolid. Serious TEAEs occurred in 1.4% of omadacycline patients and 1.4% of linezolid patients; only one serious TEAE was considered related to the study drug and the event occurred in a linezolid patient.

Phase II studies

In a small study (N=111) conducted in cSSSI patients omadacycline showed comparable efficacy and safety to linezolid IV/PO ± aztreonam. However, the design of the Phase II study (and a truncated Phase III study with 68 patients) was no longer consistent with newer FDA guidance issued for ABSSSI in 2008 which required, among other changes, an early efficacy read-out at 48-72 hours.

In addition, this early omadacycline program used a 200 mg oral step-down dose that proved to not be bioequivalent to the 100 mg IV dose. Hence, these data are now considered supportive and cannot be merged easily with the larger pivotal program trials in ABSSSI and CABP that were conducted with FDA guidance and bioequivalent IV to oral step-down dosing.

A Phase II study (IV and oral) in patients with acute pyelonephritis was initiated by Paratek in 2018.

Phase I studies

Omadacycline has been evaluated in multiple Phase I studies, including food-effect, age and gender, and renal/hepatic insufficiency studies.

Omadacycline has a very favorable PK profile. It was absorbed well; its plasma $T\ ^1/_2$ of 14-20 hours permitted once-daily dosing. The drug was not metabolized and drug-drug interactions were minimal. In contrast to other tetracyclines, which paradoxically display dose-dependent increases in protein binding, 80% of omadacycline remained available as free drug. Excretion was via biliary and urinary routes. Data from hepatic and renal impairment studies showed that dose adjustments are not needed for patients with either condition.

In bioequivalence studies, the 300 mg oral dose was found to match the area under the curve of the 100 mg IV dose.

Omadacycline was negative on hERG testing and had no appreciable effect on cardiac conduction in a Thorough QT trial at supra-therapeutic doses. However, in animal tests and during Phase I, a dose-dependent elevation of blood pressure (systolic and diastolic) and heart rate were observed. Omadacycline was found to be an acetylcholine antagonist for muscarinic receptor subtype M2, essentially acting as a vagolytic agent. In subsequent patient studies, these effects were less pronounced or absent and clinically asymptomatic. All Phase II and III studies included systematic cardiovascular pre-and post-dose monitoring of blood pressure and heart rate to further characterize these effects both qualitatively and quantitatively.

An ELF study showed excellent penetration of omadacycline into bronchoalveolar lavage fluid and into alveolar macrophages.

A cystitis (uUTI) study was conducted by Paratek to obtain PK information for different oral dosing regimens of omadacycline.

Our Clinical Trial Designs and Strategy for Omadacycline in the China Market

We have completed the technology transfer stage and discussed with key opinion leaders our planned China development activities in preparation for NMPA interactions. We have submitted documents and filed for an investigational new drug application, or IND, with Chinese medical regulatory authorities in December 2017 and submitted our NDA in December 2019. In May 2020, the NMPA has granted priority review status to our NDA for omadacycline for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

We have actively engaged key opinion leaders in discussions on our planned China development strategy, on our study design in China, and the interpretation or data from the program. We have also completed a bioequivalence study for the oral tablet, which is required by the authority to compare the PK exposures of the locally-manufactured formulation to the formulation used by the licensor. The study has showed that the formulation locally manufactured in China has comparable PK exposures compared to that used by Paratek.

We have completed a microbiology study investigating the activity of omadacycline against pathogens obtained from Chinese and other Asian patients. In this trial of 3,832 isolates, omadacycline activity was essentially identical to the susceptibility results obtained in a larger 2016 surveillance study of 21,000 isolates conducted outside China (mainly in the United States and the European Union). These data have been published in an article titled "Antimicrobial Activity of Omadacycline Tested against Clinical Bacterial Isolates from Hospitals in China, Hong Kong and Taiwan: Results from the SENTRY Antimicrobial Surveillance Program (2013 to 2016)" in Antimicrobial Agents and Chemotherapy 2019 63 (3): e02262-18. doi: 10.1128/AAC.02262-18]. We have also completed a microbiology study against 1,041 more recent patient isolates from China. This study further confirmed the undiminished activity of omadacycline against ABSSSI and CABP pathogens; publication of this data is pending.

We have also conducted a PK study in Chinese patients with both the IV and oral formulation. This study showed similar exposure to Caucasians with the selected dosing regimens for the IV formulation and somewhat higher but well tolerated exposures with the PO formulation. PK/PD analysis suggest that omadacycline IV and PO at standard doses will provide excellent coverage against pathogens from Chinese sources.

We have enrolled 125 patients in an ABSSSI in our clinical efficacy study with linezolid as comparator. Results showed equal clinical efficacy in both treatment arms. Likewise, the safety/tolerability of omadacycline in Chinese patients was excellent. These studies were part of our bridging plan for regulatory approval in China as discussed with regulators. They also were designed, conducted and analyzed in collaboration with Chinese KOLs in PK, microbiology and infectious disease.

We have completed a Phase III study in China to evaluate the efficacy and safety of omadacycline for the treatment of ABSSSI and CABP. In May 2020, the NMPA has granted priority review status to our NDA for omadacycline for the treatment of CABP and ABSSSI.

Durlobactam

Overview

Durlobactam (ZL-2402) is a novel β-lactamase inhibitor of class A, C, and D beta-lactamases. As such it is active against multiple members of the β-lactamases commonly found in Acinetobacter baumannii. In particular, it is a potent inhibitor of several Class D enzymes which confer MDR to many β-lactam antibiotics. In combination with sulbactam, durlobactam reduces the minimum inhibitory concentration, or MIC, against this organism and restores susceptibility to sulbactam. It is being developed by Entasis as SUL-DUR, a combination of durlobactam and sulbactam. The microbiologic efficacy of this combination was demonstrated in large studies of well-characterized MDR Acinetobacter isolates from diverse regions, including Asia. SUL-DUR was bactericidal and active against penem-resistant Acinetobacter organisms. SUL-DUR was synergistic with imipenem, further lowering MICs on in-vitro testing. The FDA has granted SUL-DUR QIDP, Fast Track and Priority Review status.

Durlobactam without sulbactam but in combination with other β-lactams lowered the MICs for E. coli, K. pneumoniae and P. aeruginosa compared to the partner β-lactam antibiotic alone. Entasis has conducted a comprehensive Phase I safety and PK program for durlobactam. Single ascending dose and multiple ascending dose studies showed that durlobactam alone and in combination with sulbactam or imipenem is well tolerated and safe. There were no noticeable drug-drug interactions.

Entasis plans to develop SUL-DUR for the treatment of severe A. baumannii infections. Entasis has finished a Phase II cUTI trial in 2018, reviewed clinical Phase III plans with FDA and started enrollment in the pivotal Phase III trial in MDR Acinetobacter infections in the second half of 2019.

We obtained the exclusive license from Entasis to develop and commercialize durlobactam in China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan in April 2018. For further details of the exclusive license, see "– Overview of Our License and Strategic Collaboration Agreements – Entasis."

Market Opportunity

Background on Acinetobacters

Acinetobacter is one of the most resistant pathogens encountered in clinical practice. It is one of the ESKAPE pathogens, a leading cause of nosocomial infections throughout the world, for which new treatment options are needed as these organisms are MDR to most antibiotics currently available. Approximately 60% of Acinetobacter isolates are carbapenem resistant (so-called CRAB pathogens) and can only be treated with polymyxin, a rather toxic drug, or tigecycline which is often ineffective.

Of great concern, colistin resistance has been reported in recent years, especially from Asia, in E. coli and in K. pneumoniae. So far, there is only scattered report of mcr-1 resistance in Acinetobacter have been reported but the risk is high that chromosomal and – more ominously – plasmid mediated resistance may spread to other bacteria, especially in an environment with high veterinary colistin use like in China. Recent case reports of successful treatment with experimental phage therapy as a last resort when available antibiotics fail. Severe Acinetobacter infections are associated with mortality rates of 50-60% despite intensive medical care. These infections usually present as blood-stream infections or hospital-acquired pneumonia. Less severe infections of the skin and urinary tract are not uncommon.

The frequency of Acinetobacter infections is on the rise world-wide. In the United States and the European Union, the incidence of infection is between 80,000 and 120,000 patients per year in each region. The incidence is higher in the Asia Pacific region and especially in China where the organism ranks among the most frequent isolates in intensive care unit patients. In 2015, over 180,000 infections were reported from China alone. In Japan, over 30,000 cases were reported for 2015, which is an increase of approximately 50% since 2012.

Background on Sulbactam

Sulbactam, a β-lactam derivative, has been in use since the 1980s. It is a IV BLI used in combination with ampicillin, known in the United States as Unasyn and widely used since 1987. It is a β-lactam with a proven safety record. Sulbactam has antibiotic activity of its own, notably against Acinetobacter. However, β-lactamase-mediated resistance to sulbactam has developed and is now common in Acinetobacter.

Durlobactam is a non-β-lactam BLI of the DBO class. It has structural similarities to avibactam, a BLI approved in combination with ceftazidime (Avycaz). However, durlobactam has demonstrated much greater potency against many β-lactamases, especially the Class D OXA enzymes prevalent in Acinetobacter.

Our Clinical Trial Designs and Strategy for Durlobactam in the China Market

We and our partner, Entasis Therapeutics, will cooperate in conducting the trial in China with us taking the operational lead by conducting the screening, enrollment and treatment of patients and coordinating development, registration and commercialization of SUL-DUR in specified countries in the Asia-Pacific region including Japan. In May 2020, the first Chinese patient was enrolled into the global Phase III ATTACK trail of durlobactam for Acinetobacter infections.

Set forth below is a table summarizing the clinical trials disclosed in the following sections headed "Our Marketed Core Products," "Our Oncology Pipeline" and "Our Infectious Disease Pipeline."

Study Code	Official Title	NCT number	Study initiation date
NORA	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Phase III Clinical Trial Evaluating the Efficacy and Safety of ZL-2306 (Niraparib) for Maintenance Treatment in Patients With Platinum-sensitive Relapsed Ovarian Cancer, Fallopian Tube Carcinoma or Primary Peritoneal Cancer (Collectively Referred to as Ovarian Cancer)	NCT03705156	June 2017
NOVA	A Phase 3 Randomized Double-blind Trial of Maintenance With Niraparib Versus Placebo in Patients With Platinum Sensitive Ovarian Cancer	NCT01847274	June 2013

Study Code	Official Title	NCT number	Study initiation date
PRIME.	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Phase III Clinical Trial Evaluating the Efficacy and Safety of ZL-2306 (Niraparib) for Maintenance Treatment in Patients With Advanced Ovarian Cancer, Fallopian Tube Carcinoma or Primary Peritoneal Cancer (Collectively Referred to as Ovarian Cancer) Who Have Achieved Effective Response After First-line Platinum-containing Chemotherapy	NCT03709316	June 2018
PRIMA	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients With Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy	NCT02655016	July 2016
EF-11.	A Prospective, Multi-center Trial of NovoTTF-100A Compared to Best Standard of Care in Patients With Progressive or Recurrent GBM	NCT00379470	September 2006
EF-14.	A Prospective, Multi-center Trial of NovoTTF-100A Together With Temozolomide Compared to Temozolomide Alone in Patients With Newly Diagnosed GBM	NCT00916409	June 2009

Study Code	Official Title	NCT number	Study initiation date
INVICTUS. . .	A Phase 3, Interventional, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Ripretinib In Patients With Advanced Gastrointestinal Stromal Tumors Who Have Received Treatment With Prior Anticancer Therapies	NCT03353753	February 2018
INTRIGUE . .	A Phase 3, Interventional, Randomized, Multicenter, Open-Label Study of DCC-2618 vs Sunitinib in Patients With Advanced Gastrointestinal Stromal Tumors After Treatment With Imatinib	NCT03673501	February 2019
TRIDENT-1 . .	A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients With Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements	NCT03093116	February 2017
SOPHIA.	A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients With HER2+ Metastatic Breast Cancer Who Have Received Prior Anti-HER2 Therapies and Require Systemic Treatment	NCT02492711	August 2015

Study Code	Official Title	NCT number	Study initiation date
MAHOGANY.	Phase 2/3 Trial to Evaluate Margetuximab in Combination With INCMGA00012 and Chemotherapy or MGD013 and Chemotherapy in Patients With Metastatic or Locally Advanced, Treatment-naïve, HER2-Positive Gastric or Gastroesophageal Junction Cancer	NCT04082364	September 2019
FIGHT.	A Phase 2 Randomized, Double-Blind, Controlled Study Evaluating Bemarituzumab (FPA144) and Modified FOLFOX6 in Patients With Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer: Phase 2 Preceded by Dose-Finding in Phase 1	NCT03694522	September 2018
ATTACK	A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients With Infections Caused by Acinetobacter Baumannii-calcoaceticus Complex	NCT03894046	April 2019

Internal Clinical Programs with Global Rights

ZL-1201

ZL-1201 is a humanized, IgG4 monoclonal antibody engineered to reduce effector function, that specifically targets CD47. The emerging clinical data for agents targeting the CD47-SIRPalpha axis continues to look promising. We made modifications to the antibody which may reduce the incidence of hemolysis seen with other agents in the class based on pre-clinical data. CD47 has recently emerged as a novel macrophage immune checkpoint and a promising target for therapeutic intervention. Our pipeline includes several assets, including a novel bi-specific T cell engager and checkpoint inhibitors, that lend themselves to rational combinations with a CD47-targeted therapeutic. The therapeutic potential of these ZL-1201 combinations will be assessed in both solid tumors and hematological malignancies. First-in-human was achieved in June 2020 in the US.

ZL-1102

ZL-1102 is a human nanobody targeting IL-17 with high affinity and avidity. ZL-1102 is being developed for the topical treatment of chronic plaque psoriasis. The role of IL-17 in psoriasis has been confirmed. IL-17 blockers have consistently demonstrated lesion clearance relative to older therapeutics. Despite their unprecedented efficacy, therapy with IL-17 antibodies can result in certain safety issues due to immunosuppression. Labeling therefore restricts their use to more severely affected patient populations. Like other full-size monoclonal antibodies, therapy with IL-17 antibodies have to be administered by IV or SC injection. In contrast, ZL-1102 is smaller molecule designed to be administered topically, thus avoiding significant systemic exposure. As a result of these distinguishing properties, ZL-1102 may have an improved safety and tolerability profile over available biologics targeting IL-17. If confirmed in clinical trials, ZL-1102 could potentially enable treatment of the majority of psoriasis patients, including those with milder disease, and for whom currently available IL-17 inhibitors are not indicated. In July 2020, we achieved first-in-human dosing in the global Phase I study in Australia.

Our Discovery Pipeline

Our in-house discovery team, nearly all of whom hold a PhD degree, is dedicated to the research and discovery of novel therapeutics in the areas of oncology and autoimmune diseases, with a focus on large market opportunities with unmet clinical needs. Our Shanghai research facility was established in 2015 with a focus on internal development of small and large molecule therapeutics and San Francisco, California research facility, established in 2018, focuses on internal discovery. We continue to expand our U.S. presence to enhance internal drug discovery and clinical development, with the opening of a new 20,000 sq.ft research facility in Menlo Park, California. Our current San Francisco-based discovery operations team will move into the Menlo Park research facility and commence operations in second half of 2020. We have collaborations with leading academic institutions in China, Tsinghua University and and Shanghai Institute of Organic Chemistry under the Chinese

Academy of Sciences, to support our in-house research projects. We aim to submit up to two global INDs in 2020. We believe our discovery efforts will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new products and drug candidates for patients around the world.

Our discovery efforts have resulted in the identification of a number of proprietary candidates against targets in our focus areas with high scientific validation including immuno-oncology, DNA damage response/repair and oncogenic signaling. We identify pre-clinical assets through both internal-discovery efforts and co-development collaboration with our business partners. Both ZL-1102 and ZL-1201 are internally-developed drug candidates. As of the Latest Practicable Date, we had achieved FPIs for our internally generated drug candidates, including ZL-1102 in autoimmune diseases and ZL-1201 in oncology. Depending on the Phase I clinical trial results, we may proceed with Phase II clinical trial with promising indications. Our discovery pipeline also includes ZL-1211, ZL-2201 and ZL-2103, which will be potentially developed for the treatment of oncology and/or autoimmune diseases.

Overview of Regulatory Status

The following table summarizes the details of the PRC regulatory status of our products and drug candidates as of the Latest Practicable Date.

Program	Type of Regulatory Application	Status	Date for Obtaining the Current Status	Application Number
ZEJULA	NDA	Approved	2019-12-26 2020-01-20	Original Number (原始編號): 31160076 Acceptance Number (受理號): CXHS180043國 Approval Number (批件號): 2019S00731
	sNDA	Approved	2020-09-08	Acceptance Number (受理號): CXHS2000009
Ripretinib	NDA	Accepted	Accepted: 2020-7-20	JXHS2000121國
Omadacycline . .	CTA	Approved	2018-07-03	Original Number (原始編號): 31170071 Acceptance Number (受理號): CXHL1700339 Approval Number (批件號): 2018L02776
	CTA	Approved	2018-07-03	Original Number (原始編號): 31170070 Acceptance Number (受理號): CXHL1700338 Approval Number (批件號): 2018L02775
	NDA – Priority Review	Accepted	2020-02-07	Acceptance Number (受理號): CXHS2000003國
		Accepted	2020-02-07	Acceptance Number (受理號): CXHS2000002國

Program	Type of Regulatory Application	Status	Date for Obtaining the Current Status	Application Number
Tebotelimab . . .	CTA	Approved	2020-1-20	JXSL1900114
	CTA	Approved	2020-2-10	JXSL1900116
	CTA	Approved	2020-2-10	JXSL1900134
	CTA	Approved	2020-2-10	JXSL1900135
	CTA	Approved	2020-5-6	JXSB2000090
	CTA	Approved	2020-6-2	JXSL2000031
Optune	Approval	Approved	2020-5-11	國械注進20203090269
Repotrectinib . .	CTA	Submitted	2020-8-31	TBD
Odronextamab . .	CTA	Approved	2020-9-7	JXSL2000105 JXSL2000106 JXSL2000107 JXSL2000108 JXSL2000109
Margetuximab . .	CTA	Approved	2020-2-10	JXSL1900113
	CTA	Approved	2020-2-3	JXSL1900115
		Approved	2020-6-3	JYSB2000178
Retifanlimab . . .	CTA	Approved	2020-2-10	JXSL1900119
	CTA	Approved	2020-2-10	JXSL1900118
	CTA	Approved	2020-2-12	JXSL1900140
	CTA	Approved	2020-9-4	JXSL2000083
	CTA	Approved	2020-9-8	JXSL2000087
Bemarituzumab .	CTA	Approved	2018-5-18	JXSL1800003
Durlobactam . . .	CTA	Approved	2019-7-26	JXHL1900112
ZL-1201	CTA	Approved	2020-7-16	CXSL2000096
ZL-1102*	NA	NA	NA	NA

Note:

* We have not yet started regulatory application process in China.

OVERVIEW OF OUR LICENSE AND STRATEGIC COLLABORATION AGREEMENTS

GSK

In September 2016, we entered into a collaboration, development and license agreement with Tesaro (now GSK) under which we obtained an exclusive sublicense under certain patents and know-how that Tesaro (now GSK) licensed from Merck, Sharp & Dohme Corp. ("Merck") and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize GSK's proprietary PARP inhibitor, ZEJULA, in China, Hong Kong and Macau in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). Janssen Biotech, Inc. entered a worldwide collaboration and license agreement with Tesaro (GSK) for exclusive rights to the investigational compound niraparib (ZEJULA) in prostate cancer in April 2016 before we entered the license agreement with Tesaro. We also obtained the right of first negotiation to obtain a license to develop and commercialize certain follow-on compounds of ZEJULA being developed by GSK in our licensed field and licensed territory. Under the agreement, we agreed not to research, develop or commercialize certain competing products and we also granted GSK the right of first refusal to license certain immuno-oncology assets developed by us.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory. We are also responsible for funding all development and commercialization of the licensed products in our licensed territory.

We also agree to take any action or omission reasonably requested by GSK that is necessary or advisable to maintain compliance with the terms of the license agreements between GSK and each of Merck and AstraZeneca UK Limited.

Under the terms of the agreement, we made an upfront payment of US$15.0 million and accrued two development milestone payments in total of US$4.5 million to Tesaro (now GSK). On top of those, if we achieve other specified regulatory, development and commercialization milestones, we may be additionally required to pay further milestone payments of up to US$36.0 million to GSK. In addition, if we successfully develop and commercialize the licensed products, we will pay GSK tiered royalties at percentage rates in the mid-to high-teens on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. In February 2018, we entered into an amendment with GSK to eliminate GSK's option to co-market ZEJULA in the licensed territory.

The agreement with GSK will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy or insolvency or by mutual agreement of the parties. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to GSK. Upon early termination of the agreement, we must grant to GSK an exclusive license under certain of our intellectual property to develop and commercialize the licensed products outside the licensed territory

Novocure

In September 2018, we entered into a license and collaboration agreement with Novocure. Under the terms of the agreement, Novocure exclusively licensed to us the rights to perform clinical studies, sublicensable to affiliates and third parties (subject to Novocure's consent), sell, offer for sale and import Tumor Treating Fields products in the field of oncology, each, a licensed product and collectively, the licensed products, in China, Hong Kong, Macau and Taiwan, or the territory. In partial consideration for the license grant to us for the territory, we paid Novocure a non-refundable, upfront license fee in the amount of US$15.0 million and a milestone payment of US$2.0 million. In addition, we accrued a milestone payment of US$8.0 million. We also agreed to pay certain development, regulatory and commercial milestone payments in total of up to an aggregate of US$68.0 million, and tiered royalties at percentage rates from ten up to the mid-teens on the net sales of the licensed products in the Territory.

We will purchase licensed products exclusively from Novocure at Novocure's fully burdened manufacturing cost. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such licensed product and such region as specified in the agreement. Each party may terminate the agreement upon the material breach of the agreement by the other party, subject to certain cure periods. In addition, we may terminate the agreement for convenience on twelve months' prior notice prior to commercializing a licensed product and on eighteen months' prior notice after commercializing a licensed product, and Novocure may terminate the agreement due to our diligence failure or material FCPA violation, subject to certain cure periods and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the agreement.

Deciphera

In June 2019, we entered into a license agreement with Deciphera. Under the terms of the agreement, Deciphera exclusively licensed to us the rights to perform clinical studies, sublicenseable to affiliates without Deciphera's consent and third parties (subject to Deciphera's consent), sell, offer for sale and import ripretinib, a licensed product, in the field of the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in China, Hong Kong, Macau and Taiwan. In partial consideration for the license grant to us for the territory, we paid Deciphera a non-refundable, upfront license fee in the amount of US$20.0 million and one milestone payment of US$5.0 million. In addition, we

accrued a milestone payment of US$2.0 million. We also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of US$178.0 million, and tiered royalties at percentage rates from low-to high-teens on the net sales of the licensed products in the territory.

We will purchase the licensed products exclusively from Deciphera at a certain mark up of Deciphera's fully burdened manufacturing cost. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such licensed product and such region as specified in the agreement. Each party may terminate the agreement upon the material breach of a material term of the agreement by the other party, subject to the ability to cure. In addition, we may terminate the agreement for convenience on 180 days' prior notice, and Deciphera may terminate the agreement due to our patent challenge against certain Deciphera's patents, subject to the ability to cure and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the agreement. In January 2020, we entered into an amendment with Deciphera to clarify several operational matters.

Regeneron

In April 2020, we entered into a strategic collaboration with Regeneron for the development and exclusive commercialization of odronextamab in oncology in mainland China, Hong Kong, Taiwan and Macau, or the territory. We can also sublicense such rights to affiliates and third parties (subject to Regeneron's consent). In partial consideration for the rights grant to us for the territory, we paid Regeneron a non-refundable, upfront fee in the amount of US$30 million. We also agreed to pay certain regulatory and commercial milestone payments of up to US$160 million, as well as royalties based on a percentage of net sales of odronextamab in the territory.

We will purchase odronextamab exclusively from Regeneron at Regeneron's fully burdened manufacturing cost. The agreement continues in effect after the date of the agreement and until, unless earlier terminated, such time when we have ceased development and commercialization activities on odronextamab for six consecutive months (other than due to a delay by Regeneron or a regulatory authority).

Turning Point

In July 2020, we entered into an exclusive license agreement with Turning Point Therapeutics, Inc., or Turning Point. Under the terms of the exclusive license agreement, Turning Point exclusively licensed to us the rights to develop and commercialize products containing repotrectinib (licensed products), in China, Hong Kong, Macau and Taiwan, or the territory. In partial consideration for the license grant to us for the territory, we will pay Turning Point an upfront licensee fee in the amount of US$25 million, with potential for

Turning Point to receive up to an additional US$151 million in development, regulatory and sales-based milestone payments. We also agreed to pay mid-to-high teen royalties based on annual net sales of licensed products in the territory.

Under the exclusive license agreement, we are responsible for funding all development and commercialization activities related to the products in our licensed territory, subject to certain exceptions pursuant to which Turning Point may be responsible for the cost. Turning Point will be responsible for funding global clinical studies of the licensed products. The agreement continues in effect until expiration of the last royalty term for a licensed product in any region in the licensed territory, where the royalty term for a licensed product in a region continues until the later of (i) the date of the last-to-expire valid claim within Turning Point's patent rights that covers the licensed product in such region in the licensed territory; (ii) the expiry of the regulatory exclusivity for such licensed product in such region; or (iii) the close of business of the day that is exactly 10 years after the date of the first commercial sale of such licensed product in such region. In addition, we may terminate the agreement for convenience by providing written notice to Turning Point, which termination will be effective following a prescribed notice period. Turning Point may terminate the agreement under specified circumstances if we or certain other parties challenge its patent rights. Either party may terminate the agreement for the other party's uncured material breach of the agreement, with a customary notice and cure period, for the other party's insolvency or if the other party is acquired in a change of control transaction and the acquirer is engaged in activities with a competing product that is not divested or discontinued within a specified period.

MacroGenics

In November 2018, we entered into a collaboration agreement with MacroGenics. Under the terms of the collaboration agreement, MacroGenics exclusively licensed to us regional development and commercialization rights to margetuximab, tebotelimab and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, or the TRIDENT molecule, and, together with margetuximab and tebotelimab, each, a licensed product, in China, Hong Kong, Macau and Taiwan, or the territory. In partial consideration for the license grant to us for the territory, we paid MacroGenics a non-refundable, upfront license fee in the amount of US$25.0 million and two milestone payments in total of US$4.0 million. We also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of US$136.0 million, and tiered royalties at percentage rates of mid-teens to 20% for net sales of Margetuximab in the territory, mid-teens for net sales of tebotelimab in the territory and 10% for net sales of TRIDENT molecule in the territory.

As part of the collaborative clinical development effort, we and MacroGenics intend to initiate a global study using combination regimens containing margetuximab in order to maximize potential clinical benefit in gastric cancer, the fifth most common cancer in the world and the second most common in China.

The collaboration agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our payment obligations applicable to such licensed product and such region as specified in the collaboration agreement. Each party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party, subject to certain cure periods. In addition, at any time after November 29, 2020, we may terminate the collaboration agreement for convenience with prior notice to MacroGenics. MacroGenics may terminate the collaboration agreement in its entirety or on a licensed product-by-licensed product basis with prior notice if one or more major safety issues have occurred with respect to such licensed product prior to the first commercial sale of such licensed product in the territory and MacroGenics has discontinued the global development, manufacturing and commercialization activities with respect to such licensed product.

Incyte

In July 2019, we entered into a collaboration and license Agreement with Incyte. Under the terms of the agreement, Incyte exclusively licensed to us the rights to perform clinical studies, sublicenseable to affiliates in China, Hong Kong, Macau and Taiwan without Incyte's consent and other affiliates and third parties (subject to Incyte's consent), sell, offer for sale and import retifanlimab (PD-1) in the field of the treatment, palliation, diagnosis or prevention of diseases in the fields of hematology or oncology in humans in China, Hong Kong, Macau and Taiwan. In partial consideration for the license grant to us for the territory, we paid Incyte a non-refundable, upfront license fee in the amount of US$17.5 million. We also agreed to pay certain development, regulatory and commercial milestone payments of up to an aggregate of US$60.0 million, and tiered royalties at percentage rates from low-to high-twenties on the net sales of retifanlimab (PD-1) in China, Hong Kong, Macau and Taiwan.

We will purchase licensed products exclusively from Incyte at Incyte's fully burdened manufacturing cost. The agreement continues, on a region-by-region and Licensed Product-by-Licensed Product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such Licensed Product and such region as specified in the agreement. Each party may terminate the agreement upon the material breach of a material term of the agreement by the other party, subject to the ability to cure. In addition, we may terminate the agreement for convenience on 60 days' prior notice, and Incyte may terminate the agreement due to our development or commercialization diligence failures, subject to the ability to cure and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the agreement.

Five Prime

In December 2017, we entered into a license and collaboration agreement with Five Prime, under which we obtained exclusive rights to develop and commercialize Five Prime's proprietary afucosylated FGFR2b antibody known as bemarituzumab (FPA144), and all fragments, conjugates, derivatives and modifications thereof in China, Hong Kong, Macau and Taiwan, or the licensed territory.

We are responsible for (i) developing and commercializing licensed products under a territory development plan (ii) performing certain development activities to support Five Prime's global development and registration of licensed products, including Five Prime's global Phase III registrational trial of bemarituzumab (FPA144) in combination with FOLFOX in front-line gastric and gastroesophageal cancer, or the bemarituzumab (FPA144)-004 Study, in the licensed territory under a global development plan.

Under the terms of the agreement, we made an upfront payment of US$5.0 million and a milestone payment of US$2.0 million to Five Prime. Additionally, we may be required to pay further development and regulatory milestone payments of up to an aggregate of US$37.0 million to Five Prime.

We are also be obligated to pay Five Prime a royalty, on a licensed product-by-licensed product and region-by-region basis, in the high teens or low twenties, depending on the number of patients we enroll in the bemarituzumab (FPA144)-004 study, subject to reduction in certain circumstances, on net sales of each licensed product in the licensed territory until the latest of (i) the 11th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region.

Under the terms of the agreement, provided that we enroll and treat a specified number of patients in the bemarituzumab (FPA144)-004 study in China, we are eligible to receive a low single-digit percentage royalty, on a licensed product-by-licensed product basis on net sales of a licensed product outside the licensed territory until the 10th anniversary of the first commercial sale of each such licensed product outside the licensed territory.

Unless earlier terminated by either party, the agreement will expire on a licensed product-by-licensed product and region-by-region basis upon the expiration of our payment obligations with respect to each licensed product under the agreement. We may terminate the agreement in its entirety at any time with advance written notice. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. Five Prime may terminate the agreement in its entirety with written notice for the material breach of our diligence obligations with respect to development and obtaining marketing approval, and may terminate the agreement on a region-by-region basis for the breach of our diligence obligations with respect to timely commercialization of a licensed product in a region following marketing approval. Five Prime may terminate the agreement in its entirety if we or one of our affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of Five Prime's patents in the licensed territory. Either party also may terminate the agreement in its entirety upon certain insolvency events involving the other party.

Paratek

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda Ltd., a subsidiary of Paratek, under which we obtained both an exclusive license under certain patents and know-how of Paratek Bermuda Ltd. and an exclusive sub-license under certain intellectual property that Paratek Bermuda Ltd. licensed from Tufts University to develop, manufacture, use, sell, import and commercialize omadacycline (ZL-2401) in China, Hong Kong, Macau and Taiwan, or licensed territory, in the field of all human therapeutic and preventative uses other than biodefense, or the licensed field. Under certain circumstances, our exclusive sub-license to certain intellectual property Paratek Bermuda Ltd. licensed from Tufts University may be converted to a non-exclusive license if Paratek Bermuda Ltd.'s exclusive license from Tufts University is converted to a non-exclusive license under the Tufts Agreement. We also obtained the right of first negotiation to be Paratek Bermuda Ltd.'s partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek Bermuda Ltd. retains the right to manufacture the licensed product in our licensed territory for use outside our licensed territory. We also granted to Paratek Bermuda Ltd. a non-exclusive license to certain of our intellectual property for Paratek Bermuda Ltd. to develop and commercialize licensed products outside of our licensed territory. Under the agreement, we agreed not to commercialize certain competing products in our licensed territory. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory, including making certain regulatory filings within a specified period of time.

Under the terms of the agreement, we made an upfront payment of US$7.5 million and two milestone payments in total of US$8.0 million to Paratek Bermuda Ltd. and we may be required to pay further milestone payments of up to an aggregate of US$46.5 million to Paratek Bermuda Ltd. for the achievement of certain development and sales milestone events. In addition, we will pay to Paratek Bermuda Ltd. tiered royalties at percentage rates in the range of low-to mid-teens on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The agreement with Paratek Bermuda Ltd. will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to Paratek Bermuda Ltd. Paratek Bermuda Ltd. has the right to terminate the agreement if we challenge its patents. Upon termination of the agreement, our license of certain intellectual property to Paratek Bermuda Ltd. will continue for Paratek Bermuda Ltd. to develop and commercialize licensed products worldwide.

Entasis

In April 2018, we entered into a collaboration and license agreement with Entasis under which we obtained exclusive rights to develop and commercialize Entasis' proprietary compounds known as durlobactam and SUL-DUR, with the possibility of developing and commercializing a combination of such compounds with Imipenem, in China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan, or the territory. Our rights to develop and commercialize the licensed products are limited to the lead product (SUL-DUR) until such product receives FDA approval in the U.S.

Under the terms of the agreement, we are responsible for (i) developing and commercializing the licensed products in the territory under a mutually agreed development plan and (ii) providing Entasis (or its CRO) with clinical and financial support in the territory for the global pivotal Phase III clinical trial of SUL-DUR as set forth in mutually agreed development plans.

We made an upfront payment of US$5.0 million and two development milestone payments of US$7.0 million to Entasis. Additionally, we may be required to pay Entasis development, regulatory and research milestone payments (other than existing ones) and commercial milestone payments of up to an aggregate of US$91.6 million. We are also responsible for a portion of the costs of the global pivotal Phase III clinical trial of SUL-DUR outside of the territory.

We are also obligated to pay Entasis a royalty based on a percentage of net sales of licensed products ranging from the high single digits to low teens, depending on the amount of net sales of licensed products in the territory, subject to reduction in certain circumstances, until, with respect to a licensed product in a region in the territory, the latest of (i) the 10th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region.

Unless earlier terminated by either party, the agreement will expire on a country-by-country basis upon the expiration of our payment obligations applicable to such country under the agreement. We may terminate the agreement in its entirety at any time with advance written notice. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. Entasis may terminate the agreement on a country-by-country basis if we cease to commercialize the licensed products in such country for a certain period of time. Entasis may terminate the agreement in its entirety if we or one of our affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of Entasis's patents in the licensed territory. Either party also may terminate the agreement in its entirety upon certain insolvency events involving the other party.

Bristol-Myers Squibb

In March 2015, we entered into a license agreement with BMS, under which we obtained an exclusive license under certain patents and know-how of BMS to develop, manufacture, use, sell, import and commercialize BMS's proprietary multi-targeted kinase inhibitor, brivanib in China, Hong Kong and Macau, or the licensed territory, in the field of diagnosis, prevention, treatment or control of oncology indications, or licensed field, with the exclusive right to expand our licensed territory to include Taiwan and Korea under certain conditions. BMS retains the non-exclusive right to use the licensed compounds to conduct internal research and the exclusive right to use the licensed compounds to manufacture compounds that are not brivanib. Under the agreement, we agreed not to develop and commercialize certain competing products for specified time periods.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory. BMS has the option to elect to co-promote the licensed products in our licensed territory. If BMS exercises its co-promotion option, BMS will pay us an option exercise fee and we will share equally with BMS the operating profits and losses of the licensed products in our licensed territory.

If BMS does not exercise its co-promotion option, we may be required to pay BMS milestone payments for the achievement of certain development and sales milestone events of up to an aggregate of US$114.5 million, and also tiered royalties at percentage rates in the mid-to high-teens on the net sales of the licensed products in our licensed territory, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the twelfth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

We also have the right to opt-out of the commercialization of the licensed products in our licensed territory under certain conditions. If we elect to opt-out, BMS will have the right to commercialize the licensed products in our licensed territory and will pay us royalties on the net sales of the licensed products in our licensed territory.

BMS has the option to use the data generated by us from our development of the licensed products to seek regulatory approval of the licensed products outside our licensed territory, and if BMS exercises such option, BMS will be obligated to make certain payments to us, including upfront, milestone and royalty payments.

The agreement with BMS will remain in effect until the expiration of all payment obligations, and may be earlier terminated by either party for the other party's uncured material breach, safety reasons or failure of the development of the licensed products. In addition, we have the right to terminate the agreement for convenience after a certain specified time period upon advance notice to BMS. BMS may also terminate the agreement for our bankruptcy or insolvency.

INTELLECTUAL PROPERTY

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates and our core technologies and other know-how to operate without infringing, misappropriating or otherwise violating on the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We expect that we will seek to protect our proprietary and intellectual property position by, among other methods, licensing or filing our own U.S., international and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties. As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

Patents

Patents, patent applications and other intellectual property rights are important in the sector in which we operate. We consider on a case-by-case basis filing patent applications with a view to protecting certain innovative products, processes, and methods of treatment. We may also license or acquire rights to patents, patent applications or other intellectual property rights owned by third parties, academic partners or commercial companies which are of interest to us. For the internally developed drug candidates, we identify patents through both self-development effort and joint-development through collaboration with business partners such as academic institutions. We have global rights with respect to the patents identified through self-development effort, and we will be automatically granted with global rights with respect to the patents identified through joint-development efforts upon business partners' transfer of such patents to us under the terms of collaboration agreement.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our drug candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive or license in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of our patents and patent applications over third-party patents and patent applications. In addition, because of the extensive time required for clinical development and regulatory review of a drug candidate we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following

commercialization, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information regarding the risks related to our intellectual property, please see "Risk Factors – Risks Related to Intellectual Property."

ZEJULA

As of June 30, 2020, we exclusively licensed two issued patents in China directed to ZEJULA's free base compound, and salts thereof, and analogues of ZEJULA. These issued patents are projected to expire between 2027 and 2028. We also exclusively licensed one pending patent application in China directed to a salt that covers 4-methylbenzenesulfonate monohydrate, the API of ZEJULA. If this patent application issues as a patent, such patent will be projected to expire in 2029. Besides, we also exclusively licensed one pending patent application in China directed to methods of treating ovarian cancer. If this patent application issues as a patent, such patent will be projected to expire in 2037. We have filed an application in China and a PCT application that cover intermediate synthesis process. The claims in the Chinese application had been allowed, and the PCT application has entered into the United States, the European Union, Israel, Japan, Korea and India. We own this PRC application and the PCT application.

Tumor Treating Fields

As of June 30, 2020, we licensed eight issued patents in China and one issued patent in Hong Kong that relate to Tumor Treating Fields. Additional patent applications that relate to Tumor Treating Fields are pending, including five in China and in Hong Kong. We are pursuing patent rights to protect our rights in these technologies and has continued our efforts to secure patent rights in China for our devices and technologies for applying electric fields to a patient for treating a disease or condition, especially diseases that promote tumor growth.

Ripretinib

As of June 30, 2020, we exclusively licensed one issued patent and two pending patent applications in China as well as one issued in Hong Kong directed to dihydronaphthyridines, the API of ripretinib. These issued patent and pending patent applications are projected to expire by 2032. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong, Macau or Taiwan.

Odronextamab

As of June 30, 2020, we exclusively licensed two issued patents in China, one issued patent in Hong Kong, five issued patents in Taiwan. These issued patents are directed to CD3/CD20 bispecific antibody odronextamab, and are projected to expire between 2030 and 2034. We have also exclusively licensed four pending patent applications in China, three pending patent applications in Hong Kong and two pending patent applications in Taiwan that relate to methods of tumor treatment using CD3/CD20 bispecific antibody and related

combination therapy. If issued, claims of these patent applications are projected to expire between 2035 and 2037. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong, Macau and Taiwan.

Repotrectinib

As of June 30, 2020, we exclusively licensed one issued patent and two pending patent applications in China, one issued patent and two pending patent applications in Hong Kong, one issued patent and one pending patent application in Taiwan. These issued patents or pending applications are directed to Repotrectinib, and are projected to expire in 2025. We have also exclusively licensed three pending patent applications in China, three pending patent applications in Hong Kong and one pending patent application in Taiwan, that relate to chiral diaryl macrocycles, diaryl macrocycles polymorph, the use thereof and combination therapy involving diaryl macrocyclic compounds. If issued, claims of these patent applications are projected to expire between 2037 and 2038. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong, Macau or Taiwan.

Margetuximab

As of June 30, 2020, we exclusively licensed two pending patent applications in China and one issued patent in Hong Kong. The pending patent applications in this portfolio cover antibody sequences and therapeutic uses of margetuximab. The issued patent in Hong Kong that we exclusively licensed is projected to expire in 2029.

Retifanlimab

As of June 30, 2020, we exclusively licensed two pending patent applications in China, one issued patent and one pending patent application in Taiwan and one pending patent application in Hong Kong directed to the API of retifanlimab (PD-1). If these patent applications issue as patents, such patents will be projected to expire in 2036 to 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong, Macau or Taiwan.

Tebotelimab

As of June 30, 2020, we exclusively licensed four pending patent applications in China, three pending patents in Hong Kong, and two issued patents and one pending patent application in Taiwan. The pending patent applications in this portfolio cover antibody sequences and therapeutic uses of tebotelimab. The issued patents that we exclusively licensed are projected to expire between 2035 and 2036.

Bemarituzumab

As of June 30, 2020, we exclusively licensed one issued patent in China and two issued patents in Hong Kong. These issued patents are directed to certain anti-FGFR2b antibodies, and are projected to expire in 2029. We have also exclusively licensed one pending patent application in China, two issued patents in Taiwan, one issued patent in Hong Kong. The issued patents that we exclusively licensed are projected to expire in 2034. Besides, we also exclusively licensed one pending patent applications in China and one pending patent applications in Taiwan directed to anti-FGFR2b antibodies in combination with immune stimulating agents in cancer treatment. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong, Macau and Taiwan.

Omadacycline

As of June 30, 2020, we exclusively licensed four issued patents in China directed to omadacycline's compound, formulations and crystal form and two pending patent applications in China directed to other crystalline forms of omadacycline. The issued composition of matter patent covering omadacycline is projected to expire in 2021 and the other three issued patents are projected to expire in 2029. We have also exclusively licensed one issued patent in Hong Kong and two issued patents in Taiwan, respectively that cover a crystalline salt form of omadacycline, which expire in 2029. We have also exclusively licensed four pending patent applications in China, three pending patent applications in Hong Kong and three pending patent applications in Taiwan, respectively that relate to different methods of treatment related to omadacycline. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong, Macau and Taiwan.

Durlobactam

As of June 30, 2020, we exclusively licensed one issued patent in China, one issued patent in Japan, and one corresponding issued patent or pending patent application in each of several additional jurisdictions in the territory covered by our agreement with Entasis, including Hong Kong, Taiwan and Korea. These issued patents or pending applications are directed to certain beta-lactamase inhibitor compounds, and are projected to expire in 2033. We have also exclusively licensed a second family of patent applications with three issued applications in China, Hong Kong and Australia and two pending patent applications in Taiwan and Korea. If issued, claims of these patent applications are projected to expire in 2035. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the territory of the Entasis Agreement.

Brivanib

As of June 30, 2020, we exclusively licensed four issued patents in China and one issued patent in Hong Kong that relate to brivanib. Of these issued patents, two patent in China are composition-of-matter patents that cover the brivanib compound and its analogues, and are projected to expire in 2023. Our exclusively licensed patents also include a patent in China that covers a manufacturing process for intermediates useful in the synthesis of brivanib's API. This patent is projected to expire in 2027. In addition, one patent we exclusively licensed in China covers a crystal form of brivanib alaninate and is projected to expire in 2026. The issued patent in Hong Kong that we exclusively licensed is projected to expire in 2023. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than China, Hong Kong and Macau.

The following table summarizes the details of the granted material patents and filed material patent applications in connection with our products and drug candidates.

Summary of granted material patents and filed material patent applications of our products and drug candidates

Product/Drug Candidate	Scope of Patent Protection	Jurisdiction (Country/Region)	Status	Commercial Rights of Zai Lab
ZEJULA	Directed to structure and its use	China and Hong Kong	Granted	Exclusive license to develop and commercialize in China, Hong Kong and Macau
	Directed to salts and their use	China	Pending	
	Directed to preparation process	United States, Japan, Europe, India, Israel and Korea	Pending	Owned by Zai Lab
		China	Granted	
Tumor Treating Fields	Directed to device and its use	China and Hong Kong	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
	Directed to detection method		Pending	
Ripretinib	Directed to structure and its use	China and Hong Kong	Granted	License to develop and commercialize in China, Hong Kong, Macau and Taiwan
Odronextamab . .	Directed to structure and its use	Taiwan	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
		China and Hong Kong	Pending	
	Directed to combination therapy	China	Pending	
Repotrectinib . .	Directed to structure and its use	China, Hong Kong and Taiwan	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
		Macau	Pending	
	Directed to polymorph and its use	China and Hong Kong	Pending	
	Directed to combination therapy	China, Hong Kong and Taiwan	Pending	
Margetuximab . .	Directed to structure and its use	Hong Kong	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
		China	Pending	

Product/Drug Candidate	Scope of Patent Protection	Jurisdiction (Country/Region)	Status	Commercial Rights of Zai Lab
Retifanlimab . . .	Directed to structure and its use	Taiwan	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
		China and Hong Kong	Pending	
Tebotelimab . . .	Directed to structure and its use	Taiwan	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
		China and Hong Kong	Pending	
Bemarituzumab .	Directed to structure and its use	China and Hong Kong	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
Omadacycline . .	Directed to structure and its use	China, Hong Kong and Taiwan	Granted	Exclusive license to develop and commercialize in China, Hong Kong, Macau and Taiwan
	Directed to formulation and its use	China	Granted	
	Directed to salts and polymorphs and their use	China, Hong Kong, Macau and Taiwan	Granted	
	Directed to preparation process	China	Pending	
		Hong Kong	Granted	
Durlobactam . .	Directed to structure and its use	New Zealand and Singapore	Pending	Exclusive license to develop and commercialize in China, Hong Kong, Macau, Taiwan, South Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan
		China, Hong Kong, South Korea and Taiwan	Granted	
	Directed to combination therapy	China, South Korea, Japan, Taiwan, the Philippines and Singapore	Pending	
		Hong Kong and Australia	Granted	
Brivanib	Directed to structure and its use	China and Hong Kong	Granted	Exclusive license to develop and commercialize in China, Hong Kong and Macau
	Directed to crystalline forms and its use	China	Granted	
	Directed to preparation process	China	Granted	

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions that we principally operate in, a patent term is 20 years from the earliest filing date of a non-provisional patent application. Under China Patent Law, the term of patent protection starts from the date of application. Patents relating to inventions are effective for twenty years, and utility models and designs are effective for ten years from the date of application.

The laws of each jurisdiction vary, and patent term adjustment or patent term extension may not be available in any or all jurisdictions in which we own or license patents. For example, there are currently no patent term adjustments or patent term extensions available for issued patents in China. However, the government recently announced a proposal which is under consideration to allow a five-year patent term extension for innovative drugs if they will be concurrently reviewed for marketing authorizations in and outside China.

As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

Trade Secrets

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. For more information regarding the risks related to our trade secrets, please see "Risk Factors – Risks Related to Intellectual Property – If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed."

Trademarks and domain names

We conduct our business using trademarks with various forms of the "ZAI LAB" and "再鼎医药" brands, as well as domain names incorporating some or all of these trademarks.

RESEARCH AND DEVELOPMENT

We believe research and development is critical to our future growth and our ability to remain competitive in the biopharmaceutical market in China. We are dedicated to discover or license, develop and commercialize proprietary therapeutics that address areas of large unmet medical need in the China and global markets, including in the fields of oncology, infectious and autoimmune diseases.

We have built an integrated drug discovery and development platform that aims to bring both in-licensed and internally-discovered medicines to patients in China and globally. We have assembled an in-house research and development team with nearly 400 dedicated personnel who have extensive experience from discovery, translational medicine to late stage development. Our in-house research and development team had previously been directly involved in the discovery and development of several innovative drug candidates at Hutchison Medi-Pharma, including fruquintinib and savolitinib. Our in-house research and development team focuses on the development of innovative therapeutics for the treatment of oncology and autoimmune diseases. We believe our discovery efforts will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new products and

drug candidates for patients around the world. This effort has resulted in the identification of a number of proprietary candidates against targets in our focus areas that include immuno-oncology, DNA damage response/repair and oncogenic signaling that we are moving into pre-clinical development. Our company has a leadership team with extensive pharmaceutical research, development and commercialization track records in both global and Chinese biopharmaceutical companies. We believe this team and our in-house discovery and development capabilities will enable us to achieve our long-term goal of commercializing our internally discovered innovative medicine for patients worldwide. In addition, we collaborate with external research partners, such as leading CROs, academic institutions and commercial partners. We contract with these parties for execution of our pre-clinical and clinical trials. For details, see "– Suppliers."

For the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, our research and development expenses were US$120.3 million, US$142.2 million and US$102.0 million, respectively.

Clinical Development

We believe clinical development capabilities are critical to success in our industry. We have built internal clinical development capabilities, which we believe provide a competitive advantage over other biopharmaceutical companies in China. As of the Latest Practicable Date, we had 244 clinical development staff. Led by our experienced in-house clinical development team, we had more than over 25 ongoing or planned clinical trials in China, the United States and Australia across over 20 indications, as of the Latest Practicable Date. We believe that the global experience and local expertise of our clinical development team enables us to take advantage of significant regulatory reforms in China by integrating China and global clinical development.

Highlights of Our Research Efforts

The scope of research that we are permitted to conduct with respect to the in-licensed drug candidates is subject to the terms of respective license agreement. For example, with respect to ZEJULA, we have the right to develop ZEJULA for treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer) in China, Hong Kong and Macau, which allows us to conduct a combination trial with tebotelimab in patients with advanced or metastatic gastric cancer who failed prior treatment. Janssen Biotech, Inc. entered a worldwide collaboration and license agreement with Tesaro (GSK) for exclusive rights to the investigational compound niraparib (ZEJULA) in prostate cancer in April 2016 before we entered the license agreement with Tesaro (GSK). To the extent further research and/or development is permitted under respective license agreement, we typically evaluate academic and/or industry research, pre-clinical and clinical results and rationale for clinical pharmacology to explore the possibility of treatment for diseases or conditions other than those that are being studied, or conducting combination trials with or among our drug candidates. For instance, we believe tebotelimab together with brivanib has the potential to treat HCC patients in China, given the relative high prevalence of HCC in China, and merits further clinical trials.

As our late-stage drug candidates had been in clinical development outside of China at the time when we in-licensed from our business partners, we have primarily focused our R&D on the clinical development of these drug candidates since the in-licensing. Typically, we formulate clinical development plans and clinical protocols that consider the characteristics of the Chinese population and clinical practices in China. We also investigate candidate hospitals to evaluate their suitability as potential clinical sites. To ensure consistency in clinical trial operations, we organize training sessions to educate potential investigators about clinical protocols. Below are select highlights of our research and/or clinical studies that we are conducting with respect to our late-stage drug candidates.

ZEJULA

- In May 2018, we completed enrollment ahead of schedule for our Phase I pharmacokinetics, or PK, study for Chinese patients with platinum-sensitive ovarian cancer. In August 2018, we completed our PK study for Chinese patients with platinum-sensitive ovarian cancer, which demonstrated a comparable efficacy profile to studies in non-Chinese patients.

- We initiated the Phase III study of ZEJULA (NORA Trial) in patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy in September 2017 and completed NORA Trial in July 2020, at which time we completed the study report. The NORA trial met all primary and secondary endpoints with improved safety profile in Chinese patients. The full results from the NORA study will be presented at European Society for Medical Oncology (ESMO) 2020 Virtual Congress on September 19, 2020. We have obtained the NMPA approval for ZEJULA as treatment for patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy.

- We dosed the first patient in registrational bridging trial for late-line ovarian cancer treatment in August 2020.

- On September 8, 2020, the NMPA approved our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

- In February 2020, we dosed the first patient in the Phase Ib dose escalation and expansion clinical study of ZEJULA in China, in combination with tebotelimab, for the treatment of patients with advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma (collectively as gastric cancer) who failed prior treatment.

- We plan to initiate additional indications and combinations for niraparib in collaboration with our partner GSK.

Tumor Treating Fields

- We have obtained MAA approval from NMPA for GBM without the need of a clinical trial.

- We plan to file MAA for mesothelioma in China in first half of 2021.

- We are collaborating with Novocure in a pilot Phase II study aimed to evaluate the efficacy and safety of Tumor Treating Fields concomitant with chemotherapy as first-line treatment of unresectable gastroesophageal junction or gastric adenocarcinoma initiated in Greater China.

- We are preparing to join global Phase III pivotal trials in non-small cell lung cancer, brian metastases and locally advanced pancreatic cancer in Greater China by early 2021.

- We are in the planning phase for clinical trials in liver cancer and ovarian cancer in Greater China.

Ripretinib

- We have completed patient enrollment for a bridging study to evaluate the safety, tolerability, and efficacy of ripretinib in patients with fourth-line GIST (i.e. with GIST who have received at least three prior lines of treatment) in China. We have submitted NDA to the NMPA based on the study results, which is under priority review.

- We have commenced a bridging study of ripretinib to assess efficacy, safety and pharmacokinetics in patients with second-line GIST (i.e. with GIST who was treated with imatinib) in China. Our CTA for the China bridging study has been approved by the NMPA.

- We are in the planning phase for clinical trials in systemic mastocytosis in China.

Odronextamab

- We are exploring regulatory approval pathways for odronextamab in R/R B-NHL in China by joining the global Phase II program with multiple, potentially registrational cohorts of different subtypes of R/R B-NHL.

- We have submitted Phase II pivotal CTA to the NMPA and plan to enroll the first Chinese patient into the potentially registrational global Phase II study by early 2021.

Repotrectinib

- We have submitted Phase II registrational CTA and anticipate opening additional sites in China to join the global TRIDENT-1 Phase II registrational clinical study of repotrectinib. TRIDENT-1 is an ongoing Phase I/II trial for the treatment of patients with *ROS1*+ advanced NSCLC and patients with *NTRK*+ advanced solid tumors.

Margetuximab

- We are conducting and dosed the first patient in a potentially registration enabling Phase II bridging trial study to evaluate the efficacy and safety of margetuximab plus chemotherapy head-to-head compared with trastuzumab plus chemotherapy in Chinese patients (Mainland China, Hong Kong and Taiwan) with advanced HER2+ breast cancer who have received at least two prior lines of anti-HER2 directed therapy in the metastatic setting and such prior lines of therapy must include trastuzumab (Herceptin) treatment.

- We expect to enroll the first Chinese patient in second half of 2020 in MacroGenics sponsored Phase II/III global studies of margetuximab (MAHOGANY) in combination with retifanlimab (PD-1) or tebotelimab (PD-1 x LAG-3) in the front-line treatment of HER2+ gastric cancer.

Tebotelimab

- In February 2020, we dosed the first patient in an open-label, single-arm, multicenter, Phase Ib dose escalation and expansion clinical study to assess the safety and antitumor activity of ZEJULA, in combination with tebotelimab, in patients with advanced or metastatic gastric cancer who failed prior treatment.

- We are conducting a Phase I/II dose escalation and expansion clinical study in China to evaluate the safety and efficacy of tebotelimab as monotherapy and in combination with brivanib in patients with advanced liver cancer.

- We expect to enroll Chinese patients in second half of 2020 in Phase II/III global MAHOGANY study of margetuximab in combination with retifanlimab or tebotelimab in gastric cancer sponsored by MacroGenics in HER2+ first line treatment of gastric cancer and to initiate MAHOGANY Cohort B in Greater China.

- We have obtained CTA in June 2020 and are conducting a Phase I (proof of concept) clinical trial for second-line melanoma in Greater China.

- We have obtained Phase I CTA approval in January 2020 and intend to enroll the first Chinese patient in the second half of 2020 for tebotelimab into its global Phase I basket trial sponsored by MacroGenics.

Retifanlimab

- We have also obtained Phase III CTA approval and plan to enroll the first Chinese patient into the Incyte-sponsored global Phase III study of retifanlimab with platinumbased chemotherapy in first-line metastatic squamous and nonsquamous non-small cell lung cancer in second half of 2020.

- Our CTA application for Phase II confirmatory study has been accepted for second-line MSI-high endometrial cancer. We plan to enroll the first Chinese patient into the Incyte-sponsored global Phase I/II potentially registration-enabling study in second half of 2020.

Bemarituzumab

- Our partner, Five Prime, announced the FIGHT trial has been converted to a Phase II randomized, double-blind trial, based on the approximately 150 patients enrolled. The Phase II FIGHT study is expected to generate clinical data to inform the further development strategy of bemarituzumab by the end of the year or early 2021. We have halted the enrollment in China, and will wait for our partner to provide further guidance.

Omadacycline

- We have completed a Phase III bridging study in China to evaluate the efficacy and safety of omadacycline for the treatment of ABSSSI and CABP, evidenced by the completion of the study reports. The NMPA granted priority review to the NDA for omadacycline for the treatment of ABSSSI and CABP in May 2020.

Sulbactam-Durlobactam

- In May 2020, we enrolled the first Chinese patient into the global Phase III ATTACK trial of durlobactam for Acinetobacter infections.

- We and our partner, Entasis Therapeutics, will cooperate in conducting the trial in China with us taking the operational lead by conducting the screening, enrollment and treatment of patients and coordinating development, registration and commercialization of SUL-DUR in specified countries in the Asia-Pacific region including Japan.

ZL-1201

- We are conducting a Phase I study of anti-CD47 antibody in subjects with advanced cancer in the US. The major aims of the study are to define the safety, tolerability and preliminary antitumor activity of this new drug, and to determine a recommended dose and schedule for potential additional trials.

ZL-1102

- We are conducting a Phase I study in Australia to investigate the safety, tolerability, efficacy and pharmacokinetics of ZL-1102 in subjects with mild-to-moderate chronic plaque psoriasis.

Our Scientific Advisory Board

Our research and development capabilities are supplemented by support from our Scientific Advisory Board, which currently comprises of five globally renowned biophysicists and key opinion leaders, including Lieping Chen, M.D., Ph.D., Richard A. Flavell, Ph.D., Neal Rosen, M.D., Ph.D., Timothy Yap, M.D., Ph.D. and Alex A. Adjei, M.D., Ph.D., FACP.

Lieping Chen, M.D., Ph.D. has served on our Scientific Advisory Board since 2018. Dr. Chen is the scientific founder and Chair of the Scientific Advisory Board of NextCure (NASDAQ ticker: NXTC), a clinical-stage biopharmaceutical company focused on discover and developing novel immunomedicines to treat cancer. Dr. Chen is the United Technologies Corporation Professor in Cancer Research, Co-Director of the Cancer Immunology Program at the Yale Cancer Center and a Professor of Immunobiology, Dermatology and Medicine (Medical Oncology) at the Yale University School of Medicine.

Richard A. Flavell, Ph.D., FRS has served on our Scientific Advisory Board since 2017. Since 2002, Dr. Flavell has been the Sterling Professor of Immunobiology at Yale University School of Medicine.

Neal Rosen, M.D., Ph.D. has served on our Scientific Advisory Board since 2016. Dr. Rosen is the scientific advisor of the following companies: Ribon Therapeutics, a clinical-stage biotechnology company focused on the discovery and development of molecular inhibitors to block the fundamental ability of cancer cells to survive under stress; BeiGene (NASDAQ ticker: BGNE), a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of molecularly targeted and immune-oncology drugs for the treatment of cancer; and Kura Oncology Inc., (NASDAQ ticker: KURA) a clinical-stage biopharmaceutical company focuses on the discovery and development of personalized therapeutics for the treatment of tumors and blood cancers. Dr. Rosen is a Member of the Department of Medicine and a Member of the Molecular Pharmacology and Chemistry Program at Memorial Sloan Kettering Cancer Center, where he serves as Head of Developmental Therapeutics.

Timothy Yap, M.D., Ph.D. has served on our Scientific Advisory Board since 2019. Dr. Yap is the scientific advisor of the following companies: I-MAB (NASDAQ ticker: IMAB), a clinical stage biopharmaceutical company focuses on the discovery, development and commercialization of novel biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders; and Cybrexa Therapeutics (also known as

Cybrexa Inc.), an oncology-focused biotechnology company. Dr. Yap is an Associate Professor in the Department of Investigational Cancer Therapeutics and Medical Director of The Institute for Applied Cancer Science at The University of Texas MD Anderson Cancer Center, Houston, TX.

Alex A. Adjei, M.D., Ph.D., FACP has served on our Scientific Advisory Board since 2019. Dr. Adjei is a Consultant in Oncology, Professor of Oncology and Professor of Pharmacology at Mayo Clinic and Mayo College of Medicine, in Rochester, MN.

We believe by virtue of the valuable and unique expertise and insights of the members of our Scientific Advisory Board in various disciplines, we are able to further enhance our research and development capabilities. As of the Latest Practicable Date, we are not aware of any conflict of interest of between any member of our Scientific Advisory Board and us.

SALES AND MARKETING

Commercialization

As we believe the scale and sophistication of our commercial operation are crucial to our business, we have invested, and will continue to invest, substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of the sales of our commercialized products. We successfully launched ZEJULA in Hong Kong in the fourth quarter of 2018 and achieved over majority market share in the PARP inhibitor category with in terms of sales in 2019. Leveraging the valuable marketing experience and strong physician endorsement we accumulated from the successful commercial launch of ZEJULA, we launched Optune in Hong Kong in December 2018. As of the Latest Practicable Date, we have commercialized ZEJULA in Hong Kong, Macau and China, and Optune in Hong Kong and China. We believe our initial commercial success in Hong Kong allows us to establish our commercial presence in Greater China.

As of the Latest Practicable Date, our commercialization team consisted of 401 sales and marketing staff, covering major medical centers across Greater China. Our commercialization team has a proven track record and experience from top-selling oncology multinational pharmaceutical companies including AstraZeneca, Roche, Novartis and BMS in China. In anticipation of the increased market demand for ZEJULA and Optune in China, and more late-stage drug candidates becoming available for sale, if approved, we plan to further expand our sales and marketing force in the next few years to scale up the precedence of our ZEJULA and Optune in China and ramp up the sales of our commercialized products in the target markets.

Our commercial team has capabilities that cover the product sales cycle, including medical affairs, market access, and distributor management. We tailor our commercialization strategies according to our individual products and their different market potential to drive product launch and ensure post-launch success. For ZEJULA, we plan to increase market penetration in China and substantially increase our hospital coverage in China by 2021. To implement this commercial strategy, we plan to increase the number of sales in our ZEJULA sales team to facilitate greater product access for more patients. For Optune, we plan to increase brand awareness in China and provide more post-launch product support services to patients in China. To implement this commercial strategy, we plan to increase the number of device support staff to build up our Optune product service team.

We consider many factors in determining our pricing strategies and we continuously monitor market prices as development and clinical and regulatory progress of other similar drug candidates. As of the Latest Practicable Date, ZEJULA in China is priced at RMB24,990 per box with 2 boxes per month, which leads to monthly end-patient price of RMB49,980. In China, we have collaborated with charitable foundations to provide patient assistance program (PAP) to patients who meet certain medical and socioeconomic criteria. Under the PAP, eligible patients are able to receive one box of ZEJULA free for every box purchased. After being treated with a total of 24 boxes, they are also entitled to receive free boxes of ZEJULA until disease progression.

With respect to the pricing details of LYNPARZA, according to Frost & Sullivan, after reimbursement under the NRDL (which is only available for second-line treatment), as of the Latest Practicable Date, it is priced at RMB9,464 per box with 2 boxes per month, which leads to monthly end-patient price being RMB18,928. Patient will self-pay 5% to 30% of the total cost, depending on the regional reimbursement policies, according to the Frost & Sullivan Report.

As of the Latest Practicable Date, monthly end-patient price for Optune in China is RMB132,998 per month. Similar to ZEJULA, for Optune, we have also collaborated with charitable foundations to provide PAP to patients who meet certain medical and socioeconomic criteria. Under the PAP, eligible patients can buy one month's supply of Optune transducer array (an accessory component of Optune) and get one month's supply for free. After this initial one-month supply period, patients can qualify for further assistance under the PAP.

With respect to the patient cost of TMZ, a chemotherapy used for the treatment of GBM, the total monthly cost is in the range of RMB13,000 to RMB33,000; and after reimbursement under the NRDL, depending on whether it is generic or original, patients are estimated to pay in the range of RMB2,600 to RMB6,000 on a monthly basis, according to the Frost & Sullivan Report.

As of the Latest Practicable Date, neither of ZEJULA nor Optune was subject to the bulk procurement program in China.

Our Distribution Channel

We rely on our independent third party distributors in China to sell our commercialized products, which is consistent with the pharmaceutical industry norm. We believe our distributors help us effectively execute our marketing strategies specifically tailored to each geographical location and the hospitals located within their locations across China. We started to engage distributors in China in 2020 after we launched ZEJULA and Optune in China to rapidly ramp up sales of these two commercialized products. As of the Latest Practicable Date, we had collaborated with 48 such distributors in China, which are independent third parties, and have not terminated the relationship with any of our distributors. The relationship between our distributors and us constitutes a seller and buyer relationship. Accordingly, we recognize revenue when our products are delivered to and accepted by the distributors.

We selected our distributors based on their business qualifications and distribution capabilities, such as distribution network coverage, quality, number of personnel, cash flow conditions, creditworthiness, logistics, compliance standard and past performance, and its capacities in customer management. As of the Latest Practicable Date, we were not aware of any potential abuses or improper use of our name by our distributor which could adversely affect our reputation, business operation or financial condition.

Set forth below are the key contractual terms of our agreements with our distributors in the PRC:

- *Duration and termination*. The distribution agreement typically has a term of one year, subject to early termination by us upon at least 90 days' prior written notice or under certain conditions provided in the agreement. The term of agreement can be renewed by mutual agreement.

- *Geographic exclusivity*. Our distributors shall not sell or otherwise distribute the products outside the PRC, unless otherwise agreed by us in writing.

- *Rights and obligations of parties involved*. We offer rebates to our distributors, consistent with pharmaceutical industry practice. We retain no ownership control over the products sold to our distributors, and all significant risks (including inventory risks) and rewards associated with the products are generally transferred to the distributors upon delivery to and acceptance by the distributors.

- *Sales and pricing policies*. We sell our products to our distributors at a fixed price provided in the agreement, which is subject to change upon a 30 days' prior notice by us. Our distributors retain the discretion to determine the retail prices with reference to local market conditions, competition and customer demand in the regions where they operate, whether greater or lesser than any prices charged by us.

- *Obsolete stock arrangements*. There is no obsolete stock arrangements condition.

- *Return and exchange policy*. We have in place a return and exchange policy that is in line with industry practice. Our distributors may submit return or exchange applications to us, which shall provide the details of the products to be returned or exchanged. Upon inspection and approval by us, we fully or partially refund the returned products and we typically allow exchange for the same type of products. We had not experienced any material product return during the Track Record Period.

- *Sales and inventory reports and estimates*. Our distributors shall provide to us monthly reports containing full details about the sales, products sold, inventory and forecasts of the products.

- *Minimum sales target and purchase amounts*. We do not require our distributors to meet any minimum sales target and purchase amounts. Our distributors may from time to time place orders for our products depending on their own demands.

- *Payment and credit terms*. Credit term is generally 40 days following the invoice date.

- *Use of confidential information*. Our distributors shall have a non-sublicensable, non-transferable, non-assignable and non-exclusive right to use our confidential information, including trademark, in connection with selling our products during the contract term.

We started to engage distributors in China in 2020 after we launched ZEJULA and Optune in China to rapidly ramp up sales of these two commercialized products. Four of our five largest customers in the six months ended June 30, 2020 are also major distributors for the same period. For their background information, please see "– Customers."

MANUFACTURING

We currently operate two manufacturing facilities in Suzhou, China, which support clinical and commercialized production of certain of our products and drug candidates, including ZEJULA, one of our Core Products. We do not manufacture Optune, one of our Core Products; instead, we source Optune from our licensor, Novocure. In early 2017, we built a cGMP-compliant small molecule facility in Suzhou capable of supporting clinical and commercialized production. In 2018, we completed construction of a large molecule facility in Suzhou using GE Healthcare FlexFactory platform technology capable of supporting the clinical production of our drug candidates. We are investing in the expansion of the manufacturing site to anticipate the increased sales of our current commercialized products and the launch of our clinical drug candidates. We believe that possessing manufacturing and commercialization capabilities presents benefits, which include maintaining better control over the quality and compliance of our operations with increasingly stringent industry regulations. As of the Latest Practicable Date, our manufacturing team consisted of 60 employees.

Our two manufacturing facilities feature an oral solid dosage and a biological processing/formulation production lines and are designed to comply with both the PRC and PIC/S drug manufacturing standards. The facilities cover the entire production process from mixing, roller compression, tableting to bottling. We procure our manufacturing equipment from leading domestic and international suppliers. We have acquired manufacturing licenses for both oral solid dosage and biological facilities, and are in the process of applying MAH manufacturing license. We have passed an onsite inspection by NMPA for ZEJULA, our first commercialized product. We expect our two manufacturing facilities to be able to satisfy the commercial as well as clinical needs and support the growth of our business in the near future.

Our small molecule manufacturing facility mainly supports the commercial production of ZEJULA. The production capacity of our small molecule manufacturing facility is up to 50 million units per year for both commercial oral tablets and capsules. During the Track Record Period, less than 10 percent of the total production capacity of our small molecule manufacturing facility was utilized. Our large molecule manufacturing facility supports the clinical production of ZL-1201. The annual production capacity of our large molecule manufacturing capacity is up to eighteen 1,000 liter clinical batches of large molecule drug substance. During the Track Record Period, approximately 40% of the production capacity of our large molecule manufacturing facility was utilized.

In addition, we outsource to a limited number of external CMOs the production of some drug substances and drug products, and we expect to continue to do so to meet the preclinical, clinical and commercial requirements of our drug products and candidates. By outsourcing a portion of our manufacturing activities, we can increase our focus on core areas of competence such as drug candidate development, commercialization and research. We have adopted procedures to ensure that the production qualifications, facilities and processes of our third-party CMOs comply with the relevant regulatory requirements and our internal guidelines. We select our CMOs carefully by taking into account a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and terms offered by such CMOs. As of the Latest Practicable Date, we had engaged approximately six CMOs, who are independent third parties. Under the respective licensing and/or collaboration agreements, we have the right to manufacture ZEJULA and omadacycline. We use Asymchem Laboratories as the API (chemical) MAH for ZEJULA and omadacycline. We also use Zhejiang Hisun Pharmaceutical and Haimen Pharma as the formulation (manufacturing) MAH for omadacycline. We believe we have readily accessible alternative suppliers to provide the raw materials necessary to manufacture ZEJULA and omadacycline. In light of the current situations and the peculiarities of the biopharmaceutical industry, we are of the view that the U.S. – China tension has not had any material impact on our business operations and manufacturing, including our collaborations with business partners. Please refer to "Risk Factors – Changes in U.S. and international trade policies and relations, particularly with regard to China, may adversely impact our business and operating results."

We enter into agreements with our CMOs, under which they generally provide services to us on a short-term and project-by-project basis. Agreements with our CMOs typically set out terms, including but not limited to product quality or service details, technical standards or methods, delivery terms, agreed price and payment, and product inspection and acceptance criteria. Our CMOs procure raw materials themselves. We are required to make payments to the CMOs in accordance with the payments schedule set forth in the agreement. We may terminate the agreements by serving a 30 days' prior notice to the CMO.

CUSTOMERS

We commercially launched ZEJULA in Hong Kong in the fourth quarter of 2018 and started to generate revenue from the sales of ZEJULA to our customers. As we continued to expand our footprint across China with our successful launch of ZEJULA and Optune in China in January 2020 and May 2020, respectively, we have been rapidly broadening our customer base and deriving substantial revenue from our distributors in China. For details of the commercial arrangements with our distributors in China, see "– Sales and Marketing – Our Distribution Channel."

During the Track Record Period, our top five customers accounted for 89.6%, 85.0% and 44.5% of our total revenues for the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, respectively. During the same period, revenues from our largest customer accounted for approximately 39.6%, 41.6% and 16.8% of our total revenues, respectively.

Please see below a summary of the sales to our five largest customers for the periods indicated:

Five Largest Customers for the year ended December 31, 2018	**Customer Background**	**Covered Region**	**Our Products**	**Sales Amount**	**Percentage of Total Revenue**
				US$'000	
Customer A . . .	A private medical center	Hong Kong	ZEJULA	51.3	39.6%
Customer B . . .	A private oncology center	Hong Kong	ZEJULA	34.2	26.4%
Customer C . . .	A private clinic specializing internal medicine oncology	Hong Kong	ZEJULA	13.7	10.6%
Customer D . . .	A private clinical oncology center	Hong Kong	ZEJULA	10.0	7.7%
Customer E . . .	A private clinic specializing clinical oncology	Hong Kong	ZEJULA	6.8	5.3%
Total				116.0	89.6%

Five Largest Customers for the year ended December 31, 2019	Customer Background	Covered Region	Our Products	Sales Amount	Percentage of Total Revenue
				US$'000	
Customer A . . .	A private medical center offering medical services in general medicine, specialist areas as well as out-patient surgeries, diagnostic screening, etc.	Hong Kong	ZEJULA	5,397.2	41.6%
Customer F . . .	A private oncology center	Hong Kong	Optune	4,682.4	36.1%
Customer G . . .	A private medical group	Hong Kong	ZEJULA and Optune	541.8	4.2%
Customer H . . .	A private general hospital	Hong Kong	ZEJULA	223.4	1.7%
Customer I. . . .	A public district general hospital	Hong Kong	ZEJULA	186.1	1.4%
Total				11,030.9	85.0%

Five Largest Customers for the six months ended June 30, 2020	Customer Background	Covered Region	Our Products	Sales Amount	Percentage of Total Revenue
				US$'000	
Customer J. . . .	A pharmaceutical distributor	China	ZEJULA and Optune	3,236.2	16.8%
Customer F . . .	A private oncology center	Hong Kong	Optune	1,815.1	9.5%
Customer K . . .	A pharmaceutical distributor	China	ZEJULA	1,774.5	9.2%
Customer L . . .	A pharmaceutical distributor	China	ZEJULA	961.1	5.0%
Customer M . . .	A pharmaceutical distributor	China	ZEJULA	769.5	4.0%
Total				8,556.3	44.5%

As of the Latest Practicable Date, none of our Directors or any Shareholder, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the Global Offering (but without taking into account the exercise of the Over-allotment Option) nor any of their respective associates had any interest in any of our five largest customers.

SUPPLIERS

During the Track Record Period, our suppliers consisted primarily of (i) third party licensors from which we obtained license rights in respect of our in-licensed products and drug candidates; (ii) selected CROs; and (iii) suppliers of other raw materials for our clinical trial activities. For details of the agreements with our licensors, see "– Overview of Our License and Strategic Collaboration Agreements."

We engage a limited number of highly reputable third-party CROs to monitor, manage data and execute for some of our ongoing pre-clinical and clinical programs. We select our CROs by considering their track record, industry reputation, compliance with relevant regulatory agencies and cost competitiveness.

We obtain raw materials for our clinical trial activities from multiple suppliers who we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, a risk exists that an interruption to supplies would materially harm our business. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. While we do experience price fluctuations associated with our raw materials, we have not experienced any material disruptions in the supply of these raw materials in the past. In addition, we have suppliers across the world and do not rely exclusively on the imports from the suppliers in the U.S. In particular,

- with respect to our ZEJULA, we have been using Asymchem Laboratories, a PRC-based company, as the API (chemical) MAH. In addition, we operate a small molecule manufacturing facility, mainly supporting the commercial production of ZEJULA. During the Track Record Period, we have not experienced any material disruptions to the supplies or manufacturing of ZEJULA. We believe reasonable alternatives to Asymchem Laboratories are readily accessible. Furthermore, we plan to source domestically manufactured drug substances if the supply from overseas are not available. See "Risk Factors – We have limited experience manufacturing our products and drug candidates on a large clinical or commercial scale. We are or will be dependent on third party manufacturers for the manufacture of certain of our products and drug candidates as well as on third parties for our supply chain, and if any of these third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices, our business could be harmed;" and

- with respect to Optune and our other late-stage drug candidates, we primarily rely on the supplies from our licensors who have global manufacturing capabilities. During the Track Record Period, we have not experienced any material disruptions to the supplies or manufacturing of such late-stage candidates and we expect to be able to maintain adequate sources of quality supplies in the foreseeable future. However, we cannot guarantee that we will always have access to such supplies at reasonable price or at all. See "Risk Factors – We rely on supplies from our licensors, which may severely harm our business and results of operations."

For the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, purchases from our five largest suppliers accounted for approximately 52.0%, 44.3% and 50.3% of our total purchases, respectively. During the same period, purchases from our largest supplier accounted for approximately 21.2%, 19.7% and 28.9% of our total purchases, respectively.

The table below sets forth the details of our five largest suppliers during the Track Record Period.

Five Largest Supplier for the Year ended December 31, 2018	**Supplier Background**	**Type of Products/Services Provided**	**Purchase Amount**	**Percentage of Total Purchase**
			US$'000	
Supplier A*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and clinical supplies and manufacturing related activities	25,515.2	21.2%
Supplier B*	An oncology company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and purchase of inventory	14,664.4	12.2%

Five Largest Supplier for the Year ended December 31, 2018	Supplier Background	Type of Products/Services Provided	Purchase Amount	Percentage of Total Purchase
			US$'000	
Supplier C*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	11,124.4	9.3%
Supplier D	A private company providing R&D and one-stop production services	Manufacturing of active pharmaceutical ingredients	6,147.0	4.9%
Supplier E*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates	5,307.1	4.4%
Total			62,758.0	52.0%

Note: * a US publicly listed company

Five Largest Supplier for the Year ended December 31, 2019	Supplier Background	Type of Products/Services Provided	Purchase Amount	Percentage of Total Purchase
			US$'000	
Supplier F*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	27,965.8	19.7%
Supplier G*	A pharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	18,362.3	12.9%

Five Largest Supplier for the Year ended December 31, 2019	Supplier Background	Type of Products/Services Provided	Purchase Amount	Percentage of Total Purchase
			US$'000	
Supplier H*	A pharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	8,918.8	4.8%
Supplier D	A private company providing R&D and one-stop production services	Manufacturing of active pharmaceutical ingredients	7,862.7	3.8%
Supplier C*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	4,588.9	3.2%
Total			67,698.5	44.3%

Note: * a US publicly listed company

Five Largest Supplier for the Six Months ended June 30, 2020	Supplier Background	Type of Products/Services Provided	Purchase Amount	Percentage of Total Purchase
			US$'000	
Supplier I*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	31,022.0	28.9%
Supplier B*	An oncology company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and purchase of inventory	12,312.8	11.5%

Five Largest Supplier for the Six Months ended June 30, 2020	Supplier Background	Type of Products/Services Provided	Purchase Amount	Percentage of Total Purchase
			US$'000	
Supplier A*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and clinical supplies and manufacturing related activities	5,204.5	4.9%
Supplier E*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates	3,018.6	2.8%
Supplier F*	A biopharmaceutical company	Licensor from which we obtained intellectual property rights in respect of our in-licensed drug candidates and development and research services	2,428.5	2.3%
Total			53,986.4	50.3%

Note: * a US publicly listed company

As of the Latest Practicable Date, none of our Directors or any Shareholder, who to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the Global Offering (but without taking into account the exercise of the Over-allotment Option) nor any of their respective associates had any interest in any of our five largest suppliers.

PROPERTIES

We are headquartered in Shanghai where we have our main administrative and laboratory offices, which is 3,632 square meters in size. The lease for this facility expires in 2023. We also have a 2,475 square meter commercial office for in Shanghai, the lease for which expires in 2022, and a 493 square meter office in Beijing, the lease for which expires in 2020. We have a 445 square meter commercial office in Hong Kong, the leases for which expire in 2022. We lease an administrative office in Guangzhou from a third party. We also have a 2,652 square

feet administrative office and an 18,707 square feet laboratory office in San Francisco, the leases for which expire in 2021 and 2026, respectively. We also lease from a third party an administrative office in Boston. In early 2017, we built a small molecule drug product facility in Suzhou, China, capable of supporting clinical and commercialized production, which is 4,223 square meters. The lease for this facility expires in 2023. In 2018, we built a large molecule facility in Suzhou, China, using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates, which is 4,223 square meters. The lease for this facility expires in 2021 and we do not expect difficulties in renewing such lease. The cost to complete the small molecule facility was approximately US$6.7 million and was paid with cash on hand. The construction of the large molecule facility was completed in 2018, which cost approximately US$12.9 million and was financed with cash. We believe our current facilities are sufficient to meet our near-term needs. In 2019, we acquired land use rights of 50,851 square meters in Suzhou for the purpose of constructing and operating the research center and biologics manufacturing facility in Suzhou. The terms of the land use rights are 30 years.

COMPETITION

Our industry is highly competitive and subject to rapid and significant change. While we believe that our management's research, development and commercialization experience provide us with competitive advantages, we face competition from global and China-based biopharmaceutical companies, including specialty pharmaceutical companies, generic and biosimilar drug companies, biologics drug companies, academic institutions, government agencies and research institutions.

For our global drug candidates, we expect to face competition from a broad range of global and local pharmaceutical companies. Many of our competitors have significantly greater financial, technical and human resources than we have, and mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future drug candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. We maintain liability insurance for certain clinical trials, which covers the patient human clinical trial liabilities such as bodily injury, product liability insurance to cover our product liability claims and general insurance policies covering property loss due to accidents or natural disasters. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation. We do not maintain "key person" insurance for any of our executives or other employees. We believe the coverage of the insurance obtained by us is adequate and consistent with industry norm for our business and operations.

EMPLOYEES

As of the Latest Practicable Date, we had 913 full-time employees, 886 of which were located in Greater China and 27 were located abroad. Of the total of 913 full-time employees, 377 employees are in R&D department. The number of employees by function as of Latest Practicable Date was as follows:

By Function	Number of employees
Research and Development	377
Commercial	401
Manufacturing	64
General and Administrative	71
Total	913

We provide formal and comprehensive company-level and department-level training to our new employees followed by on-the-job training. We also provide training and development programs to our employees from time to time to ensure their awareness and compliance with our various policies and procedures. Given our emphasis on operating a seamless, fully-integrated platform for our drug development processes, some of the training is conducted jointly by different groups and departments serving different functions but working with or supporting each other in our day-to-day operations.

As required under PRC regulations, we participate in housing fund and various employee social security plans that are organized by applicable local municipal and provincial governments, including housing, pension, medical, work-related injury and unemployment benefit plans, under which we make contributions at specified percentages of the salaries of our employees. As advised by our PRC Legal Advisor, we had complied with all statutory social security plans and housing fund payment obligations in all material respects.

None of our employees is represented by a labor union or covered by a collective bargaining agreement. We believe that we maintain good working relationship with our employees and we have not experienced any material labor disputes or any difficulty in recruiting staff for our operations during the Track Record Period and up to the Latest Practicable Date.

Employment Agreements with Key Management and Research Staff

We enter into standard confidentiality and employment agreements with our research staff and each of our executive officers and our directors (other than our non-employee directors). The contracts with our key personnel generally include a standard non-compete clause that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for generally two years after the termination of his or her employment. As advised by our PRC Legal Advisor, to the extent such contracts governed by PRC laws, the non-compete clause set forth therein is legally enforceable. The contracts also typically include undertakings regarding assignment of inventions and discoveries made during the course of his

or her employment. For further details regarding the terms of confidentiality and employment agreements with our key management, please refer to the section headed "Directors and Senior Management" in this prospectus.

Dr. Du is employed by Zai Lab Limited, pursuant to an employment agreement that became effective December 1, 2018 and Dr. Du is also a party to an employment agreement with Zai Lab (Shanghai) Co., Ltd. (In addition, Dr. Du has entered into an agreement with our U.S. subsidiary, Zai Lab (US) LLC, pursuant to which a portion of her base salary will be paid by Zai Lab (US) LLC based on the level of services that she provides this entity). Dr. Fu, Dr. Reinhart and Mr. Edmondson are each employed by Zai Lab (US) LLC pursuant to employment agreements and amended and restated employment agreements that became effective on January 25, 2019, December 1, 2018 and August 15, 2020, respectively. Dr. Hei is employed by Zai Lab (US) LLC and also party to an employment agreement with Zai Lab (Shanghai) Co., Ltd. Mr. Cho is employed by Zai Lab (Hong Kong) Limited. Mr. Liang is employed by Zai Lab (Shanghai) Co. Ltd.

QUALITY CONTROL AND ASSURANCE

We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing and testing of our drug candidates. We have established a strict quality control system in accordance with NMPA regulations. Our laboratories are staffed with highly educated and skilled technicians to ensure quality of all batches of products released. We monitor our operations in real time throughout the entire production process, from inspection of raw and auxiliary materials, to manufacture and delivery of finished products to clinical testing at hospitals. Our quality assurance team is also responsible for ensuring that we are in compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies and managing the internal and external quality performance of the Company.

LEGAL PROCEEDINGS AND COMPLIANCE

As of the Latest Practicable Date, we were currently not a party to any actual or threatened material legal or administrative proceedings. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

ENVIRONMENT MATTERS AND WORKPLACE SAFETY

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients and communities. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We have implemented company-wide environmental, health and safety (EHS) manuals, policies and standard operating procedures.

We have not had any significant workplace accidents in the history of our Company.

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any fines or other penalties due to non-compliance with environment and workplace safety regulations.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We have adopted a consolidated risk management methodology and program which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Our audit committee, and ultimately our Directors supervise the implementation of our risk management programs. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

The following key principles outline our Group's approach to risk management and internal control:

- Our audit committee oversees and manages the overall risks associated with our business operations, including (i) reviewing and approving our risk management programs and procedures to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iii) reviewing our corporate risk matrix in the light of our corporate risk tolerance; (iv) reviewing the significant residual risks and the needs to set up mitigating controls; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Group.

- Our chief financial officer, Mr. Billy Cho, is responsible for (i) formulating and updating our risk management program and target; (ii) reviewing and approving major risk management issues of our Company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) reviewing the relevant departments' reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competences are in place across our Group; and (viii) reporting to our audit committee on our material risks

- The relevant departments in our Company, including the finance department, the legal and compliance department, and the human resources department, are responsible for implementing our risk management program and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an internal control consulting firm (the "Internal Control Consultant") to perform certain agreed-upon procedures (the "Internal Control Review") in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group's entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, sales accounts receivable and collection, procurement and vendor management, accounts payable and payment, fixed assets and assets under construction, human resources and payroll management, cash and treasury management, inventory management, general controls of IT system, taxation management, production and costing, insurance management, research and development and intangible assets. The Internal Control Consultant performed the Internal Control Review in August 2019 and a follow-up review in January 2020. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal control.

We regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as financial controlling, protection of intellectual property, information security, adverse event reporting, quality control, environmental protection and occupational health and safety, etc. We provide periodic training about these measures and procedures to our employees as part of our employee training program. We also constantly monitor the implementation of those measures and procedures through our on-site internal control teams for each stage of the biologics development process.

- Our senior management team and our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations. We have internally established a set of compliance policies to provide guidance to our employees on expected business practices and ethical and moral behaviors, such as Code of Conduct and Ethics Policy and Anti-Bribery and Corruption Policy. We strictly require our employees to comply with anti-corruption laws in every countries and regions that we operate or are listed e.g., the PRC, Hong Kong or the U.S. Specifically, we require our employees to comply with applicable anti-corruption laws including, but are not limited to: (i) the Criminal Law of the PRC, the Anti-Unfair Competition Law of the PRC and the related regulations and judicial interpretations, (ii) the Foreign Corrupt Practices Act of the U.S,, and (iii) other applicable anti-corruption laws or regulations. Such anti-corruption laws generally prohibit the offer, promise, payment or receipt of anything of value to obtain, retain or grant business opportunities or to exchange in an improper advantage. Any employee that violates the Anti-Bribery and Corruption Policy can be subject to disciplinary actions, up to and including termination of employment. We also prohibit employees from engaging in any illegal or unethical economic behavior and seeking benefits from it, and implement strict management and audit procedures to prevent lack of transparency and corruption during the sale or procurement process.

- We have established an audit committee in August 2017, which (i) makes recommendations to our Directors on the appointment and removal of external auditors; (ii) reviews the financial statements and render advice in respect of financial reporting and internal controls; and (iii) as well as oversee internal control procedures and any significant risks of our Group.

We maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry.

Investment Risk Management

We engage in short-term investments with surplus cash on hand. Our investment portfolio primarily consists of time deposits. Our primary objective of short-term investment is to preserve principal, and increase liquidity without significantly increasing risks. Under the supervision of our Chief Financial Officer, our finance department is responsible for managing our short-term investment activities. Before making any investment proposal, our finance department will assess our cash flow levels, operational needs and capital expenditures. We operate under our investment policy, which provides the guidelines and specific instructions on the investment of our funds.

Our investment strategy aims to minimize risks by reasonably and conservatively matching the maturities of the portfolio to anticipated operating cash needs. We make our investment decisions on a case-by-case basis after thoroughly considering a number of factors, including but not limited to macro-economic environment, general market conditions and the expected profit or potential loss of the investment. Our portfolio to date have been required to hold only instruments with an effective final maturity of 12 months or less, with effective final maturity being defined as the obligation of the issuer to repay principal and interest. Under our investment policy, we are prohibited from investing in high risk products and the proposed investment must not interfere with our business operation or capital expenditure. As of the Latest Practicable Date, our investment decisions did not deviate from our investment policy.

We believe that our internal investment policies and the related risk management mechanism are adequate. We may invest in time deposits in consistency with our investment policy where we believe it is prudent to do so after the Listing.

You should read the following discussion and analysis in conjunction with our consolidated financial information, including the notes thereto, included in the Accountants' Report set out in Appendix I to this prospectus and in particular, "Our Business." Our consolidated financial information has been prepared in accordance with U.S. GAAP.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance that involve risks and uncertainties. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical events, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. In evaluating our business, you should carefully consider the information provided in the section headed "Risk Factors" and elsewhere in in this prospectus.

For the purpose of this section, unless the context otherwise requires, references to 2018 and 2019 refer to our fiscal year ended December 31 of such year respectively. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

We are an innovative, research-based, commercial-stage biopharmaceutical company with a focus on discovering, licensing, developing and commercializing potentially global best-in-class/first-in-class therapies that address areas of large unmet medical need in the China and global markets, including the fields of oncology, infectious and autoimmune diseases. By effectively executing our plan and closely following our strategy, we have built an integrated platform to bring both in-licensed and internally-discovered novel therapeutics to patients globally. We believe we are one of the first biopharmaceutical companies in China to scale, allowing us to further capitalize on the latest innovation and business opportunities globally.

Since our inception, we have executed our strategic approach of in-licensing promising biopharmaceutical products via global collaboration and investing in internal discovery and development efforts. Our robust portfolio consists of 16 potential best-in-class/first-in-class products and drug candidates, including two commercialized products in China, Hong Kong and Macau and seven assets in pivotal or potentially registration-enabling trials in oncology and infectious diseases, which are therapeutic areas where there is a large unmet need and lack of innovative treatment options in Greater China. We are at the inflection point of commercialization with recent launches of ZEJULA and Optune in multiple regions, empowered by our commercialization team with a proven track record and heritage from top-selling MNCs and innovative oncology brands. We believe that we remain the preferred

partner of choice in our areas of focus for the biopharmaceutical industry as we provide a differentiated approach for our collaborators to achieve success while also conducting timely trials and achieving eventual commercialization of promising therapies, accelerating access to the large patient population.

Our consolidated net loss attributable to ordinary shareholders for the year ended December 31, 2018 and 2019 and for the six months ended June 30, 2019 and 2020 was US$139.1 million, US$195.1 million, US$83.3 million and US$128.6 million, respectively.

BASIS OF PRESENTATION

Our consolidated statement of operations data for the years ended December 31, 2018 and 2019 and for the six months ended June 30, 2019 and 2020 and our consolidated statement of financial position data as of December 31, 2018 and 2019 and June 30, 2020 have been derived from the Accountants' Report included in Appendix I to this prospectus. Our consolidated financial statements appearing elsewhere in this prospectus have been prepared in accordance with U.S. GAAP.

MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations, financial condition and the period-to-period comparability of our financial results have been, and are expected to continue to be, principally affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below:

Our Ability to Increase the Sales of Our Commercialized Products

We started to generate revenue from sales of our commercialized products since 2018 and have since achieved significant revenue growth. Our revenue increased from US$0.1 million in 2018 to US$13.0 million in 2019, and from US$3.4 million for the six months ended June 30, 2019 to US$19.2 million for the six months ended June 30, 2020. As we generate revenue solely from product sales, sales volume of our commercialized products, currently being ZEJULA and Optune, has a significant impact on our results of operation. Our ability to increase the sales of our commercialized products depends on whether we are able to effectively implement our marketing strategies. We intend to focus our resources on promoting ZEJULA and Optune in China. With respect to ZEJULA, we intend to leverage our dedicated commercialization team to penetrate more cities in China, thereby ramping up the sales. We will continue to leverage strong momentum in commercial insurance coverage and aim for near-term NRDL inclusion to reach more patients. With respect to Optune, we plan to rapidly drive the sales of Optune in China. We believe that our strong commercialization team and well-established sales network will enable us to execute our sales and marketing strategies and increase the sales of our commercialized products.

Research and Development Expenses

We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been steadily advancing and expanding, with seven assets in pivotal or potentially registration-enabling trials being investigated. For more information on the nature of the efforts and steps necessary to develop our drug candidates, see "Business" and "Regulatory Environment."

To date, we have financed our activities primarily through private placements, our initial public offering in September 2017 and multiple follow-on offerings. Through June 30, 2020, we have raised approximately US$164.6 million in private equity financing and approximately US$794.0 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering and our subsequent follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was US$97.5 million and US$191.0 million, for the years ended December 31, 2018 and 2019, respectively, and was US$83.2 million and US$92.3 million for the six months ended June 30, 2019 and 2020, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical assets and continue research and development of our pre-clinical assets and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. These expenditures include:

- expenses incurred for payments to CROs, investigators and clinical trial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits and equity compensation expense;
- expenses for licensors;
- the cost of acquiring, developing, and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include office leases and other overhead expenses;
- costs associated with pre-clinical activities and regulatory operations;
- expenses associated with the construction and maintenance of our manufacturing facilities; and
- costs associated with operating as a public company.

For more information on the research and development expenses incurred for the development of our drug candidates, see "– Discussion of Selected Components of Statements of Operations and Other Comprehensive Loss Items – Research and Development Expenses."

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for commercial and administrative personnel. Other selling, general and administrative expenses include product distribution and promotion costs, professional service fees for legal, intellectual property, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support our increasing commercial and research and development activities and as we continue to commercialize, develop, and manufacture our products and product assets. These increases will likely include increased headcount, increased share compensation charges, increased product distribution and promotion costs, expanded infrastructure and increased costs for insurance. We also incur increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Our Ability to Commercialize Our Products and Drug Candidates

All of our products and drug candidates are still in development in China (including, with respect to ZEJULA and Optune, for indications not yet approved in China). As of June 30, 2020, 14 of such products and drug candidates are in clinical development and various others are in pre-clinical development in China. Our ability to generate revenue from our products and drug candidates is dependent on their receipt of regulatory approval for and successful commercialization of such products, which may never occur. Certain of our products and drug candidates may require additional pre-clinical and/or clinical development, regulatory approval in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

Our License Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant assets under these agreements as well as tiered royalties based on the net sales of the licensed products. These expenses have been recorded in research and development expense in our consolidated financial statements and totaled US$59.2 million and US$58.7 million for the years ended December 31, 2018 and 2019, respectively, and US$22.7 million and US$51.7 million for the six months ended June 30, 2019 and 2020, respectively.

DISCUSSION OF SELECTED COMPONENTS OF STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS ITEMS

Revenue

We started to generate revenue from sales of our commercialized products since 2018. We recognize revenue from product sales when we deliver the prescribed products to our customers. In 2018, our revenue was primarily generated from the sales of ZEJULA in Hong Kong. In 2019, our revenue was primarily generated from the sales of ZEJULA and Optune in Hong Kong. In the six months ended June 30, 2020, we generated revenue primarily from the sales of both ZEJULA and Optune in Hong Kong and China. Our revenue was US$0.1 million and US$13.0 million for the years ended December 31, 2018 and 2019, respectively, and US$3.4 million and US$19.2 million for the six months ended June 30, 2019 and 2020, respectively.

Cost of Sales

Cost of sales primarily consists of the purchase cost of products and royalty fees. During the Track Record Period, our cost of sales was US$43.3 thousand and US$3.7 million for the years ended December 31, 2018 and 2019, respectively, and US$0.9 million and US$5.0 million for the six months ended June 30, 2019 and 2020, respectively.

Research and Development Expenses

Our research and development expenses consist of (i) personnel compensations and related costs, relating to our personnel engaged in research and development activities, (ii) licensing fees, primarily including upfront and research and development ("R&D") milestone fees related to our in-licensed products and drug candidates, (iii) payment to CROs, CMOs and investigators, representing the expenses related to our external research and development activities (excluding licensing fees), and (iv) other costs, which include lab consumables, professional service expenses, depreciation and amortization. The following table sets forth the components of our research and development expenses for the periods indicated.

	Year Ended December 31,				Six Months Ended June 30,			
	2018	%	2019	%	2019	%	2020	%
					(Unaudited)			
	(US dollars in thousands, except percentage)							
Research and development expenses:								
Personnel compensations and related costs	16,755	13.9	30,820	21.6	15,095	25.6	21,600	21.2
Licensing fees	59,152	49.2	58,682	41.3	22,700	38.5	51,720	50.7
Payment to CROs/CMOs/Investigators	32,282	26.8	36,814	25.9	14,647	24.9	19,812	19.4
Other costs	12,089	10.1	15,905	11.2	6,486	11.0	8,917	8.7
Total	120,278	100.0	142,221	100.0	58,928	100.0	102,049	100.0

The following table summarizes our research and development expenses by program for the periods indicated.

	Year Ended December 31,				Six Months Ended June 30,			
	2018	%	2019	%	2019	%	2020	%
					(Unaudited)			
	(US dollars in thousands, except percentage)							
Research and development expenses:								
Clinical programs	89,556	74.5	96,442	67.8	37,230	63.2	72,335	70.9
Pre-clinical programs	8,102	6.7	8,268	5.8	3,763	6.4	2,915	2.9
Unallocated research and development expenses	22,620	18.8	37,511	26.4	17,935	30.4	26,799	26.2
Total	120,278	100.0	142,221	100.0	58,928	100.0	102,049	100.0

We manage our external research and development expenses by program; however, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of (i) personnel compensation and related costs, including share-based compensation for commercial and administrative personnel, (ii) professional service fee, representing legal, intellectual property, consulting, auditing and tax services, and (iii) other costs, mainly including product distribution and promotion costs, depreciation and amortization and other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in selling, general and administrative activities. The following table sets forth the components of our selling, general and administrative expenses for the periods indicated.

	Year Ended December 31,				Six Months Ended June 30,			
	2018	%	2019	%	2019	%	2020	%
					(Unaudited)			
	(US dollars in thousands, except percentage)							
Selling, General and Administrative Expenses:								
Personnel compensation and related costs	13,410	62.2	43,572	62.1	19,352	65.6	27,082	63.8
Professional service fee	3,266	15.1	2,887	4.1	1,607	5.5	4,570	10.8
Other costs	4,900	22.7	23,752	33.8	8,530	28.9	10,820	25.4
Total	21,576	100.0	70,211	100.0	29,489	100.0	42,472	100.0

Interest Income

Interest income consists primarily of interest generated from cash and our short-term investments, which primarily comprise of the time deposits with original maturities between three months and one year. We generated interest income of US$3.3 million and US$8.2 million in 2018 and 2019, respectively, and US$3.4 million and US$2.9 million for the six months ended June 30, 2019 and 2020, respectively.

Other Income (Expense), Net

Other income (expense), net consists primarily of government subsidies received from local governments in China and foreign exchange income or loss. We generated other income, net of US$0.1 million and US$0.9 million in 2018 and 2019, and other expense, net of US$0.3 million and US$0.7 million for the six months ended June 30, 2019 and 2020, respectively.

Share of Loss from Equity Method Investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd., or JING, an entity that will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. We account for our investment using the equity method of accounting because we do not control the investee but have the ability to exercise significant influence over the operating and financial policies of the investee. An investment loss of US$0.6 million and US$0.8 million related to this investment was recorded in 2018 and 2019, respectively, and an investment loss of US$0.3 million and US$0.4 million related to this investment was recorded for the six months ended June 30, 2019 and 2020, respectively.

Income Tax Expense

We are subject to various rates of income tax under different jurisdictions. The following summarizes major factors affecting our applicable tax rates in the Cayman Islands, the PRC and Hong Kong.

Cayman Islands

Zai Lab Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands.

People's Republic of China

Our subsidiaries incorporated in China are governed by the EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for following five or ten years.

Hong Kong

Our subsidiaries incorporated in Hong Kong are subject to two-tiered tax rates during the Track Record Period on assessable profits earned in Hong Kong where the profits tax rate for the first HK$2 million of assessable profits is subject to profits tax rate of 8.25% and the assessable profits above HK$2 million is subject to profits tax rate of 16.5%. Our subsidiaries incorporated in Hong Kong did not have assessable profit during the Track Record Period.

RESULTS OF OPERATIONS

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

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
			(Unaudited)	
	(US dollars in thousands, except share and per share data)			
Comprehensive Loss Data:				
Revenue	129	12,985	3,420	19,213
Expenses:				
Cost of sales	(43)	(3,749)	(882)	(4,980)
Research and development	(120,278)	(142,221)	(58,928)	(102,049)
Selling, general and administrative	(21,576)	(70,211)	(29,489)	(42,472)
Loss from operations	(141,768)	(203,196)	(85,879)	(130,288)
Interest income	3,261	8,232	3,365	2,882
Interest expense	(40)	(293)	(137)	(114)
Other income (expense), net	59	938	(307)	(691)
Loss before income tax and share of loss from equity method investment	(138,488)	(194,319)	(82,958)	(128,211)
Income tax expenses	–	–	–	–
Share of loss from equity method investment	(587)	(752)	(316)	(406)
Net loss attributable to ordinary shareholders	(139,075)	(195,071)	(83,274)	(128,617)
Weighted-average shares used in calculating net loss	52,609,810	64,369,490	60,919,842	73,847,551
Net loss per share, basic and diluted	(2.64)	(3.03)	(1.37)	(1.74)

Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2019

Revenue

The following table sets forth the revenue breakdown by product for the periods indicated.

	Six Months Ended June 30,			
	2019	**%**	**2020**	**%**
	(Unaudited)			
	(US dollars in thousands, except percentage)			
ZEJULA	1,925	56.3	13,791	71.8
Optune	1,495	43.7	5,422	28.2
Total	3,420	100.0	19,213	100.0

Revenue increased significantly by US$15.8 million to US$19.2 million for the six months ended June 30, 2020 from US$3.4 million for the six months ended June 30, 2019, primarily due to the increase in revenue generated from both ZEJULA and Optune as a result of our commercial launch of these two commercialized products in China during the first half of 2020.

Cost of Sales

Cost of sales increased by US$4.1 million to US$5.0 million for the six months ended June 30, 2020 from US$0.9 million for the six months ended June 30, 2019, primarily attributable to the increased cost and royalty fees in connection with the sales of ZEJULA and Optune in China for the six months ended June 30, 2020.

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the periods indicated.

	Six Months Ended June 30,			
	2019	**%**	**2020**	**%**
	(Unaudited)			
	(US dollars in thousands, except percentage)			
Research and development expenses:				
Personnel compensations and related costs	15,095	25.6	21,600	21.2
Licensing fees	22,700	38.5	51,720	50.7
Payment to CROs/CMOs/Investigators	14,647	24.9	19,812	19.4
Other costs	6,486	11.0	8,917	8.7
Total	58,928	100.0	102,049	100.0

Research and development expense increased by US$43.1 million to US$102.0 million for the six months ended June 30, 2020 from US$58.9 million for the six months ended June 30, 2019. The increase in research and development expense included the following:

- US$6.5 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more R&D personnel and increase of compensation levels for our R&D personnel during the six months ended June 30, 2020;

- US$29.0 million for increased licensing fees which was primarily attributable to the upfront fee we paid to Regeneron under our collaboration agreement that we entered into in April 2020 and milestone payments for our existing projects;

- US$5.2 million for increased payment to CROs/CMOs/Investigators as we advanced our drug candidate pipeline; and

- US$2.4 million for increased other costs, including professional service expenses and rental expenses.

The following table summarizes our research and development expenses by program for the periods indicated.

	Six Months Ended June 30,			
	2019	**%**	**2020**	**%**
	(Unaudited)			
	(US dollars in thousands, except percentage)			
Research and development expenses:				
Clinical programs	37,230	63.2	72,335	70.9
Pre-clinical programs	3,763	6.4	2,915	2.9
Unallocated research and development expenses	17,935	30.4	26,799	26.2
Total	58,928	100.0	102,049	100.0

During the six months ended June 30, 2020, 70.9% and 2.9% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the six months ended June 30, 2019, 63.2% and 6.4% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively.

Selling, General and Administrative Expenses

	Six Months Ended June 30,			
	2019	**%**	**2020**	**%**
	(Unaudited)			
	(US dollars in thousands, except percentage)			
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	19,352	65.6	27,082	63.8
Professional service fee	1,607	5.5	4,570	10.8
Other costs	8,530	28.9	10,820	25.4
Total	29,489	100.0	42,472	100.0

Selling, general and administrative expenses increased by US$13.0 million to US$42.5 million for the six months ended June 30, 2020 from US$29.5 million for the six months ended June 30, 2019. The increase in general and administrative expenses included the following:

- US$7.7 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel as we continued to ramp up the sales of ZEJULA and Optune, and increase of compensation levels for our commercial and administrative personnel during the six months ended June 30, 2020;

- US$3.0 million for increased professional service fee in connection with the sales of ZEJULA and Optune in China after our commercial launch of these two commercialized products during the six months ended June 30, 2020; and

- US$2.3 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong and PRC.

Interest Income

Interest income decreased by US$0.5 million to US$2.9 million for the six months ended June 30, 2020 from US$3.4 million for the six months ended June 30, 2019, primarily due to the decrease of our short-term investment balance and interest rates associated with our USD-denominated investments.

Interest Expense

Interest expense decreased by US$23.0 thousand to US$114.0 thousand for the six months ended June 30, 2020 from US$137.0 thousand for the six months ended June 30, 2019 due to the decrease of our bank loan balance.

Share of Loss from Equity Method Investment

We incurred an investment loss of US$0.4 million and US$0.3 million related to our investment in JING for the six months ended June 30, 2020 and 2019, respectively.

Other Income (Expense), Net

Other expense, net increased by US$0.4 million to US$0.7 million for the six months ended June 30, 2020 from US$0.3 million for the six months ended June 30, 2019 due to foreign exchange loss.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of US$128.6 million for the six months ended June 30, 2020 compared to net loss attributable to ordinary shareholders of US$83.3 million for the six months ended June 30, 2019.

Year Ended December 31, 2019 Compared with the Year Ended December 31, 2018

Revenue

The following table sets forth the revenue breakdown by product for the periods indicated.

	Year Ended December 31,			
	2018	**%**	**2019**	**%**
	(US dollars in thousands, except percentage)			
ZEJULA	129	100.0	6,625	51.0
Optune	—	—	6,360	49.0
Total	129	100.0	12,985	100.0

Revenue increased significantly by US$12.9 million to US$13.0 million for the year ended December 31, 2019 from US$0.1 million for the year ended December 31, 2018, primarily due to the increase in revenue generated from both ZEJULA and Optune as a result of the increase in sales of ZEJULA and our commercial launch of Optune in Hong Kong in 2019.

Cost of Sales

Cost of sales increased to US$3.7 million for the year ended December 31, 2019 from US$43.0 thousand for the year ended December 31, 2018, primarily attributable to the increased cost and royalty fees in connection with the sales of ZEJULA and Optune in Hong Kong in 2019.

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the periods indicated.

	Year Ended December 31,			
	2018	**%**	**2019**	**%**
	(US dollars in thousands, except percentage)			
Research and development expenses:				
Personnel compensations and related costs	16,755	13.9	30,820	21.6
Licensing fees	59,152	49.2	58,682	41.3
Payment to CROs/CMOs/Investigators	32,282	26.8	36,814	25.9
Other costs	12,089	10.1	15,905	11.2
Total	120,278	100.0	142,221	100.0

Research and development expenses increased by US$21.9 million to US$142.2 million for year ended December 31, 2019 from US$120.3 million for year ended December 31, 2018. The increase in research and development expenses included the following:

- US$14.1 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the year ended December 31, 2019 and the grants of new share options and vesting of restricted shares to certain employees;

- US$4.5 million for increased payment to CROs/CMOs/Investigators in fiscal year 2019 as we advanced our pipeline; and

- US$3.8 million for increased other costs, including lab consumables and professional service expenses.

The following table summarizes our research and development expenses by program for the periods indicated.

	Year Ended December 31,			
	2018	%	2019	%
	(US dollars in thousands, except percentage)			
Research and development expenses:				
Clinical programs	89,556	74.5	96,442	67.8
Pre-clinical programs	8,102	6.7	8,268	5.8
Unallocated research and development expenses	22,620	18.8	37,511	26.4
Total	120,278	100.0	142,221	100.0

During the year ended December 31, 2019, 67.8% and 5.8% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the year ended December 31, 2018, 74.5% and 6.7% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively.

Selling, General and Administrative Expenses

	Year Ended December 31,			
	2018	%	2019	%
	(US dollars in thousands, except percentage)			
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	13,410	62.2	43,572	62.1
Professional service fee	3,266	15.1	2,887	4.1
Other costs	4,900	22.7	23,752	33.8
Total	21,576	100.0	70,211	100.0

Selling, general and administrative expenses increased by US$48.6 million to US$70.2 million for year ended December 31, 2019 from US$21.6 million for year ended December 31, 2018. The increase in general and administrative expenses included the following:

- US$30.2 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during year ended December 31, 2019 and the grants of new share options and vesting of restricted shares to certain employees; and

- US$18.9 million for increased other costs, including selling, rental, and travel expenses primary attributable to the commercial operation in Hong Kong and PRC for the year ended December 31, 2019.

Interest Income

Interest income increased by US$5.0 million for year ended December 31, 2019 primary attributable to interest income on higher cash and short-term investments balance in 2019.

Interest Expense

Interest expense increased by US$0.3 million for year ended December 31, 2019 primary attributable to increased balance of short-term borrowings in 2019.

Share of Loss from Equity Method Investment

We incurred an investment loss of US$0.8 million and US$0.6 million related to our investment in JING for the year ended December 31, 2019 and 2018, respectively.

Other Income (Expense), Net

Other income, net increased by US$0.9 million for year ended December 31, 2019 primarily due to the increase in governmental subsidies.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of US$195.1 million for the year ended December 31, 2019 compared to net loss attributable to ordinary shareholders of US$139.1 million for the year ended December 31, 2018.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and selling, general and administrative costs associated with our operations. We incurred net losses of US$139.1 million, US$195.1 million and US$128.6 million for the years ended December 31, 2018 and 2019 and for the six months ended June 30, 2020, respectively. As of December 31, 2019 and June 30, 2020, we had an accumulated deficit of US$444.7 million and US$573.3 million, respectively. Our primary use of cash is to fund research and development costs. Our operating activities used US$97.5 million and US$191.0 million of cash flows during the years ended December 31, 2018 and December 31, 2019, respectively, and US$92.3 million for the six months ended June 30, 2020. Historically, we have financed our operations principally through proceeds from private placements as well as proceeds from our initial public offering and subsequent follow-on offerings. As of December 31, 2019 and June 30, 2020, we had cash and cash equivalents and short-term investments of US$275.9 million and US$463.6 million, respectively. In January 2020, we raised US$280.6 million in net proceeds from our subsequent follow-on offering of 6,300,000 ADSs. Our expenditures as a company principally focused on research and development, are largely discretionary and as such our current losses and cash used in operations do not present immediate going concern issues. Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in the Accountants' Report set out in Appendix I to this prospectus are issued. However, in order to bring to fruition our research and development objectives the company will ultimately need additional funding sources and there can be no assurances that they will be made available.

Our ability to pay dividends may depend on receiving distributions of funds from our PRC subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by our PRC subsidiaries only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of our PRC subsidiaries. In accordance with the relevant applicable PRC laws and regulations, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the board of directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. Our PRC subsidiaries were established as domestic enterprises and therefore are subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2018 and 2019 and during the six months ended June 30, 2020, no appropriation to statutory reserves was made because our PRC subsidiaries had substantial losses during such periods. As a result of relevant applicable PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as a general reserve fund, our PRC subsidiaries are restricted in their ability to transfer a portion of its net assets. Foreign exchange and other regulations in China may further restrict our PRC subsidiaries from transferring funds to us in the form of dividends, loans and advances. As of December 31, 2019 and June 30, 2020, amounts restricted are the paid-in capital of our PRC subsidiaries, which amounted to US$155.9 million and US$205.9 million, respectively.

Cash Flows

The following table provides information regarding our cash flows for the periods indicated:

	Year Ended December 31,		Six Months Ended June 30,	
	2018	**2019**	**2019**	**2020**
			(Unaudited)	
		(US dollars in thousands)		
Operating cash flows before changes in operating assets and liabilities	(124,920)	(167,728)	(71,210)	(110,709)
Changes in operating assets and liabilities	27,382	(23,283)	(11,974)	18,390
Net cash (used in) operating activities	(97,538)	(191,011)	(83,184)	(92,319)
Net cash (used in) investing activities	(212,554)	(14,892)	(106,017)	(6,521)
Net cash provided by financing activities	144,147	219,302	217,880	281,500
Effect of foreign exchange rate changes	(763)	91	(28)	12
Net (decrease) increases in cash and cash equivalents	(166,708)	13,490	28,651	182,672

Net cash used in operating activities

We had net cash outflows in operating activities during the Track Record Period. Our primary uses of cash are to fund the development of both our in-licensed and internally developed drug candidates, our clinical trials, our payment for the construction of research and manufacturing facilities and for the purchase of equipment, selling and administrative expenses and other recurring expenses. Our operating cash flow will continue to be affected by our research and development expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements from proceeds from our initial public offering and subsequent follow-on offerings. As our business develops and expands, we expect to generate cash flow from operations including but not limited to the selling of our commercial products. We shall continue to advance our late stage clinical assets into NDA stage and commercialization which will bring incremental cash flow to fund our operation in the foreseeable future.

During the six months ended June 30, 2020, our operating activities used US$92.3 million of cash, which resulted principally from our net loss of US$128.6 million, adjusted for non-cash charges of US$17.9 million, and by cash provided by our operating assets and liabilities of US$18.4 million. Our net non-cash charges during the year ended June 30, 2020 primarily consisted of US$2.1 million depreciation expense, US$13.4 million share-based compensation expense and US$2.1 million non-cash lease expense.

During the six months ended June 30, 2019, our operating activities used US$83.2 million of cash, which resulted principally from our net loss of US$83.3 million, adjusted for non-cash charges of US$12.1 million, and by cash used in our operating assets and liabilities of US$12.0 million. Our net non-cash charges during the year ended June 30, 2019 primarily consisted of US$1.6 million depreciation expense, US$9.3 million share-based compensation expense and US$1.0 million non-cash lease expense.

During the year ended December 31, 2019, our operating activities used US$191.0 million of cash, which resulted principally from our net loss of US$195.1 million, adjusted for non-cash charges of US$27.3 million, and by cash used in our operating assets and liabilities of US$23.2 million. Our net non-cash charges during the year ended December 31, 2019 primarily consisted of US$3.8 million depreciation expense, US$20.3 million share-based compensation expense and US$2.8 million noncash lease expense.

During the year ended December 31, 2018, our operating activities used US$97.5 million of cash, which resulted principally from our net loss of US$139.1 million, adjusted for non-cash charges of US$14.2 million, and by cash provided by our operating assets and liabilities of US$27.4 million. Our net non-cash charges during the year ended December 31, 2018 primarily consisted of US$1.6 million depreciation expense, US$12.2 million share-based compensation expense and a US$0.6 million share of loss from equity method investment and offset by a US$0.3 million amortization of deferred income.

Net cash used in investing activities

Net cash used in investing activities was US$6.5 million for the six months ended June 30, 2020 compared to US$106.0 million for the six months ended June 30, 2019. The decrease in cash used in investing activities was primary due to the proceeds from maturity of short-term investments, net of purchases of short-term investments.

Net cash used in investing activities was US$14.9 million for the year ended December 31, 2019 compared to US$212.6 million for the year ended December 31, 2018. The decrease in cash used in investing activities was primary due to the proceeds from maturity of short-term investments, net of purchases of short-term investments.

Net cash provided by financing activities

Net cash provided by financing activities was US$281.5 million for the six months ended June 30, 2020 compared to US$217.9 million for the six months ended June 30, 2019. The net cash provided by financing activities was mainly attributable to the issuance of ADSs in our subsequent follow-on offering in January 2020.

Net cash provided by financing activities was US$219.3 million for the year ended December 31, 2019 compared to US$144.1 million for the year ended December 31, 2018. The net cash provided by financing activities was mainly attributable to the issuance of ADSs in our subsequent follow-on offering in 2019.

CASH OPERATING COSTS

The following table provides information regarding our cash operating costs for the relevant periods:

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
	(US dollars in thousands)			
Research and Development Costs for Core Products	28,427	15,809	6,712	6,848
Research and Development Costs for Other Products and Drug Candidates	40,785	104,172	44,254	61,219
Unallocated research and development costs	5,865	6,691	2,840	5,199
Workforce Employment Cost (including Research and Development Workforce Employment Cost of Core Products and Other Products and Drug Candidates)	15,845	48,210	23,071	37,324
Direct Production Cost	25	2,326	418	4,980
Non-income Taxes, Royalties and Other Governmental Charges	6	949	–	449
Contingency Allowances	–	–	–	–
Product Marketing	2,234	19,057	6,762	10,045
Other Significant Costs	–	–	–	–

CAPITAL EXPENDITURES

Our cash payment for property and equipment, intangible assets and land use right totaled US$10.1 million and US$15.2 million in 2018 and 2019, respectively, and US$4.8 million and US$1.5 million for the six months ended June 30, 2019 and 2020, respectively. We funded our capital expenditure requirements during the Track Record Period mainly from equity financing and cash at bank. We expect that our capital expenditure in 2020 and 2021 will focus on plant, laboratory equipment and leasehold improvement. We plan to fund our planned capital expenditure mainly using our cash at bank and the estimated net proceeds received from the Global Offering. We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs.

CONTRACTUAL OBLIGATIONS

The following table sets forth our contractual obligations as of June 30, 2020. Amounts we pay in future periods may vary from those reflected in the table.

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
		(US dollars in thousands)			
Contractual Obligations					
Purchase Obligations	3,971	3,971	–	–	–
Operating Lease Obligations	15,437	4,580	6,442	2,975	1,440

We also have obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones as well as tiered royalties on net sales. We have not included these commitments on our balance sheet or in the table above because the commitments are cancellable if the milestones are not completed and achievement and timing of these obligations are not fixed or determinable.

As of June 30, 2020, we had outstanding principal amounts of short-term borrowings of US$4.2 million, which were unsecured and guaranteed by Zai Lab Shanghai. As of June 30, 2020, we also had operating lease liabilities amounting to US$14.6 million, certain of which were secured by the rental deposits and all of which were unguaranteed. For detailed information of our indebtedness, see Accountants' Report included in Appendix I to this prospectus.

As of June 30, 2020, we did not have significant contingent liabilities.

Save as disclosed above, since June 30, 2020 and up to the date of this prospectus, there has not been any material and adverse change in our indebtedness and contingent liabilities. Our Directors do not foresee any potential difficulty in obtaining bank facilities should the need arise.

WORKING CAPITAL

We recorded net current assets of US$220.3 million, US$245.8 million, and US$428.3 million, respectively, as of December 31, 2018 and 2019 and June 30, 2020. The following table sets forth a breakdown of our current assets and liabilities as of the dates indicated.

The table below sets forth our current assets, current liabilities and net current assets as of the dates indicated:

	As of December 31,		As of June 30,
	2018	2019	2020
	(US dollars in thousands)		
Current assets:			
Cash and cash equivalents	62,952	75,932	258,604
Short-term investments	200,350	200,000	205,000
Accounts receivable (net of allowance of nil, nil, and US$2 as of December 31, 2018 and 2019 and June 30, 2020, respectively)	90	3,791	7,024
Inventories	4	6,005	6,569
Prepayments and other current assets	5,749	6,736	7,684
Total current assets	**269,145**	**292,464**	**484,881**
Current liabilities:			
Short-term borrowings	3,643	6,450	4,238
Accounts payable	37,432	22,660	32,392
Current operating lease liabilities	–	4,351	4,175
Other current liabilities	7,767	13,174	15,750
Total current liabilities	**48,842**	**46,635**	**56,555**
Net current assets	**220,303**	**245,829**	**428,326**

For a detailed discussion on our cash position, being the balance sheet item that has material impact on our liquidity, as well as material changes in the various working capital items, see "– Liquidity and Capital Resources."

Working Capital Confirmation

Taking into account the financial resources available to us including our cash and cash equivalents on hand and the estimated net proceeds from the Global Offering, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including selling, general, administrative and operating costs (including any production costs) and research and development costs for the next 12 months from the date of this prospectus.

KEY FINANCIAL RATIOS

The following table sets forth our key financial ratios for the periods indicated:

	As of December 31,		As of June 30,
	2018	2019	2020
Gross margin[(1)]	66.7%	71.1%	74.1%
Current ratio[(2)]	5.5	6.3	8.6
Gearing ratio[(3)]	1.5%	2.2%	0.9%

Notes:

(1) Gross margin equals gross profit divided by revenue for the period.

(2) Current ratio equals current assets divided by current liabilities as of the end of the period.

(3) Gearing ratio equals total interest-bearing loans divided by total equity as of the end of the period.

Our gross margin increased from 66.7% as of December 31, 2018 to 77.1% as of December 31, 2019, primarily because we started generating revenue only from the last quarter of 2018. Gross margin increased further to 74.1% as of June 30, 2020, mainly due to the launch of ZEJULA in China and the decrease in cost of sales resulting from the local manufacturing.

Our current ratio increased from 5.5 as of December 31, 2018 to 6.3 as of December 31, 2019, mainly due to (i) the increase in cash and cash equivalents as a result of our public offering of ADSs in May 2019 and (ii) a higher level of accounts receivable and inventories. Current ratio increased further to 8.6 as of June 30, 2020, mainly due to the increase of cash and cash equivalents resulting from the issuance of ADSs in our subsequent follow-on offering in January 2020.

Our gearing ratio increased from 1.5% as of December 31, 2018 to 2.2% as of December 31, 2019, mainly due to the increase of short-term borrowings from commercial banks and partially offset by the increase in additional paid-in capital as a result of our public offering of ADSs in May 2019. Gearing ratio decreased from 2.2% as of December 31, 2019 to 0.9% as of June 30, 2020, mainly due to the increase in additional paid-in capital as a result of our follow-on offering of ADSs in January 2020.

See sections headed "– Results of Operations – Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2019" and "– Results of Operations – Year Ended December 31, 2019 Compared with the Year Ended December 31, 2018" in this section for a discussion of the factors affecting our results of operations during the respective periods.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

We currently do not engage in trading activities involving non-exchange traded contracts or interest rate swap transactions or foreign currency forward contracts. In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk including foreign exchange risk, credit risk, cash flow interest rate risk and liquidity risk.

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of our company included aggregated amounts of RMB26.9 million, RMB47.2 million and RMB165.5 million, which were denominated in RMB, as of December 31, 2018 and 2019 and June 30, 2020, respectively, representing 6%, 9% and 9% of the cash and cash equivalents as of December 31, 2018 and 2019 and June 30, 2020.

Our business mainly operates in China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the RMB because the value of our business is effectively denominated in RMB, while the ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. On July 21, 2005, China government changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that China government would increase the flexibility of the exchange rate, and thereafter allowed the RMB 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 RMB by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day's value, respectively.

To the extent that we need to convert U.S. dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB 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 RMB would have a negative effect on the U.S. dollar amounts available to us.

Credit Risk

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents, short-term investment. The carrying amounts of cash and cash equivalents and short-term investment represent the maximum amount of loss due to credit risk. As of December 31, 2019 and 2018, and June 30, 2020, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in China and international financial institutions outside of China which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions.

Inflation

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. According to the National Bureau of Statistics of China, the Consumer Price Index in China increased by 2.9% and 2.1% in 2019 and 2018, respectively. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our financial statements in conformity with U.S. GAAP, which requires us to make judgments, estimates and assumptions. We continually evaluate these estimates and assumptions based on the most recently available information, our own historical experiences and various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from our expectations as a result of changes in our estimates. Some of our accounting policies require a higher degree of judgment than others in their application and require us to make significant accounting estimates.

The selection of critical accounting policies, the judgments and other uncertainties affecting application of those policies and the sensitivity of reported results to changes in conditions and assumptions are factors that should be considered when reviewing our financial statements. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board, or FASB, issued a comprehensive new standard which amends revenue recognition principles. In 2018, we adopted of ASC Topic 606, or ASC 606, *Revenue from Contracts with Customers*, in recognition of revenue. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Our revenue is all from product sales. We recognize revenue from product sales when we have satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the consumers. Cost of sales mainly consists of the purchase cost of products and royalty fee.

We have applied the practical expedients under ASC 606 with regard to assessment of financing component and concluded that there is no significant financing component given that the period between delivery of goods and payment is generally one year or less.

We started to generate product sales revenue since 2018. For the year ended December 31, 2018, our product revenues were generated from the sale of ZEJULA to customers. For the year ended December 31, 2019 and six months ended June 30, 2020, our product revenues were generated from the sale of ZEJULA and Optune to customers.

In China, we sell the products to distributors, who ultimately sell the products to health care providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the products delivery to distributors. Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates are recorded as a reduction of revenue if any. Estimated rebates are determined based on contracted rates, sales volumes and distributor inventories. We regularly review the information related to these estimates and adjusts the amount accordingly.

In Hong Kong, we sell the products to customers, which are typically healthcare providers such as oncology centers. We utilize a third party for warehousing services. We are a principal in the transaction since we are primarily responsible for fulfilling the promise to provide the products to the customers, maintain inventory risk until delivery to the customers and have latitude in establishing the price. Revenue was recognized at the amount to which we expected to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the third party is recognized in operating expenses.

We didn't recognize any contract assets and contract liabilities as of December 31, 2018 and 2019, and June 30, 2020.

Share-Based Compensation

We grant share options to eligible employees, management and directors and account for these share-based awards in accordance with ASC Topic 718, *Compensation-Stock Compensation*, or ASC 718.

Share-based awards are measured at the grant date fair value and recognized as an expense (i) immediately at grant date if no vesting conditions are required or (ii) using a graded vesting method over the requisite service period, which is the vesting period. See Note 17 to the consolidated financial statements included in the Accountants' Report set out in Appendix I to this prospectus for further details on the assumptions used to estimate the fair value of share-based awards granted in prior periods.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

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

We determine the fair value of the stock options granted to employees. Before 2018, the binomial option pricing model was applied in determining the estimated fair value of the options granted to employees. In 2018, we changed to use the Black-Scholes option valuation model. A change in the valuation technique is a change in accounting estimate for purposes of applying ASC 250, and has been applied prospectively to new awards.

Before January 2019, we have accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 505, *Equity-Based Payments to Non-Employees*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if we had paid cash for the services provided by the nonemployees.

From January 2019, we grant share options to eligible non-employees and accounts for these share based awards in accordance with ASC 718, *Compensation-Stock Compensation*. Non-employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. We determine the fair value of the stock options granted to non-employees using the Black-Scholes option valuation model.

Income Taxes

Current income taxes are provided on the basis of net income for financial reporting purposes, adjusted for income and expense items which are not assessable or deductible for income tax purposes, in accordance with the regulations of the relevant tax jurisdictions. We follow the liability method of accounting for income taxes.

Under this method, deferred tax assets and liabilities are determined based on the temporary differences between the financial statements carrying amounts and tax bases of assets and liabilities by applying enacted statutory tax rates that will be in effect in the period in which the temporary differences are expected to reverse. We record a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in our consolidated financial statements in the period of change.

In accordance with the provisions of ASC 740, *Income Taxes*, we recognize in our financial statements the benefit of a tax position if the tax position is "more likely than not" to prevail based on the facts and technical merits of the position. Tax positions that meet the "more likely than not" recognition threshold are measured at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. We estimate our liability for unrecognized tax benefits which are periodically assessed and may be affected by changing interpretations of laws, rulings by tax authorities, changes and/or developments with respect to tax audits, and expiration of the statute of limitations. The ultimate outcome for a particular tax position may not be determined with certainty prior to the conclusion of a tax audit and, in some cases, appeal or litigation process.

We consider positive and negative evidence when determining whether some portion or all of our deferred tax assets will not be realized. This assessment considers, among other matters, the nature, frequency and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, our historical results of operations, and our tax planning strategies. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the level of our historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe it is more likely than not that we will not realize the deferred tax assets resulted from the tax loss carried forward in the future periods.

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts, circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of December 31, 2018 and 2019, and June 30, 2020, we did not have any significant unrecognized uncertain tax positions.

RECENTLY ISSUED ACCOUNTING STANDARDS

For a summary of recently issued accounting standards, see Note 2 to the Accountants' Report included in Appendix I to this prospectus.

DIVIDEND POLICY

We have never declared or paid dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not have any present plan to pay any dividends. The declaration and payment of any dividends in the future will be determined by our board of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions. Our shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Companies Law a Cayman Islands company may

pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this prospectus, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year. If we pay dividends in the future, in order for us to distribute dividends to our shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries.

Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See "Risk Factors – Risks Relating to Doing Business in China" in this prospectus.

LISTING EXPENSE

Based on the maximum Offer Price of HK$648.00, the total estimated listing related expenses payable by us in relation to the Global Offering is approximately US$29.9 million (assuming the Over-allotment Option is not exercised). We estimate that most of the listing expenses will be recorded as a deduction in equity directly. These listing expenses mainly comprise professional fees paid and payable to the Joint Sponsors, the Joint Bookrunners, the Underwriters, legal advisors and the reporting accountants for their services rendered in relation to the Listing and the Global Offering.

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, the Directors confirm that, up to the date of this prospectus, there has been no material adverse change in our financial or trading position or prospects since June 30, 2020, being the end date of the periods reported on in the Accountants' Report included in Appendix I to this prospectus, and there is no event since June 30, 2020 that would materially affect the information as set out in the Accountants' Report included in Appendix I to this prospectus.

UNAUDITED PRO FORMA ADJUSTED NET TANGIBLE ASSETS

The following unaudited pro forma adjusted net tangible assets of the Group attributable to ordinary shareholders of the Company prepared in accordance with Rule 4.29 of the Hong Kong Listing Rules is set out to illustrate the effect of the Global Offering on the consolidated net tangible assets attributable to ordinary shareholders of the Company as at June 30, 2020 as if the Global Offering had taken place on such date.

This unaudited pro forma adjusted net tangible assets of the Group attributable to ordinary shareholders of the Company has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group, had the Global Offering been completed as of June 30, 2020 or at any further dates. It is prepared based on the audited consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as at June 30, 2020 as derived from the Accountants' Report, the text of which is set out in Appendix I to this prospectus and adjusted as described below.

	Audited consolidated net tangible assets attributable to ordinary shareholders of the Company as of June 30, 2020	Estimated net proceeds from the Global Offering	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as of June 30, 2020	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per Share	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per ADS	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per Share	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per ADS
	US$'000 *(Note 1)*	*US$'000* *(Note 2)*	*US$'000*	*US$* *(Note 3)*	*US$* *(Note 4)*	*HK$* *(Note 5)*	*HK$* *(Note 5)*
Based on the indicative offer price of HK$648.00 per Offer Share	464,250	853,378	1,317,628	15.42	15.42	119.51	119.51

Notes:

(1) The audited consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as of June 30, 2020 is derived from the Accountants' Report set out in Appendix I to this prospectus, which is based on the audited consolidated net assets of the Group attributable to ordinary shareholders of the Company as of June 30, 2020 of US$465,466,000 with adjustments for intangible assets attributable to the ordinary shareholders of the Company of US$1,216,000.

(2) The estimated net proceeds from the Global Offering are based on 10,564,050 Offer Shares at the indicative offer price of HK$648.00 per Offer Share after deduction of the estimated listing expenses and share issue costs (including underwriting fees and other related expenses) expected to be incurred by the Company subsequent to June 30, 2020 and without taking into account any allotment and issuance of any Shares upon the exercise of the Over-allotment Option, the Shares to be issued pursuant to the Share Incentive Plans and other Compensation Programs, including pursuant to the exercise of options or the vesting of restricted shares or other awards that have been or may be granted from time to time and any issuance or repurchase of Shares and/or ADSs by the Company. For the purpose of calculating the estimated net proceeds from the Global Offering, the translation of Hong Kong dollars into U.S. Dollars was made at the exchange rate of HK$7.7501 to US$1.00, which is derived from the exchange rate of Hong Kong dollars against U.S. Dollars on June 30, 2020 set forth in the Exchange Rate Conversion section of the Prospectus. No representation is made that Hong Kong dollars have been, could have been or may be converted to U.S. Dollars, or vice versa, at that rate or at any other rates or at all.

(3) The unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per Share is arrived at after the adjustments referred to in the preceding paragraphs and on the basis that 85,446,388 Shares were in issue assuming that the Global Offering had been completed on June 30, 2020 without taking into account any allotment and issuance of any Shares upon the exercise of the Over-allotment Option, the Shares to be issued pursuant to the Share Incentive Plans and other Compensation Programs, including pursuant to the exercise of options or the vesting of restricted shares or other awards that have been or may be granted from time to time and any issuance or repurchase of Shares by the Company.

(4) The unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per ADS is arrived at after the adjustments referred to in the preceding paragraphs and on the basis that one ADS represents one Shares.

(5) For the purpose of this unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company, the balances stated in U.S. Dollars are converted into Hong Kong dollars at the exchange rate of US$1.00 to HK$7.7501. No representation is made that U.S. Dollars amounts have been, could have been or may be converted into Hong Kong dollars, or vice versa, at that rate or at any other rates or at all.

(6) No adjustments have been made to the unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to the ordinary shareholders of the Company to reflect any trading results or other transactions of the Group entered into subsequent to June 30, 2020.

Our authorized share capital as of the Latest Practicable Date was US$30,000.00 divided into 500,000,000 Shares of a par value of US$0.00006 each.

As of the Latest Practicable Date, our issued share capital consisted of 75,375,511 Shares of par value of US$0.00006 each.

Assuming the Over-allotment Option is not exercised, the share capital of our Company immediately after the Global Offering will be as follows:

Description of Shares	Number of Shares	Approximate percentage of issued share capital
		%
Shares in issue	75,375,511	87.7%
Shares to be issued under the Global Offering	10,564,050	12.3%
Shares in issue upon completion of the Global Offering	85,939,561	100.0%

Assuming the Over-allotment is exercised in full, the share capital of our Company upon completion of the Global Offering will be as follows:

Description of Shares	Number of Shares	Approximate percentage of issued share capital
		%
Shares in issue	75,375,511	86.1%
Shares to be issued under the Global Offering	10,564,050	12.1%
Shares to be issued upon the full exercise of the Over-allotment Option	1,584,600	1.8%
Shares in issue upon completion of the Global Offering	87,524,161	100.0%

ASSUMPTIONS

The above tables assume that the Global Offering becomes unconditional and Shares are issued pursuant to the Global Offering. The above tables do not take into account any Shares which may be allotted and issued upon the exercise of any options granted under the Equity Plans.

RANKING

The Offer Shares are shares in the share capital of our Company and rank equally with all Shares currently in issue or to be issued and, in particular, will rank in full for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this prospectus.

GENERAL MEETINGS

See "Summary of the Constitution of the Company and Cayman Companies Law" in Appendix III to this prospectus.

EQUITY PLANS

See "Statutory and General Information – D. Share Incentive Plans and Other Compensation Programs" in Appendix IV to this prospectus.

We had 75,375,511 Shares outstanding as of the Latest Practicable Date. The following table and accompanying footnotes set forth information relating to the beneficial ownership of our Shares as of the Latest Practicable Date by:

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

Our major shareholders do not have voting rights that are different from our shareholders in general. Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Shares Beneficially Owned	
Name of beneficial owner†	**Number**	**Percent**
Executive Officers and Directors:		
Samantha Du[(1)]	6,083,054	7.8%
Billy Cho	*	*
F. Ty Edmondson	–	–
Tao Fu	*	*
Yongjiang Hei	*	*
William Liang	*	*
Harald Reinhart	*	*
Kai-Xian Chen	*	*
John Diekman	*	*
Nisa Leung	–	–
William Lis	*	*
Leon O. Moulder, Jr	*	*
Peter Wirth	*	*
All Executive Officers and Directors as a Group	7,604,401	9.6%
Beneficial Owners of 5% or More of our Shares:		
QM11 Limited[(2)]	9,072,932	12.0%
FMR, LLC[(3)]	7,075,122	9.4%
Capital Group[(4)]	5,923,328	7.9%
Investment funds affiliated with Advantech Capital[(5)]	4,551,772	6.0%

* The person beneficially owns less than 1% of our outstanding Shares.

† The business address of all directors and officers is 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210.

(1) Includes 3,087,076 Shares issuable to Dr. Du upon exercise of vested options and options exercisable within 60 days of the Latest Practicable Date and 36,820 ADSs purchased by Dr. Du in multiple open market transactions. Includes 1,959,325 Shares held by certain holders of Shares, including Zai management and their affiliates. Although Dr. Du does not have any pecuniary interest in these Shares, these shareholders have granted Dr. Du the right to vote their shares and, therefore, she may be deemed to be the beneficial owner of the Shares held by these shareholders.

(2) Based on a Schedule 13G/A filed on February 14, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. The address for QM11 Limited is Units 4205-06 Gloucester Tower, The Landmark, Central, Hong Kong.

(3) As of June 30, 2020 based on a Form 13F filed on August 14, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly-owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02110.

(4) As of June 30, 2020 based on a Form 13F filed on August 14, 2020. The address for Capital Group is 333 South Hope Street, Los Angeles, CA 90071.

(5) Based on a Schedule 13G/A filed on February 11, 2020, which is the most updated information published on the SEC as at the Latest Practicable Date. Consists of (i) 4,246,791 Shares held by Maxway Investment Limited and (ii) 304,981 Shares held by Harbor Front Investment Limited. The address for Maxway Investment Limited and Harbor Front Investment Limited is c/o DMS House, 20 Genesis Close, George Town, Grand Cayman, KY1-1103, Cayman Islands.

We are seeking a listing on the Hong Kong Stock Exchange pursuant to Chapter 19C of the Listing Rules. Pursuant to Rule 19C.11 of the Listing Rules, Chapter 14A of the Listing Rules governing connected transactions does not apply to us. The following discussion of related party transactions has been prepared pursuant to the requirements of Form 20-F of the SEC, and is included in this prospectus for disclosure purposes only.

AGREEMENTS

Registration Rights Agreement

We have entered into a shareholders agreement in January 2016, or the Registration Rights Agreement, with certain of our shareholders, in which we granted certain demand registration rights, piggyback registration rights and F-3 registration rights to holders of our registrable securities.

OTHER RELATIONSHIPS

Voting Proxy

Certain holders of our Shares, which hold 1,959,325 Shares, have granted Dr. Du the right to vote their Shares.

MEDx (Suzhou) Translational Medicine Co., Ltd. (formerly known as Qiagen (Suzhou) Translational Medicine Co., Ltd)

An immediate family member of Dr. Du is owner of MEDx (Suzhou) Translational Medicine Co., Ltd., or MEDx. We incurred US$0.1 million, US$0.2 million and US$0.2 million in research and development expenses to MEDx for drug research and development services for the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, respectively.

AGREEMENTS WITH OUR DIRECTORS AND EXECUTIVE OFFICERS

Compensation of Directors and Executive Officers

See "Directors and Senior Management – B. Compensation" for a discussion of our compensation of directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see "Directors and Senior Management – B. Compensation – Employment Arrangements with Our Executive Officers."

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. We also maintain a general liability insurance policy which covers certain liabilities of our directors and executive officers arising out of claims based on acts or omissions in their capabilities as directors or officers.

A. DIRECTORS AND SENIOR MANAGEMENT

The table below sets forth certain information in respect of our directors, officers and other key employees:

Name	Age	Position(s)	Date of Appointment as Director or Senior Management	Year of Joining our Group
Executive Officers				
Samantha Du	55	Director, Chairwoman and Chief Executive Officer	March 2013	2013
Billy Cho	43	Chief Financial Officer	March 2018	2018
F. Ty Edmondson	54	Chief Legal Officer	August 2020	2020
Tao Fu	48	Director, President & Chief Operating Officer	August 2017	2017
Yongjiang Hei	57	Chief Medical Officer, Oncology	August 2018	2018
William Liang	49	Chief Commercial Officer	June 2018	2018
Harald Reinhart	68	Chief Medical Officer, Autoimmune and Infectious Diseases	May 2017	2017
Independent Directors				
Kai-Xian Chen	74	Independent Director	August 2018	2018
John Diekman	77	Independent Director	August 2017	2017
Nisa Leung	50	Independent Director (since July 2020)	August 2014	2014
William Lis	56	Independent Director	October 2018	2018
Leon O. Moulder, Jr.	62	Independent Director	January 2020	2020
Peter Wirth	70	Independent Director (since May 2020), Senior Advisor	June 2017	2015
Other Key Employees				
Jonathan Wang	38	Senior Vice President, Head of Business Development	June 2014	2014
Ning Xu	55	Executive Vice President, Head of Clinical Operations	June 2014	2014
James Yan	56	Chief Operating Officer, R&D	April 2020	2015

Executive Officers

Samantha Du, Ph.D. founded Zai Lab and has been its Director, Chairwoman and CEO since its inception in 2014. Prior to founding Zai Lab, Dr. Du spent two years at Sequoia Capital China where she led several investments and served on their boards. From 2001 to 2011, Dr. Du co-founded Hutchison MediPharma and Hutchison China MediTech and served as their Chief Executive Officer and Chief Scientific Officer, respectively, since their inception. During her tenure, Hutchison MediPharma discovered and developed an in-house first in class/best in class portfolio, of which two products have been approved, and pioneered China's FIH green channel for innovative oncology drugs, established collaborations with multinational companies including, among others, Johnson & Johnson, Eli Lilly and Company and Merck Sereno. Dr. Du began her research career with Pfizer in the United States from 1994 till 2001. She was involved in the development of several clinical stage assets, two of which launched globally. She led the licensing activities, from the scientific side, for metabolic diseases globally as her last position at Pfizer. She received her Ph.D. in biochemistry from the University of Cincinnati in 1994 and her bachelor's degree in molecular biology from Jilin University, China in 1987. She has received many awards globally for her achievements in life sciences and is on several biopharma innovation and investment committees.

Billy Cho, M.B.A., M.A. joined our Company as our Chief Financial Officer in March 2018. Prior to joining our Company, Mr. Cho served as Managing Director and Head of Asia Healthcare Investment Banking at Citigroup. Based in Hong Kong since 2011, Mr. Cho was responsible for healthcare client coverage at Citigroup across the Asia Pacific region and led many biopharma transactions in China, including Zai Lab's U.S. initial public offering. Prior to this, he was based in New York in healthcare M&A investment banking and also spent time in corporate development for a pharmaceutical services company. Mr. Cho started his career at Ernst & Young performing financial audits of U.S.-based healthcare companies. Mr. Cho earned his M.B.A. from the Wharton School of the University of Pennsylvania in May 2011, M.S. in Accounting from University of Virginia in 2001, and a B.S. in Business Administration from the University of Southern California's Marshall School of Business in 2000.

F. Ty Edmondson joined our Company as Chief Legal Officer in August 2020. Mr. Edmondson has served in various legal and compliance roles during his tenure at Biogen Inc., a leading global biotech company where he has been from June 2014 through August 2020. Most recently, Mr. Edmondson served as Senior Vice President, Chief Corporation Counsel and Assistant Secretary. During his time at Biogen, he also served as the Chief Compliance Officer and Chief Commercial Counsel of the company. Prior to Biogen, Mr. Edmondson served as Vice President, Associate General Counsel and Corporate Secretary for Sepracor Inc. as well as in various senior legal and compliance positions in Japan and China after Sepracor's acquisition by Sumitomo Dainippon Pharma Co., Ltd. Before Sumitomo, Mr. Edmondson served in various roles with life sciences companies with a focus on international and U.S. FDA work, including Eisai, Inc., Boston Scientific and Bristol-Myers Squibb, with a focus on international and U.S. FDA work. Before his work in the life sciences industry, he was an

associate with the admiralty law firm, Royston Rayzor in Houston, Texas. Mr. Edmondson received a BA degree in British Imperial and Commonwealth History from Washington & Lee University in June 1988 and received a J.D. from the Widener University School of Law in May 1993.

Tao Fu has been our Director since 2017 and has served as our Company's President and Chief Operating Officer since September 2018. Prior to joining our Company, he was Executive Vice President, Chief Commercial and Business Officer of Portola Pharmaceuticals, Inc., a publicly traded biotechnology company specializing in cardiovascular disease, hematological disorders and cancer from June 2015 to September 2018. Prior to joining Portola in June 2015, Mr. Fu was Vice President, business development, head of M&A and alliance management at BMS. Mr. Fu led all M&A, divestiture, strategic transaction and venture investment opportunities as well as alliance management for BMS. Between 2003 and 2014, Mr. Fu worked at Johnson & Johnson in a number of roles, most recently as Vice President, business development, where he was responsible for global M&A activities in the pharmaceutical sector. Prior to joining Johnson & Johnson, Mr. Fu held managerial positions with Scios Inc., a biotechnology company in California; McKinsey & Company, a global management consulting firm; and Becton Dickinson, a leading medical device company. Mr. Fu received a master of science in cell biology from the University of Rochester, and a master of business administration in finance and marketing from Vanderbilt University. Mr. Fu received a Master of Science degree from the University of Rochester in October 1994 and an M.B.A degree from Vanderbilt University in May 1997. Mr. Fu did his undergraduate studies in biology at Tsinghua University from 1989 to 1992 and earned a Chartered Financial Analyst (CFA) designation in September 2000 awarded by the Board of Governors of the Association for Investment Management and Research (AIMR).

Yongjiang Hei, M.D., Ph.D. has been our Chief Medical Officer, oncology since 2018. Prior to joining our Company, Dr. Hei was the Chief Medical Officer at Qilu Pharmaceuticals, responsible for the overall strategy and operations of clinical development programs in all therapeutic areas. Dr. Hei joined Qilu from the San Diego-based biotechnology company Ambrx, where he served as the Chief Medical Officer responsible for the clinical strategy and operations, focusing on antibody-drug conjugates and bispecific antibodies. Prior to Ambrx, Dr. Hei had worked at Amgen for approximately ten years as the Executive Medical Director in oncology global development and medical affairs. In particular, he was the Global Development Leader for numerous oncology pipeline molecules and marketed products including small molecules such as Motesanib as well as biologics such as conatumumab and Vectibix. Additionally, during his tenure at Amgen, Dr. Hei spent three years in China as the Medical Head to build the clinical medical teams and establish product development and clinical operation capabilities for Amgen China. Before Amgen, Dr. Hei served as the U.S. Medical Director for Roche, and Senior Global Brand Medical Director/Executive Director for Novartis Oncology where he led the development and execution of medical plans and expanded investigator-initiated clinical research. In addition, Dr. Hei supported regulatory filings and submissions at the FDA, PMDA (Japan), EMA, and the CFDA. Dr. Hei holds a medical degree

from Shihezi Medical College in China, and received a graduate degree from the West China University of Medical Sciences (M.Sc) in July 1986. Dr. Hei was conferred a Doctor of Philosophy degree in November 1993 by the University of British Columbia in Canada.

William Liang, M.D. joined our Company as our Chief Commercial Officer in June 2018. Prior to joining our Company, Mr. Liang served as Vice President at AstraZeneca heading up the Oncology Business Unit in China. Under his leadership, AstraZeneca built a top performing oncology franchise in China by significantly outgrowing the market with many successful product launches, including setting a new benchmark for the successful market launch of Tagrisso. During his tenure, Mr. Liang expanded his team from approximately 500 to 2,000 professionals and introduced a patient-centric business model to establish AstraZeneca's oncology leadership position in China. Prior to AstraZeneca, he was Vice President of Oncology at BMS in China, where he rebuilt the oncology sales team to achieve substantial sales growth. Previously, he spent over 13 years in senior commercial roles at Roche, where he began his career and ultimately achieved the position of China Business Unit Director of Oncology. Mr. Liang received his Medical Degree in Clinical Medicine from Fudan University in July 1994 and his Executive MBA degree from the China Europe International Business School in September 2010.

Harald Reinhart, M.D. has been our Chief Medical Officer, autoimmune and infectious diseases since 2017. He is currently adjunct clinical professor of infectious diseases at the Yale School of Medicine. Prior to joining our Company, Dr. Reinhart worked at Shionogi US as Head of Clinical Development & Medical Affairs, where he directed a broad portfolio of antibiotics, diabetes, allergy and pain medications and guided a woman's health product through Phase III, NDA and FDA approval. Between 2003 and 2011, Dr. Reinhart held senior roles at Novartis, including Vice President and Global Project Leader of Infectious Disease, Transplantation and Immunology. He oversaw successful filings of sNDAs and NDAs for Coartem, Famvir, Sebivo, and Cubicin, managed clinical development groups in the U.S. and E.U., and supervised the transitioning of projects from research into clinical development. From 1991 until 2003 he worked at Bayer in anti-infectives and diabetes. He was International Clinical Project Manager for ciprofloxacin and acarbose and in charge of numerous successful sNDA filings. He also oversaw the strategic development of several early phase antibacterial and antiviral projects. Dr. Reinhart received his medical degree from the University of Würzburg in Germany in May 1978. He completed his medical specialty training in the United States and has been elected as a Fellow by the American College of Physicians in January 1991.

Independent Directors

Kai-Xian Chen, Ph.D. has been our independent Director since August 2018. Professor Chen has been serving as the independent non-executive Director of InnoCare Pharma Limited since March 2020. He has also been serving as the independent Director of Jiangsu Kanion Pharmaceutical Co., Ltd. since December 2019 and the independent non-executive Director of Innovent Biologics, Inc. since October 2018. From 2007 to 2017, he served as a member of the National Committee of the Chinese People's Political Consultative Conference. From 2005 to 2014, Professor Chen served as President of Shanghai University of Traditional Chinese

Medicine. From 2011 to 2018, Professor Chen served as President of the Shanghai Association for Science and Technology. Prior to that, from 1993 to 2004, Professor Chen served as Deputy Director and later, Director of Shanghai Institute of Materia Medica, or SIMM, Chinese Academy of Sciences. Professor Chen has as also served as Principal Scientist for two National Basic Research Programs by the MOST. Since 2001, professor Chen has served successively as the member of the Chief Specialists Board and the deputy Chief Technical Officer of the major science and technology projects "innovative drugs and modernization of traditional Chinese medicine" and "Innovative Drug Research & Development," where he participated in the organization and promotion of new drug research and development for China's 10th -13th Five Year Plans. In 1999, Professor Chen was elected as a member of the Chinese Academy of Sciences. Prior to that, from 1985 to 1988, he conducted postdoctoral research at Institut de Biologie Physico-Chimique in Paris. Professor Chen started his academic career at SIMM as an Associate Professor, where he later reached the level of Full Professor. Professor Chen received his Master and Ph.D. Degree at the Chinese Academy of Science in 1982 and 1985 respectively, and his Bachelor of Science from Fudan University in 1967.

John D. Diekman, Ph.D. has been our independent Director since 2017. Dr. Diekman is founding partner of 5AM Ventures, where he has served since 2002. He is director of Cleave Therapeutics, Inc., a cancer therapeutic company; and Wildcat Discovery Technologies, Inc., a technology company that discovers materials for energy storage applications; charter trustee of Princeton University; chairman of the board of directors of The Scripps Research Institute; and a member of the advisory board of the Schaeffer Center for Health Policy and Economics at the University of Southern California. During the last five years, Dr. Diekman served as the Chairman and Director of IDEAYA Biosciences from 2015 to June 2020. Dr. Diekman holds an A.B. in Organic Chemistry from Princeton University in 1965 and a Ph.D. in Chemistry from Stanford University in 1969.

Nisa Leung has been our Director since 2014 and independent Director since July 2020. Ms. Leung is a Managing Partner at Qiming Venture Partners, where she leads its healthcare investments. In addition to serving on our board of directors, Ms. Leung is also a member of the board of directors of CanSino Biologics Inc., a vaccine developer; dMed, a Shanghai-based CRO consulting startup; Gan & Lee Pharmaceuticals, a developer of insulin analog; Nurotron Biotechnology, a developer of neurostimulation systems; and Venus Medtech, a developer of interventional artificial cardiac valve systems. Ms. Leung received a Master of Business Administration from the Stanford Graduate School of Business in June 2001 and a B.S. in Hotel Administration from Cornell University in 1992.

*William Li*s has been our independent Director since October 2018. He has 28 years of biopharmaceutical experience. He is the Executive Chairman, and interim CEO of Jasper Therapeutics, Inc where he led the company's 2019 Series A financing. Previously, Mr. Lis served as Chief Executive Officer and a Director of Portola Pharmaceuticals, Inc. from 2009 until 2018 after serving as Chief Operating Officer. Under his leadership, Portola successfully grew from a discovery-stage company to a fully integrated research and development and commercial organization, and independently discovered and developed Andexxa® and Bevyxxa® through commercial launch, and advanced cerdulatinib into clinical development.

He led corporate partnerships and private and public financings including an initial public offering in 2013. The company grew into a multi-billion valuation company during his tenure. Portola was acquired by Alexion Pharmaceuticals in 2020. Mr. Lis held executive positions at Scios, Inc. (a Johnson & Johnson company) where he last served as Sr. Vice President of Business Development and New Product Development, having led efforts for the in-licensing, development and pre-commercial launch for Xarelto®; He also held positions of increasing responsibility at Millennium Pharmaceuticals, Inc. (previously COR Therapeutics, Inc.) and Rhone Poulenc Rorer in sales, marketing, medical affairs and business development. He was involved in the U.S. commercial launch of several products, including Integrilin®, Lovenox® and Rilutek®. Mr. Lis served as a member of the Bio Board of Directors for Emerging Companies and is currently an independent Director of Eidos Therapeutics, Inc. and Zai Laboratories, Inc. Mr. Lis holds a B.S. from the University of Maryland.

Leon O. Moulder, Jr. has been our independent Director since January 2020. Mr. Moulder is the Founding General Partner of Tellus BioVentures, LLC, an early-stage life sciences investment fund. He most recently served as Chief Executive Officer and Director of Tesaro, Inc. since cofounding the company in 2010. Acquired by GSK in January 2019, Tesaro was a fully-integrated Boston based oncology-focused biopharmaceutical company with operations in North America and Europe. He previously served as President and Chief Executive Officer of Abraxis BioScience, Inc., prior to the company's eventual acquisition by Celgene Corporation in 2010. Prior to that, from 2008, Mr. Moulder served as Vice Chairman of Eisai Corporation of North America following Eisai's acquisition of MGI PHARMA, where he served as President and Chief Executive Officer beginning in 2003 and previously as Executive Vice President since 1999. This followed him serving as a member of the founding management team of a venture-stage biotech company in 1997. Mr. Moulder began his career as a clinical pharmacist followed by a seventeen year career at predecessor companies of Sanofi, beginning with Marion Laboratories in 1981. Mr. Moulder is a Temple University Trustee, Chair of the Trustee Committee for Research, Chair of the Temple University Japan (TESS) Board and serves on the board of the Fox Chase Cancer Center. He is a Council Member for both the University of Chicago Booth School of Business and the Polsky Center for Entrepreneurship and Innovation. Mr. Moulder serves on the board of the Helsinn Group, is Chair of the Board of Directors of Trevena, Inc. and previously served on the Boards of Cubist Pharmaceuticals and the Biotechnology Innovation Organization (BIO). Mr. Moulder received a Pharmacy degree from Temple University in 1980 and an MBA from The University of Chicago Booth School of Business in 1997.

Peter Wirth has been our Director since 2017, independent Director since May 2020 and has been our senior advisor since 2015. He is a venture partner at Quan Capital Management, LLC, a global venture capital firm; chairman of the board of directors of FORMA Therapeutics, a Nasdaq-listed clinical stage biopharmaceutical company developing novel therapeutics for patients with rare hematological diseases and cancer; and chairman of the board of directors at Syros Pharmaceuticals, a Nasdaq-listed clinical stage biopharmaceutical company developing novel therapeutics for patients with leukemia and select solid tumors. From 2011 to 2014, Mr. Wirth served as Founder, President and Director of Lysosomal Therapeutics, Inc., a biopharmaceutical company focused on small molecule research and development in the field

of neurodegeneration. From 1996 to 2011, Mr. Wirth served as a senior executive at Genzyme, which is now part of Sanofi, and most recently as its Executive Vice President of legal and corporate development, Chief Risk Officer and corporate secretary. Until June 2015, Mr. Wirth also served as a director of Synageva BioPharma Corp., a Nasdaq-listed biopharmaceutical company which is now owned by Nasdaq-listed Alexion Pharmaceuticals. Mr. Wirth received a B.A. in Political Science from the University of Wisconsin at Madison in 1972 and a JD from Harvard Law School in 1975.

Other Key Employees and Advisors

Jonathan Wang has been our senior Vice President, head of business development since 2014. Prior to joining our Company, Mr. Wang was an investment professional at OrbiMed, where he was responsible for China healthcare investment and portfolio management. From 2005 to 2011, Mr. Wang worked as a consultant at the Boston Consulting Group in China, where he specialized in pharmaceutical and healthcare engagements, assisting multinational and local companies with their China strategy. Previously, Mr. Wang also gained financial transactional experience at Goldman Sachs Investment Banking. Mr. Wang received a master of business administration in healthcare management from Wharton Business School in 2010.

Ning Xu, M.D. has been our executive Vice President, head of clinical operations since 2014. Prior to joining our Company, he served as Vice President, head of clinical development service at Covance China. Before joining Covance, Dr. Xu served as a senior medical and regulatory affairs executive at Johnson & Johnson and GSK. Dr. Xu received a medical degree from Peking Union Medical College in 1991 and a master of business administration from the University of Illinois at Chicago in 2000. Dr. Xu also completed a postdoctoral fellowship at the Medical School, University of Illinois at Chicago. Between 2011 and 2015, he was the chairman of the Advisory Council of DIA China and a Director of DIA Global.

James Yan, Ph.D. has been our Chief Operating Officer, R&D since April 2020. Prior to this role, he was the Executive Vice President and Head of Pre-Clinical Development and Program & Portfolio Management. Prior to joining our Company, Dr. Yan was the head of the Covance early development Shanghai site, where he was responsible for all aspects of the business. Between 2009 and 2011, Dr. Yan served as the head of drug safety evaluation and program management of Hutchison Medi-Pharma. Prior to Hutchison Medi-Pharma, Dr. Yan had significant experience at Pfizer in the United States. Over the course of his career, Dr. Yan was involved in many IND and NDA filings for multiple drug candidates and gained substantial experience working with regulatory agencies in several countries. Dr. Yan received a Ph.D. from Peking Union Medical University and completed post-doctoral training at the University of Chicago's Ben-May Institute for Cancer Research. He is a diplomat of the American Board of Toxicology (DABT), a council member of the China Society of Toxicology and a member of the Drug Toxicity and Drug Safety Evaluation Committee, a member of Pharmaceutical Toxicology Committee of China Pharmacology Society and vice chairman of Drug R&D Committee of China Pharmaceutical Innovation and Research Association (PhIRDA).

Save as disclosed above, none of our Directors, executive officers or key employees holds any other directorships in any other company listed in Hong Kong or overseas during the three years immediately preceding the date of this prospectus.

In addition, our Board is advised by our Scientific Advisory Board, which comprises Lieping Chen, M.D., Ph.D., Richard A. Flavell, Ph.D., Neal Rosen, M.D., Ph.D., Timothy Yap, M.D., Ph.D. and Alex A. Adjei, M.D., Ph.D., FACP. Please refer to "Business – Our Scientific Advisory Board" for further details.

B. COMPENSATION

Employment Arrangements with Our Executive Officers

We have entered into employment agreements with each of our executive officers. Dr. Du is employed by our Company pursuant to an amended and restated employment agreement that became effective December 1, 2018. Dr. Du also is a party to an employment agreement with Zai Lab Shanghai. In addition, Dr. Du has entered into an agreement with our U.S. subsidiary, Zai Lab (US) LLC, pursuant to which a portion of her base salary will be paid by Zai Lab (US) LLC based on the level of services that she provides this entity. Dr. Fu, Dr. Reinhart and Mr. Edmondson are each employed by Zai Lab (US) LLC pursuant to employment agreements and amended and restated employment agreements that became effective on January 25, 2019, December 1, 2018 and August 15, 2020, respectively. Dr. Hei is employed by Zai Lab (US) LLC and also party to an employment agreement with Zai Lab Shanghai. Mr. Cho is employed by Zai Lab HK. Mr. Liang is employed by Zai Lab Shanghai.

Employment Agreements with Executive Officers at Zai Lab HK, Zai Lab (US) LLC and the Company

Under the terms of the Zai Lab HK, Zai Lab (US) LLC and our Company employment agreements with our executive officers, we may terminate an executive officer's employment at any time, with or without "cause," by giving such executive officer a notice of termination. In the event of a voluntary termination other than for "good reason" or a termination by the company for cause, the executive officer will receive the unpaid portion of his or her base salary, computed pro rata to the date of termination, plus reimbursement for unpaid business expenses ("accrued compensation"). In the event of a termination without "cause" or a resignation of the executive officer for "good reason," the executive officer, other than Dr. Du, will receive (i) accrued compensation, (ii) a separation benefit consisting of either six or twelve months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over such period following the effective date of such officer's termination of employment, depending on service, (iii) a pro-rated portion of the executive officer's target bonus (other than Mr. Cho and Dr. Hei), (iv) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted (in the case of Mr. Edmondson only) and (v) any additional compensation that may be required by applicable law (the "Severance Benefits"). In the event that Dr. Du's employment is terminated without "cause" or she resigns for "good reason," Dr. Du will

receive (i) the accrued compensation, (ii) a separation benefit consisting of eighteen months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the eighteen-month period following the effective date of her termination of employment, (iii) a pro-rated portion of her target bonus, (iv) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to Dr. Du prior to such termination (the "Du Equity Acceleration") and (v) any additional compensation that may be required by applicable law (the "Du Severance Benefits"). In the event the employment of an executive officer, other than Dr. Du, is terminated without "cause" or the executive officer resigns for "good reason" within twelve months following a change in control (as defined in the executive officer's employment agreement), the executive officer is entitled to receive (i) accrued compensation, (ii) a separation benefit consisting of either twelve months' or fifteen months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over such period following the effective date of such officer's termination of employment, depending on service, (iii) a pro-rated portion of the executive officer's target bonus, (iv) any additional compensation that may be required by applicable law and (v) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to the executive officer prior to such termination. In the event Dr. Du's employment is terminated without "cause" or she resigns for "good reason" within twelve months following a change in control (as defined in her employment agreement), in addition to the Du Equity Acceleration, Dr. Du is entitled to receive (i) the accrued compensation, (ii) a separation benefit consisting of eighteen months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the eighteen-month period following the effective date of her termination of employment and (iii) an additional lump-sum payment equal to the sum of (x) six (6) months' base salary, (y) two times her target bonus and (z) six months of the company's portion of monthly premiums for health, dental, and vision insurance coverage.

For purposes of the employment agreements described above, "cause" generally means (1) the executive officer's repeated drunkenness or use of illegal drugs (or, in the case of Mr. Fu, the executive officer's drunkenness or use of illegal drugs and, in the case of Mr. Edmondson, the executive officer's use of legal or illegal drugs, including alcohol) which adversely interferes with the performance of the executive officer's obligations and duties in the company, (2) the conviction (or, in the case of Mr. Edmondson, the commission) of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws, (3) the executive officer's either mismanagement or gross mismanagement of the business and affairs of the company or of its subsidiaries that directly results in a material loss (or, in the case of Mr. Edmondson, that could reasonably be expected to result in material harm) to the company (and for executive officers other than Mr. Edmondson, and for which the company has reasonable proof was committed by the executive officer), (4) the executive officer's material violation of any terms of the employment agreement or the restrictive covenants agreement between him or her and the company, (5) a conclusive finding by an independent fact finder appointed by the board of directors for any willful misconduct, dishonesty or acts of moral turpitude by the executive, which is materially detrimental to the

interests and well-being of the company, including, without limitation harm to its business or reputation (or, in the case of Mr. Edmondson, the executive officer's material failure to perform or substantial negligence in the performance of his obligations and duties to the company or any other conduct by the executive officer which is or could reasonably be expected to be materially detrimental to the interest and well-being of the company) or (6) in the case of Mr. Edmondson only, the suspension or loss of his license to practice law for misconduct in any jurisdiction in which he is licensed as an attorney. For this purpose, "good reason" means (1) any material diminution of the executive officer's duties or responsibilities (except in connection with a termination for cause, or by reason of death or "disability") or an assignment of duties or responsibilities that are materially inconsistent with the executive officer's position, (2) any material breach of the employment agreement by the company which is not cured within ten (10) business days after written notice is given to the company (or, in the case of Mr. Edmondson, which is not cured within thirty (30) days after written notice is given to the company), (3) relocation of the executive officer's location from the place of the assignment by the company (for Samantha Du, relocation from the place of assignment of the founder by the company, for Mr. Cho, Dr. Hei, relocation from the place of initial assignment by the company, for Mr. Fu and Dr. Reinhart, relocation from the place of assignment by the company and for Mr. Edmondson, relocation from the primary location from which he performs his services to the company), without consent, to a location more than thirty (30) kilometers from such location, other than temporary relocations of no longer than six (6) calendar months or (4) in the case of Mr. Edmondson only, any material diminution of his base salary and non-discretionary compensation or any change in his reporting structure such that he no longer reports to the Chief Executive Officer of the Company.

In the event of termination of employment by reason of death or disability (or, in the case of Mr. Edmondson, only in the event of a termination of employment by reason of death), the executive officer is entitled to receive the accrued compensation, a payment equal to one month's base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage plus any other additional compensation required by law and, with respect to Dr. Du only, the Equity Acceleration. For purposes of the employment agreements, "disability" means the executive officer is incapacitated or disabled by accident, sickness or otherwise, so as to render him or her mentally or physically incapable of performing the services under the employment agreement for a period of ninety (90) or more consecutive days, or for ninety (90) days during any six (6) month period. In the event of termination of Mr. Edmondson's employment by reason of disability, Mr. Edmondson is entitled to the Severance Benefits.

As a condition to receiving payments during an applicable severance period, the executive officer must execute a release of claims that is satisfactory to the company.

Each executive officer has generally agreed to assign to us or our designee all rights and titles to any inventions created while he or she is performing services within the scope of employment with us or utilizing our facilities. Each executive officer has also agreed, during his or her employment with us and thereafter, not to use, disclose or transfer any confidential information of our company other than as authorized by us within the scope of his or her duties.

Moreover, each of our executive officers has agreed to execute the company's compliance agreement regarding confidentiality, trade secrets, intellectual property and competitive activities, which subjects the executive to certain restrictive covenant obligations, including an agreement by the executive, for the term of his or her employment and for a period of one to two years thereafter, not to (i) directly or indirectly, compete with our business within any country where we conduct or, at the time of his or her employment, are actively engaged in planning to conduct, our business (for Dr. Hei and Mr. Fu, this restriction is limited to their period of employment, and for Mr. Edmondson, this restriction is subject to certain limitations under Massachusetts law) or (ii) solicit for any employees of our Company or orders from any person, firm or company which was at any time during the twelve months prior to termination of such employment a customer or supplier of our Company, or to modify its business relationship with our Company in a manner adverse thereto.

Employment Agreements with Executive Officers at Zai Lab Shanghai

Dr. Du, Dr. Hei and Mr. Liang are each party to a service agreement with Zai Lab Shanghai. The employment agreements with Zai Lab Shanghai provide that we engage each executive officer on a fixed term. Dr. Du's agreement with Zai Lab Shanghai does not have a fixed term. We provide labor protection and work conditions that comply with the safety and sanitation requirements stipulated by the relevant PRC laws. Relevant executive officers (except non-PRC nationals) and the Company contribute to statutory social insurance and other benefits.

During any probation period, we may immediately terminate an executive's employment agreement without payment of severance or other liability if the executive fails to meet the company's recruiting requirements. Outside any probation period, we may terminate an executive officer's employment with Zai Lab Shanghai by providing the executive with thirty (30) days' notice or one month's base salary in lieu of such notice and a severance benefit in accordance with local law if (i) the executive is ill or suffers any injury that is not work-related, and fails to perform the original work after the prescribed treatment period or fails to perform other work arranged by the company, (ii) the executive is not qualified for the job, and still fails to be qualified for the job after training is given or the position is adjusted, (iii) there is a significant change to the objective circumstances on which this contract is based, resulting in the failure to perform this contract, and after the consultations by both parties, no agreement can be reached in respect of the modification of the content of this contract, (iv) the company needs to terminate employees during any reorganization to avoid bankruptcy, or because it experiences serious difficulties in production or operation, and (v) other circumstances prescribed by PRC laws or regulation. In addition, we may terminate the executive's employment without notice or payment if (i) the executive seriously or continuously violates, or violates several times, the employment rules and policies of the company, (ii) the executive commits serious dereliction in the performance of his or her duties, or practices graft, or engages in malpractice to seek private benefit, as applicable, in either case causing severe damage to the interests of the company, (iii) the executive commits fraud or uses coercive measures or takes advantage of the company's vulnerability to make it enter into this contract or to make amendments thereto against the company's will, (iv) the executive is prosecuted for

criminal liability, or (v) under other circumstances as permitted by PRC laws and regulations. Each executive officer may voluntarily terminate his or her contract without cause with thirty (30) days' prior notice to us. In the event the employment of Mr. Liang is terminated without "cause" or resigns for "good reason" within twelve months following a change in control (as defined in his employment agreement). Mr. Liang is entitled to receive (i) the accrued compensation, (ii) a separation benefit consisting of twelve months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the twelve-month period following the effective date of his termination of employment, (iii) a pro-rated portion of Mr. Liang's target bonus, (iv) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to the executive officer prior to such termination and (v) any additional compensation that may be required by applicable law.

Each executive officer has agreed to comply with our rules and policies regarding confidentiality and, during his or her employment with us and thereafter, has agreed not to use or disclose any confidential information of our company other than as authorized by us within the scope of his or her duties. Moreover, each of our executive officers has agreed that during his or her employment and for two years after his or her employment with us at Zai Lab Shanghai, he or she will not work for another company or individual that is in competition with us directly or indirectly or provide services to any company or individual that is in competition with us, and will not setup or operate any business which is in competition with us directly or indirectly, or with any other third party, or through any other form. Each of our executive officers is entitled to receive monthly compensation during their 24-month non-compete period in an amount equal to 30% of their respective average monthly salaries received during the 12 months immediately preceding the termination of their employment. Each of the executives has agreed that, during employment and within one year after the termination thereof, certain "Work For Hire," as defined in the agreements, shall belong to the company.

In addition, we have been advised by our PRC counsel, Zhong Lun Law Firm, that notwithstanding any provision to the contrary in our employment agreements at Zai Lab Shanghai, we may still be required to make severance payments upon termination without cause to comply with the PRC labor laws and other relevant PRC regulations, which entitle employees to severance payments in case of early termination.

Compensation of Directors and Executive Officers

In the year ended December 31, 2019, we paid aggregate salaries, bonuses and benefits (excluding equity-based grants) of approximately US$4.92 million to our executive officers listed in this section. Executive officers are eligible to receive an annual incentive bonus, as determined by our board of directors, based on achievement of pre-established individual, departmental and company performance goals. Other than 401(k) and social insurance benefits that we provide to our U.S. executive officers, we do not otherwise separately set aside any amounts for pensions, retirement or other benefits for our executive officers, other than pursuant to relevant statutory requirements, and health and life insurance. In the year ended

December 31, 2019, we paid aggregate cash retainers (excluding equity-based grants and consulting fees) of approximately US$282,418 to our non-employee directors pursuant to our non-employee director compensation policy, described below.

For information regarding equity-based grants to our executive officers and directors and other compensation programs, see "Appendix IV – Statutory and General Information – D. Share Incentive Plans and Other Compensation Programs."

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy under which each member of our board of directors who is not an employee of our Company or one of our affiliates (each a "non-employee director") will be eligible to receive an annual cash retainer payment of US$50,000. In addition, each non-employee director who was appointed to our board of directors following the adoption of this policy and whose appointment was effective prior to our IPO received an award of 25,000 restricted shares under our 2017 Equity Plan, which vests ratably on each of the first three anniversaries of the date of grant, subject to continued service as a member of our board of directors through such date. In addition to this initial grant,in calendar years 2018 and 2019, non-employee directors received an annual grant of 12,500 restricted shares under our 2017 Equity Plan, which vested in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date. Commencing in calendar year 2020, non-employee directors will receive an annual grant of 10,000 restricted shares under our 2017 Equity Plan, which vest in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date.

In addition, the non-employee director compensation policy provides for the following additional annual cash retainer payments for the members and chairpersons of our board committees: audit committee chair, US$20,000; audit committee member, US$10,000; compensation committee chair, US$15,000; compensation committee member, US$7,500; nominating committee chair, US$10,000; and nominating committee member, US$5,000.

Composition of Our Board

Our board of directors consists of eight directors, of whom six qualify as independent directors under the rules and regulations of the SEC and Nasdaq Stock Market. Our directors hold office until they are removed from office by Ordinary Resolution or by the Board at anytime before the expiration. In addition, a director will cease to be a director if the director (i) dies, becomes bankrupt or makes any arrangement or composition with his or her creditors, (ii) is found to be or becomes of unsound mind or (iii) resigns his office by notice in writing to our Company.

Duties of Directors

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

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating committee.

Audit Committee

Our audit committee consists of John Diekman, William Lis and Leon O. Moulder, Jr., with Dr. Diekman serving as chairman of the committee. We have determined that Mr. Lis qualifies as a financial expert as set forth under the applicable rules of the SEC and that Mr. Lis, Dr. Diekman and Mr. Moulder each satisfy the independence requirements under the rules of the Nasdaq Stock Market and under Rule 10A-3 of the Exchange Act.

The audit committee oversees our accounting and financial reporting processes and the audits of our financial statements. Our audit committee is responsible for, among other things:

- selecting, and evaluating the qualifications, performance and independence of, the independent auditor;
- approving or, as permitted, pre-approving auditing and non-auditing services permitted to be performed by the independent auditor;
- considering the adequacy of our internal accounting controls and audit procedures;
- reviewing with the independent auditor any audit problems or difficulties and management's response;
- reviewing and approving related party transactions;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;

- establishing procedures for the receipt, retention and treatment of complaints received from our employees regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;

- meeting separately, periodically, with management, internal auditors and the independent auditor; and

- reporting regularly to the full board of directors.

Compensation Committee

Our compensation committee consists of Peter Wirth, Nisa Leung and Leon O. Moulder, Jr., with Mr. Wirth serving as chairman of the committee.

Our compensation committee is responsible for, among other things:

- reviewing, evaluating and, if necessary, revising our overall compensation policies;

- reviewing and evaluating the performance of our directors and executive officers and determining the compensation of our executive officers;

- reviewing and approving our executive officers' employment agreements with us;

- determining performance targets for our executive officers with respect to our incentive compensation plan and equity-based compensation plans;

- administering our equity-based compensation plans in accordance with the terms thereof; and

- carrying out such other matters that are specifically delegated to the compensation committee.

Nominating Committee

Our nominating committee consists of Samantha Du, Nisa Leung and John Diekman, with Dr. Du serving as Chairwoman of the committee.

Our nominating committee is responsible for, among other things:

- electing the board nominees for election by the shareholders or appointment by the board;

- periodically reviewing with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience and diversity;

- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and

- advising the board periodically with regards to significant developments in corporate governance law and practices as well as our compliance with applicable laws and regulations, and making recommendations to the board on corporate governance matters.

Board Diversity

The Board has adopted a board diversity policy (the "Board Diversity Policy") in order to enhance the effectiveness of our Board and to maintain high standard of corporate governance. The Board Diversity Policy sets out the criteria in selecting candidates to our Board, including but not limited to gender, age, cultural and educational background and professional experience. The ultimate decision will be based on merit and contribution that the selected candidates will bring to our Board. Our Directors have a balanced mix of knowledge and skills, including knowledge and experience in the areas of business management, medical clinical research, scientific research, financial management and accounting. They obtained degrees in various areas including biochemistry, business administration, law, biology, medicine, science, chemistry and pharmacy.

The nominating committee is responsible for reviewing the diversity of the Board. After Listing, the nominating committee will monitor and evaluate the implementation of the Board Diversity Policy from time to time to ensure its continued effectiveness.

Code of Ethics

Our board of directors has adopted a code of ethics to set standards for our directors, officers and employees as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the reports and documents that we file or submit to the applicable stock exchanges, and in any other public communications; (iii) compliance with applicable governmental and regulatory laws, rules, codes and regulations; (iv) prompt internal reporting of any violations of the code of ethics; and (v) accountability for adherence to the code of ethics.

Complaints Procedures

Our board of directors has adopted procedures for the confidential receipt, retention, and treatment of complaints from, or concerns raised by, employees regarding accounting, internal accounting controls and auditing matters as well as illegal or unethical matters. The complaint procedures are reviewed by the audit committee from time to time as warranted to ensure their continuing compliance with applicable laws and listing standards as well as their effectiveness.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the Global Offering of approximately HK$6,613.8 million after deducting estimated underwriting fees and the estimated offering expenses payable by us, assuming the Over-allotment Option is not exercised and based upon an indicative maximum offer price of HK$648.00 per Offer Share.

The International Offer Price in the International Offering may be higher than, or the same as, the Public Offer Price in the Hong Kong Public Offering. See "Structure of the Global Offering – Pricing and Allocation."

We plan to use the net proceeds we will receive from the Global Offering for the following purposes:

- approximately HK$3,055.6 million, or 46.2%, is expected to be allocated to our Core Products.
    - approximately HK$1,468.3 million, or 22.2% is expected to be allocated to R&D efforts with respect to our Core Products:
        - approximately HK$1,058.2 million, or 16.0% is expected to be allocated to one of our Core Products, ZEJULA, among which approximately HK$813.5 million or 12.3% is expected to be used to seek indication expansion and hire high-caliber R&D staff dedicated to the development of ZEJULA, and approximately HK$244.7 million, or 3.7%, is expected to be used to develop and improve our manufacturing facilities to bring ZEJULA, to commercialization, as further described in the "Business" section of this prospectus; and
        - approximately HK$410.1 million, or 6.2% is expected to be used to fund our ongoing and planned clinical trials and preparation for registration filings of Tumor Treating Fields in multiple solid tumor cancer indications.
    - approximately HK$1,587.3 million, or 24.0%, is expected to enhance our commercialization capabilities for our Core Products, among which
        - approximately HK$1,058.2 million, or 16.0%, is expected to be used for ZEJULA to enhance our commercialization capabilities through increasing our sales and marketing headcounts, among other efforts, see "Business – Our Strategies – Efficiently grow our world-class organization and invest in our capabilities to support our global aspirations" for detailed discussion on the commercialization plan; and
        - approximately HK$529.1 million, or 8.0%, is expected to be used to strengthen commercialization efforts for Tumor Treating Fields through recruiting key talents in relevant indications to drive sales and future potential product launch;

- approximately HK$780.4 million, or 11.8%, is expected to fund our ongoing and planned clinical trials and preparation for registration filings of other drug candidates in our pipeline, especially our late-stage drug candidates:

    - approximately HK$231.5 million, or 3.5%, is expected to be allocated to ripretinib;

    - approximately HK$324.1 million, or 4.9%, is expected to be allocated to margetuximab;

    - approximately HK$224.9 million, or 3.4%, is expected to be allocated to other late-stage drug candidates;

- approximately HK$1,653.4 million, or 25.0%, is expected to be used to explore new global licensing and collaboration opportunities and bring in potentially global best-in-class/first-in-class assets with clinical validation, synergistic with our our current pipeline and aligned to our expertise, especially around our disease strongholds within oncology, infectious and autoimmune diseases. During the Track Record Period, we have entered into six license agreements and/or collaboration agreements with global biopharmaceutical companies. We continuously seek potential global licensing and collaboration opportunities to further expand its drug pipeline by leveraging our relationship with the existing partners and expertise in our focused therapeutic areas. We also expect to seek such opportunities through our well-established industry network and dedicated business development team;

- approximately HK$463.0 million, or 7.0%, is expected to be used to continue investing in and expanding our internal discovery pipeline and recruit and train high-caliber talent globally, in particular talent with expertise and experience in R&D, with a goal to enhance our internal research platform and discovery efforts;

    - approximately HK$172.0 million, or 2.6%, is expected to be allocated to ZL-1201 and ZL-1102;

    - approximately HK$291.0 million, or 4.4%, is expected to be allocated to other internal discovered drug candidates; and

- approximately HK$661.4 million, or 10.0%, is expected to fund working capital and other general corporate purposes.

To the extent that the net proceeds are not immediately applied to the above purposes and to the extent permitted by the relevant law and regulations, we plan to use the proceeds which are not immediately applied for the intended purposes for interest-bearing deposits with licensed commercial banks or financial institutions.

HONG KONG UNDERWRITERS

J.P. Morgan Securities (Asia Pacific) Limited
Goldman Sachs (Asia) L.L.C.
Citigroup Global Markets Asia Limited
Jefferies Hong Kong Limited
Merrill Lynch (Asia Pacific) Limited
Credit Suisse (Hong Kong) Limited
China International Capital Corporation Hong Kong Securities Limited
Haitong International Securities Company Limited

UNDERWRITING

This prospectus is published solely in connection with the Hong Kong Public Offering. The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters on a conditional basis. The International Offering is expected to be fully underwritten by the International Underwriters. If, for any reason, we do not agree with the Joint Representatives (for themselves and on behalf of the Underwriters) on the pricing of the Offer Shares, the Global Offering will not proceed and will lapse.

The Global Offering comprises the Hong Kong Public Offering of initially 771,700 Hong Kong Offer Shares and the International Offering of initially 9,792,350 International Offer Shares, subject, in each case, to reallocation on the basis as described in "Structure of the Global Offering" as well as to the Over-allotment Option (in the case of the International Offering).

UNDERWRITING ARRANGEMENTS AND EXPENSES

Hong Kong Public Offering

Hong Kong Underwriting Agreement

Pursuant to the Hong Kong Underwriting Agreement, we are offering the Hong Kong Offer Shares for subscription on the terms and conditions set out in this prospectus and the Hong Kong Underwriting Agreement at the Public Offer Price.

Subject to: (a) the Hong Kong Stock Exchange granting approval for the listing of, and permission to deal in, the Shares in issue and to be issued pursuant to the Global Offering (including the Shares which may be issued pursuant to the exercise of the Over-allotment Option) and the Shares to be issued pursuant to the Equity Plans on the Main Board of the Hong Kong Stock Exchange and such approval not having been subsequently revoked prior to the commencement of trading of the Shares on the Stock Exchange and (b) certain other conditions set out in the Hong Kong Underwriting Agreement, the Hong Kong Underwriters have agreed severally but not jointly to procure subscribers for, or themselves to subscribe for, their

respective applicable proportions of the Hong Kong Offer Shares being offered which are not taken up under the Hong Kong Public Offering on the terms and conditions set out in this prospectus and the Hong Kong Underwriting Agreement.

The Hong Kong Underwriting Agreement is conditional on, among other things, the International Underwriting Agreement having been executed and becoming unconditional and not having been terminated in accordance with its terms.

Grounds for termination

If any of the events set out below occur at any time prior to 8:00 a.m. on the Listing Date, the Joint Representatives (for themselves and on behalf of the Hong Kong Underwriters) shall be entitled, in their absolute discretion and by giving written notice to the Company to terminate the Hong Kong Underwriting Agreement with immediate effect:

(a) there develops, occurs, exists or comes into force:

(i) any event, or series of events, in the nature of force majeure (including, without limitation, any acts of government, declaration of a national or international emergency or war, calamity, crisis, epidemic, pandemic, large-scale outbreaks, escalation, mutation or aggravation of diseases (including, without limitation, SARS, swine or avian flu, H5N1, H1N1, H7N9, contagious coronavirus (COVID-19) and such related/mutated forms), economic sanctions, strikes, labour disputes, lock-outs, fire, explosion, flooding, tsunami, earthquake, volcanic eruption, civil commotion, riots, rebellion, public disorder, acts of war, outbreak or escalation of hostilities (whether or not war is declared), acts of God or acts of terrorism (whether or not responsibility has been claimed)) in or affecting Hong Kong, the PRC, the Cayman Islands, the United States, the United Kingdom, the European Union (or any member thereof) (collectively, "Relevant Jurisdictions");

(ii) any material change in short or long term debt of the Company or any of its subsidiaries, or any development involving a prospective change, in or affecting the general affairs, management, financial position, shareholders' equity or results of operations of the Company and its subsidiaries, otherwise than as set forth or contemplated in this prospectus;

(iii) a suspension or material limitation in trading in securities generally on the Nasdaq, the New York Stock Exchange, The Stock Exchange of Hong Kong Limited, the Shenzhen Stock Exchange, the Shanghai Stock Exchange, the London Stock Exchange or Tokyo Stock Exchange;

(iv) a suspension or material limitation in trading in the Company's securities on the Nasdaq;

(v) a general moratorium on commercial banking activities in New York (imposed at the U.S. Federal or New York State level or by any other competent authority), Hong Kong (imposed by the Financial Secretary or the Hong Kong Monetary Authority or other competent authority), the PRC, the Cayman Islands, London or the European Union (or any member thereof) declared by the relevant authorities, or a material disruption in commercial banking or securities settlement or clearance services in the United States, Hong Kong, the PRC or the Cayman Islands;

(vi) a change or development involving a prospective change in taxation affecting the Company, any of its subsidiaries or the Shares or the transfer thereof;

(vii) the enactment, publication, decree or other promulgation of any statute, regulation, rule or order of any governmental agency materially affecting the business or operations of the Company or its subsidiaries;

(viii) the outbreak or escalation of hostilities or act of terrorism involving the United States, Hong Kong, the PRC or the Cayman Islands or the declaration by the United States, Hong Kong, the PRC or the Cayman Islands of a national emergency or war;

(ix) any change or development involving a prospective change, or any event or circumstances or series of events likely to result in any change or development involving a prospective change, in any local, national, regional or international financial, economic, political, military, industrial, legal, fiscal, regulatory, currency, credit or market matters or conditions, equity securities or exchange control or any monetary or trading settlement system or other financial markets (including, without limitation, conditions in the stock and bond markets, money and foreign exchange markets, the interbank markets and credit markets), in or affecting any of the Relevant Jurisdictions or elsewhere;

(x) any litigation, proceedings, investigations, processes for administrative sanctions or other actions initiated or threatened by any authority before any authority, in each case with due authority, against or involving any party hereto, in the PRC or elsewhere, that seeks to declare non-compliance, unlawful or illegal, under PRC laws, rules and regulations, the issuance and sales of the Shares, the listing and the trading of the Shares on the Main Board of the Stock Exchange and Hong Kong Underwriting Agreement and the transactions contemplated thereby or hereby;

(xi) the enactment, publication, decree or other promulgation of any new statute, regulation, law, rule, order or any change or development involving a prospective change in existing laws or regulations or materially affecting the business or operations of the Company or member of the Group or any change or development involving a prospective change in the interpretation or application thereof by any court or any governmental authority in or affecting any of the Relevant Jurisdictions;

(xii) the imposition of economic sanctions, in whatever form, directly or indirectly, by, or for, any of the Relevant Jurisdictions;

(xiii) any change or development involving a prospective change or amendment in or affecting taxation or foreign exchange control, currency exchange rates or foreign investment regulations (including, without limitation, a material devaluation of the Hong Kong dollar or RMB against any foreign currencies, a change in the system under which the value of the Hong Kong dollar is linked to that of the United States dollar or RMB is linked to any foreign currency or currencies), or the implementation of any exchange control, in any of the Relevant Jurisdictions or adversely affecting an investment in the Offer Shares;

(xiv) other than with the prior written consent of the Joint Representatives, the issue or requirement to issue by the Company of a supplement or amendment to this prospectus, Green Application Form or other documents in connection with the offer and sale of the Offer Shares pursuant to the Companies (WUMP) Ordinance or the Listing Rules or upon any requirement or request of the Stock Exchange and/or the SFC;

(xv) the Chairwoman and Chief Executive Officer is vacating her office;

(xvi) any director being charged with an indictable offence or prohibited by operation of Law or otherwise disqualified from taking part in the management of a company;

(xvii) any order or petition for the involuntary winding-up or liquidation of any member of the Group or any composition or arrangement made by any member of the Group with its creditors or a scheme of arrangement entered into by any member of the Group or any resolution for the voluntary winding-up of any member of the Group or the appointment of a provisional liquidator, receiver or manager over all or part of the material assets or undertaking of any member of the Group or anything analogous thereto occurring in respect of any member of the Group;

(xviii) any litigation, dispute, legal action or claim being instigated against any member of the Group;

(xix) any contravention by the Company or any member of the Group of any applicable laws and regulations including the Listing Rules;

(xx) there is a material breach of any of the obligations imposed upon the Company under this Agreement; or

(xxi) there is a breach of, or any event or circumstance rendering untrue, incorrect, incomplete or misleading in any respect, any of the warranties given by the Company in this Agreement or the International Underwriting Agreement, as applicable;

which, individually or in the aggregate, in the sole and absolute opinion of the Joint Representatives (for themselves and on behalf of the Hong Kong Underwriters):

(1) has or will or is likely to have a material adverse effect on the assets, liabilities, general affairs, business, management, prospects, shareholders' equity, profit, losses, earnings, results of operations, performance, position or condition, financial or otherwise, of the Group as a whole;

(2) has or will have or is likely to have a material adverse effect on the success or marketability of the Global Offering or the level of applications or the distribution of the Offer Shares under the Hong Kong Public Offering or the level of interest under the International Offering;

(3) makes or will make or is likely to make it inadvisable, inexpedient, impracticable or incapable for the Hong Kong Public Offering and/or the International Offering to proceed or to market the Global Offering or the delivery or distribution of the Offer Shares on the terms and in the manner contemplated by this prospectus; or

(4) has or will or is likely to have the effect of making any material part of the Hong Kong Underwriting Agreement (including underwriting) incapable of performance in accordance with its terms or preventing the processing of applications and/or payments pursuant to the Global Offering or pursuant to the underwriting thereof; or

(b) there has come to the notice of the Joint Representatives that:

(i) any statement contained in this prospectus, the Green Application Form, the Formal Notice and/or any notices, announcements, advertisements, communications or other documents (including any announcement, circular, document or other communication pursuant to the Hong Kong Underwriting Agreement) issued or used by or on behalf of the Company in connection with the Hong Kong Public Offering and the Global Offering (including any supplement or amendment thereto (the "Offer-Related Documents") but excluding information relating to the Underwriters) was, when it was issued, or has become, untrue, incorrect, inaccurate, or incomplete in any material respect or misleading or deceptive, in light of circumstances under which it was made, or that any estimate, forecast, expression of opinion, intention or expectation contained in any of such documents is not fair and honest and based on reasonable grounds or reasonable assumptions;

(ii) any matter has arisen or has been discovered which would, had it arisen or been discovered immediately before the date of this prospectus, constitute a material omission from, or misstatement in, any of the Offer-Related Documents;

(iii) there is an event, act or omission which gives or is likely to give rise to any material liability of the Company pursuant to the indemnities given by any of them under the Hong Kong Underwriting Agreement or the International Underwriting Agreement;

(iv) there is any material adverse change or development or likely to be any prospective material adverse change or development in the assets, liabilities, general affairs, business, management, prospects, shareholders' equity, profits, losses, earnings, solvency, liquidity position, funding, results of operations, performance, position or condition, financial or otherwise, of the Group as a whole;

(v) the approval of the Hong Kong Stock Exchange of the listing of, and permission to deal in, the Shares in issue and the Shares to be issued pursuant to the Global Offering (including the additional Shares which may be issued upon the exercise of the Over-Allotment Option) is refused or not granted, other than subject to customary conditions, on or before the date of the Listing, or if granted, the approval is subsequently withdrawn, cancelled, qualified (other than by customary conditions), revoked or withheld;

(vi) any person has withdrawn its consent to the issue of this prospectus with the inclusion of its reports, letters and/or legal opinions (as the case may be) and references to its name included in the form and context in which it respectively appears;

(vii) the Company withdraws this prospectus (and/or any other documents issued or used in connection with the Global Offering) or the Global Offering; or

(viii) there is a prohibition by a competent authority on the Company for whatever reason from offering, allotting, issuing or selling any of the Offer Shares pursuant to the terms of the Global Offering.

Undertakings Pursuant to the Hong Kong Underwriting Agreement

We have undertaken to each of the Joint Representatives, the Joint Sponsors and the Hong Kong Underwriters that for the period commencing on the Price Determination Date and ending on, and including, the date that is 90 days after the Price Determination Date (the "Lock-Up Period"), or such earlier date that the Joint Sponsors (for themselves and on behalf of the Underwriters) consent to in writing, and unless in compliance with the requirements of the Listing Rules, we will not, directly or indirectly, take any of the following actions with respect to our Shares or ADSs, or any securities convertible into or exchangeable or exercisable for any of our Shares or ADSs ("Lock-Up Securities"):

a. offer, sell, issue, pledge, contract to sell or otherwise dispose of Lock-Up Securities;

b. offer, sell, issue, contract to sell, contract to purchase or grant any option, right or warrant to purchase Lock-Up Securities;

c. establish or increase a put equivalent position or liquidate or decrease a call equivalent position in Lock-Up Securities within the meaning of Section 16 of the U.S. Exchange Act;

d. enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Lock-Up Securities, whether any such transaction described in clauses (a) or (b) is to be settled by delivery of Lock-Up Securities, in cash or otherwise; or

e. file with the SEC a registration statement under the U.S. Securities Act relating to Lock-Up Securities, other than registration statements on Form S-8 relating to the issuance, vesting, exercise or settlement of equity awards granted or to be granted pursuant to any employee benefit plan described in this prospectus,

without the prior written consent of the Joint Sponsors, provided, however, that we shall be permitted during the Lock-Up Period to:

(1) sell, or cause to be sold, the Offer Shares to be sold and/or issued hereunder;

(2) issue Shares or ADSs or the grant of options to purchase Shares, restricted shares, or any other equity-linked rights issuable under our Equity Plans existing on the date of the Hong Kong Underwriting Agreement, including the effect of one or more bulk issuances of Shares, or ADSs upon deposit of Shares with the depositary, and delivered to our brokerage accounts existing on the date of the Hong Kong Underwriting Agreement, in contemplation of future issuance under our Equity Plans existing on the date of the Hong Kong Underwriting Agreement;

(3) effect any capitalization issue, capital reduction or consolidation or sub-division of the Shares;

(4) issue securities upon the exercise of an option or a warrant or the vesting of any share award granted under the Equity Plans or the conversion of a security outstanding on the date hereof;

(5) repurchase securities pursuant to the Company's share repurchase programs; and

(6) issue any Shares pursuant to the conversion or exchange of convertible or exchangeable securities, including preferred shares and warrants, as described in the registration statement, the pricing disclosure package and this prospectus; or

f. make or agree to make any public disclosure of any intention to make any such offer, pledge, sale or disposition, or enter into any such transaction, swap, hedge or other arrangement, or file any such registration statement as specified in clauses (a) to (e) above.

International Offering

International Underwriting Agreement

In connection with the International Offering, we expect to enter into the International Underwriting Agreement with the Joint Representatives (for themselves and on behalf of the International Underwriters) and the Joint Sponsors on the Price Determination Date. Under the International Underwriting Agreement and subject to the Over-allotment Option, the International Underwriters would, subject to certain conditions set out therein, agree severally but not jointly to procure subscribers for, or themselves to subscribe for, their respective applicable proportions of the International Offer Shares initially being offered pursuant to the International Offering. The International Offering will consist of a U.S. offering and a non-U.S. offering. It is expected that the International Underwriting Agreement may be terminated on similar grounds as the Hong Kong Underwriting Agreement. Potential investors should note that in the event that the International Underwriting Agreement is not entered into, the Global Offering will not proceed. See "Structure of the Global Offering – The International Offering."

Over-allotment Option

We expect to grant to the International Underwriters the Over-allotment Option, exercisable by the Joint Representatives on behalf of the International Underwriters at any time from the date of International Underwriting Agreement until 30 days after the last day for lodging applications under the Hong Kong Public Offering, pursuant to which we may be required to issue up to an aggregate of 1,584,600 Shares, representing not more than 15% of the number of Offer Shares initially available under the Global Offering, at the International Offer Price, to cover over-allocations in the International Offering, if any. See "Structure of the Global Offering – International Offering – Over-allotment Option."

Commissions and expenses

The Underwriters will receive an underwriting commission of 2.0% of the aggregate offer price of all the Offer Shares (including any Offer Shares to be issued by us pursuant to the exercise of the Over-allotment Option), out of which they will pay any sub-underwriting commissions and other fees. The Underwriters may receive an incentive fee of up to 0.75% of the aggregate offer price of all the Offer Shares (including any Offer Shares to be issued by us pursuant to the exercise of the Over-allotment Option), which is to be determined at the sole discretion of the Company.

For any unsubscribed Hong Kong Offer Shares reallocated to the International Offering, the underwriting commission will not be paid to the Hong Kong Underwriters but will instead be paid, at the rate applicable to the International Offering, to the relevant International Underwriters.

The aggregate underwriting commissions and fees together with the Hong Kong Stock Exchange listing fees, the SFC transaction levy and the Hong Kong Stock Exchange trading fee, SEC registration fees, legal and other professional fees and printing and all other expenses relating to the Global Offering are estimated to be up to approximately HK$260.1 million (assuming an indicative maximum offer price of HK$648.00 per Offer Share for both Hong Kong Public Offering and International Offering and the exercise of the Over-allotment Option in full) and will be paid by our Company.

ACTIVITIES BY SYNDICATE MEMBERS

The underwriters of the Hong Kong Public Offering and the International Offering (together, the "Syndicate Members") and their affiliates may each individually undertake a variety of activities (as further described below) which do not form part of the underwriting or stabilizing process.

The Syndicate Members and their affiliates are diversified financial institutions with relationships in countries around the world. These entities engage in a wide range of commercial and investment banking, brokerage, funds management, trading, hedging, investing and other activities for their own account and for the account of others. In the ordinary course of their various business activities, the Syndicate Members and their respective

affiliates may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers. Such investment and trading activities may involve or relate to assets, securities and/or instruments of the Company and/or persons and entities with relationships with the Company and may also include swaps and other financial instruments entered into for hedging purposes in connection with the Group's loans and other debt.

In relation to the Shares, the activities of the Syndicate Members and their affiliates could include acting as agent for buyers and sellers of the Shares, entering into transactions with those buyers and sellers in a principal capacity, including as a lender to initial purchasers of the Shares (which financing may be secured by the Shares) in the Global Offering, proprietary trading in the Shares, and entering into over the counter or listed derivative transactions or listed or unlisted securities transactions (including issuing securities such as derivative warrants listed on a stock exchange) which have as their underlying assets, assets including the Shares. Such transactions may be carried out as bilateral agreements or trades with selected counterparties. Those activities may require hedging activity by those entities involving, directly or indirectly, the buying and selling of the Shares, which may have a negative impact on the trading price of the Shares. All such activities could occur in Hong Kong and elsewhere in the world and may result in the Syndicate Members and their affiliates holding long and/or short positions in the Shares, in baskets of securities or indices including the Shares, in units of funds that may purchase the Shares, or in derivatives related to any of the foregoing.

In relation to issues by Syndicate Members or their affiliates of any listed securities having the Shares as their underlying securities, whether on the Stock Exchange or on any other stock exchange, the rules of the stock exchange may require the issuer of those securities (or one of its affiliates or agents) to act as a market maker or liquidity provider in the security, and this will also result in hedging activity in the Shares in most cases.

All such activities may occur both during and after the end of the stabilizing period described in "Structure of the Global Offering." Such activities may affect the market price or value of the Shares, the liquidity or trading volume in the Shares and the volatility of the price of the Shares, and the extent to which this occurs from day to day cannot be estimated. It should be noted that when engaging in any of these activities, the Syndicate Members will be subject to certain restrictions, including the following:

(a) the Syndicate Members (other than the Stabilization Manager or any person acting for it) must not, in connection with the distribution of the Offer Shares, effect any transactions (including issuing or entering into any option or other derivative transactions relating to the Offer Shares), whether in the open market or otherwise, with a view to stabilizing or maintaining the market price of any of the Offer Shares at levels other than those which might otherwise prevail in the open market; and

(b) the Syndicate Members must comply with all applicable laws and regulations, including the market misconduct provisions of the SFO, including the provisions prohibiting insider dealing, false trading, price rigging and stock market manipulation.

Certain of the Syndicate Members or their respective affiliates have provided from time to time, and expect to provide in the future, investment banking, commercial banking and other services to the Company and each of its affiliates for which such Syndicate Members or their respective affiliates have received or will receive customary fees and commissions.

In addition, the Syndicate Members or their respective affiliates may provide financing to investors to finance their subscriptions of Offer Shares in the Global Offering.

LOCK-UP UNDERTAKINGS BY OUR DIRECTORS, EXECUTIVE OFFICERS AND QM11 LIMITED

Each of our directors, executive officers who holds interest in our Shares, and QM11 Limited, has agreed with the Hong Kong Underwriters and International Underwriters that, he/she/it will not, during the period beginning on the Price Determination Date and ending on the date that is 90 days after the Price Determination Date, without the prior written consent of the Joint Representatives, among other things: (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any ADSs or Shares or any securities convertible into or exercisable or exchangeable for ADSs or Shares (including without limitation, ADSs or Shares or such other securities which may be deemed to be beneficially owned by the lock-up parties in accordance with the rules and regulations of the U.S. Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant), or publicly disclose the intention to make any offer, sale, pledge or disposition, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ADSs or Shares or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ADSs or Shares or such other securities, in cash or otherwise or (3) make any demand for or exercise any right with respect to the registration of any ADSs or Shares or any security convertible into or exercisable or exchangeable for ADSs or Shares.

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

- transfers of ADSs or Shares or such other securities as a bona fide gift or gifts or by testate succession or intestate distribution;

- any ADSs or Shares acquired by a lock-up party in the open market;

- the exercise of stock options or other similar awards granted pursuant to our equity incentive plans, as described herein; provided that the terms of the lock-up agreement shall apply to any ADSs or Shares of a lock-up party issued upon such exercise;

- any Shares or such other securities that are used for the primary purpose of satisfying any tax or other governmental withholding obligation, through cashless surrender or otherwise, with respect to any award or equity-based compensation granted pursuant to our equity incentive plans, as described herein, or in connection with tax or other obligations as a result of testate succession or intestate distribution;

- transfers to immediate family member or members, or to a trust, the direct or indirect beneficiaries of which are a lock-up party and/or a member or members of his or her immediate family;

- transfers of Shares or any security convertible into or exercisable or exchangeable for Shares to us pursuant to any contractual arrangement that provides for the repurchase of the lock-up party's Shares or such other securities by us or in connection with the termination of the lock-up party's employment with us or the lock-up party's failure to meet certain conditions set out upon receipt of such Shares or other such securities;

- where applicable, any Shares loaned to the Stabilization Manager pursuant to the Stock Borrowing Agreement;

- subject to certain limitations, distributions of ADSs, Shares or such other securities to members or shareholders of the lock-up parties or to any corporation, partnership or other person or entity that is a direct or indirect affiliate of the lock-up party;

- any transfers, sales, tenders or other dispositions of Shares or any security convertible into or exercisable or exchangeable for Shares pursuant to a bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction made to or involving all holders of Shares or such other securities pursuant to which one hundred percent (100%) of our ownership is transferred to such third party (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the lock-up party may agree to transfer, sell, tender or otherwise dispose of Shares or other such securities in connection with such transaction, or vote any Shares or other such securities in favor of any such transaction); provided that such tender offer merger, amalgamation, consolidation or other similar transaction is completed; and

- in the case of our directors and executive officers, any sales made pursuant to a trading plan adopted pursuant to Rule 10b5-1 of the Exchange Act prior to the date of the lock-up agreements, subject to certain conditions, or the establishment of a trading plan adopted pursuant to Rule 10b5-1 under the Exchange Act on or after the date of the lock-up agreements, provided that no transfers occur under such plan during the lock-up period and certain other conditions are satisfied.

THE GLOBAL OFFERING

This prospectus is published in connection with the Hong Kong Public Offering as part of the Global Offering. J.P. Morgan Securities (Far East) Limited, Goldman Sachs (Asia) L.L.C. and Citigroup Global Markets Asia Limited are the Joint Representatives of the Global Offering.

The listing of the Shares on the Main Board of the Hong Kong Stock Exchange is sponsored by the Joint Sponsors. The Joint Sponsors have made an application on our behalf to the Hong Kong Stock Exchange for the listing of, and permission to deal in, the Shares in issue and to be issued as mentioned in this prospectus.

10,564,050 Offer Shares will initially be made available under the Global Offering comprising:

(a) the Hong Kong Public Offering of initially 771,700 Shares (subject to reallocation) in Hong Kong as described in "Hong Kong Public Offering" below; and

(b) the International Offering of initially 9,792,350 Shares (subject to reallocation and the Over-allotment Option) pursuant to the shelf registration statement on Form F-3ASR that was filed with the SEC and became effective on March 29, 2019, and the preliminary prospectus supplement filed with the SEC on September 16, 2020 and the final prospectus supplement to be filed with the SEC on or about September 22, 2020.

Investors may either:

(a) apply for Hong Kong Offer Shares under the Hong Kong Public Offering; or

(b) apply for or indicate an interest for International Offer Shares under the International Offering,

but may not do both.

The Offer Shares will represent approximately 12.3% of the total Shares in issue immediately following the completion of the Global Offering, assuming the Over-allotment Option is not exercised and without taking into account the Shares to be issued pursuant to the Equity Plans including pursuant to the exercise of share options or other awards that have been or may be granted from time to time. If the Over-allotment Option is exercised in full, the Offer Shares (including the Shares issued pursuant to the Over-allotment Option) will represent approximately 13.9% of the total Shares in issue immediately following the completion of the Global Offering and the full exercise of the Over-allotment Option (without taking into account the Shares to be issued pursuant to the Equity Plans including pursuant to the exercise of share options or other awards that have been or may be granted from time to time).

References in this prospectus to applications, application monies or the procedure for applications relate solely to the Hong Kong Public Offering.

THE HONG KONG PUBLIC OFFERING

Number of Offer Shares Initially Offered

We are initially offering 771,700 Shares for subscription by the public in Hong Kong at the Public Offer Price, representing approximately 7.3% of the total number of Offer Shares initially available under the Global Offering. The number of Offer Shares initially offered under the Hong Kong Public Offering, subject to any reallocation of Offer Shares between the International Offering and the Hong Kong Public Offering, will represent approximately 0.9% of the total Shares in issue immediately following the completion of the Global Offering (assuming the Over-allotment Option is not exercised and without taking into account the Shares to be issued pursuant to the Equity Plans including pursuant to the exercise of share options or other awards that have been or may be granted from time to time).

The Hong Kong Public Offering is open to members of the public in Hong Kong as well as to institutional and professional investors. Professional investors generally include brokers, dealers, companies (including fund managers) whose ordinary business involves dealing in shares and other securities and corporate entities that regularly invest in shares and other securities.

Completion of the Hong Kong Public Offering is subject to the conditions set out in "Conditions of the Global Offering" below.

Allocation

Allocation of Offer Shares to investors under the Hong Kong Public Offering will be based solely on the level of valid applications received under the Hong Kong Public Offering.

The basis of allocation may vary, depending on the number of Hong Kong Offer Shares validly applied for by applicants. Such allocation could, where appropriate, consist of balloting, which could mean that some applicants may receive a higher allocation than others who have applied for the same number of Hong Kong Offer Shares, and those applicants who are not successful in the ballot may not receive any Hong Kong Offer Shares.

For allocation purposes only, the total number of Hong Kong Offer Shares available under the Hong Kong Public Offering (after taking into account any reallocation referred to below) will be divided equally (to the nearest board lot) into two pools: pool A and pool B. The Hong Kong Offer Shares in pool A will be allocated on an equitable basis to applicants who have applied for Hong Kong Offer Shares with an aggregate price of HK$5 million (excluding the brokerage, the SFC transaction levy and the Hong Kong Stock Exchange trading fee payable) or less. The Hong Kong Offer Shares in pool B will be allocated on an equitable basis to

applicants who have applied for Hong Kong Offer Shares with an aggregate price of more than HK$5 million (excluding the brokerage, the SFC transaction levy and the Hong Kong Stock Exchange trading fee payable) and up to the total value in pool B.

Investors should be aware that applications in pool A and applications in pool B may receive different allocation ratios. If any Hong Kong Offer Shares in one (but not both) of the pools are unsubscribed, such unsubscribed Hong Kong Offer Shares will be transferred to the other pool to satisfy demand in that other pool and be allocated accordingly. For the purpose of the immediately preceding paragraph only, the "price" for Hong Kong Offer Shares means the price payable on application therefor (without regard to the Public Offer Price as finally determined). Applicants can only receive an allocation of Hong Kong Offer Shares from either pool A or pool B and not from both pools. Multiple or suspected multiple applications under the Hong Kong Public Offering and any application for more than 385,850 Hong Kong Offer Shares is liable to be rejected.

Reallocation

The allocation of the Offer Shares between the Hong Kong Public Offering and the International Offering is subject to reallocation. Paragraph 4.2 of Practice Note 18 of the Listing Rules requires a clawback mechanism to be put in place which would have the effect of increasing the number of Offer Shares under the Hong Kong Public Offering to a certain percentage of the total number of Offer Shares offered under the Global Offering if certain prescribed total demand levels are reached. We have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange has granted us, a waiver from strict compliance with Paragraph 4.2 of Practice Note 18 of the Listing Rules such that, in the event of over-subscription, the alternative clawback mechanism shall be applied. 771,700 Offer Shares are initially available in the Hong Kong Public Offering, representing approximately 7.3% of the Offer Shares initially available under the Global Offering. The allocation of Shares between the Hong Kong Public Offering and the International Offering is subject to adjustment.

If the number of Offer Shares validly applied for under the Hong Kong Public Offering represents: (a) 14 times or more but less than 45 times, (b) 45 times or more but less than 85 times and (c) 85 times or more of the total number of Offer Shares initially available under the Hong Kong Public Offering, then Offer Shares will be reallocated to the Hong Kong Public Offering from the International Offering. As a result of such reallocation, the total number of Offer Shares available under the Hong Kong Public Offering will be increased to 1,373,350 Offer Shares (in the case of (a)), 1,901,550 Offer Shares (in the case of (b)) and 3,591,800 Offer Shares (in the case of (c)), representing approximately 13%, 18% and 34% of the total number of Offer Shares initially available under the Global Offering, respectively (before any exercise of the Over-allotment Option). In each case, the additional Offer Shares reallocated to the Hong Kong Public Offering will be allocated between pool A and pool B and the number of Offer Shares allocated to the International Offering will be correspondingly reduced in such manner as the Joint Representatives deem appropriate.

In addition, the Joint Representatives may reallocate Offer Shares from the International Offering to the Hong Kong Public Offering to satisfy valid applications under the Hong Kong Public Offering.

If the Hong Kong Public Offering is not fully subscribed, the Joint Representatives may reallocate all or any unsubscribed Hong Kong Offer Shares to the International Offering, in such proportions as the Joint Representatives deem appropriate.

The Offer Shares to be offered in the Hong Kong Public Offering and the Offer Shares to be offered in the International Offering may be reallocated between these offerings at the discretion of the Joint Representatives, pursuant to the alternative clawback mechanism applied for to the Hong Kong Stock Exchange as detailed above. In accordance with the Guidance Letter HKEX-GL91-18 issued by the Hong Kong Stock Exchange, if such reallocation is done other than pursuant to the clawback mechanism above, the maximum total number of Offer Shares that may be reallocated to the Hong Kong Public Offering following such reallocation shall be not more than double the initial allocation to the Hong Kong Public Offering (i.e., 1,543,400 Shares, representing approximately 14.6% of the total number of Offer Shares initially available under the Global Offering).

Applications

Each applicant under the Hong Kong Public Offering will be required to give an undertaking and confirmation in the application submitted by him/her that he/she and any person(s) for whose benefit he/she is making the application has not applied for or taken up, or indicated an interest for, and will not apply for or take up, or indicate an interest for, any International Offer Shares under the International Offering. Such applicant's application is liable to be rejected if such undertaking and/or confirmation is/are breached and/or untrue (as the case may be) or if he/she has been or will be placed or allocated International Offer Shares under the International Offering.

Applicants under the Hong Kong Public Offering are required to pay, on application, the maximum Public Offer Price of HK$648.00 per Offer Share in addition to the brokerage, the SFC transaction levy and the Hong Kong Stock Exchange trading fee payable on each Offer Share, amounting to a total of HK$32,726.49 for one board lot of 50 Shares. If the Public Offer Price, as finally determined in the manner described in "Pricing and allocation" is less than the maximum Public Offer Price of HK$648.00 per Offer Share, appropriate refund payments (including the brokerage, the SFC transaction levy and the Hong Kong Stock Exchange trading fee attributable to the surplus application monies) will be made to successful applicants, without interest. Further details are set out in "How to Apply for Hong Kong Offer Shares."

THE INTERNATIONAL OFFERING

Number of Offer Shares Initially Offered

The International Offering will consist of an offering of initially 9,792,350 Offer Shares, representing approximately 92.7% of the total number of Offer Shares initially available under the Global Offering (subject to reallocation and the Over-allotment Option). The number of Offer Shares initially offered under the International Offering, subject to any reallocation of Offer Shares between the International Offering and the Hong Kong Public Offering, will represent approximately 11.4% of the total Shares in issue immediately following the completion of the Global Offering (assuming the Over-allotment Option is not exercised and without taking into account the Shares to be issued pursuant to the Equity Plans including pursuant to the exercise of share options or other awards that have been or may be granted from time to time).

Allocation

The International Offering will include U.S. offering of Offer Shares in the United States as well as non-U.S. offering to institutional and professional and other investors in other jurisdictions outside the United States. Professional investors generally include brokers, dealers, companies (including fund managers) whose ordinary business involves dealing in shares and other securities and corporate entities that regularly invest in shares and other securities. Allocation of Offer Shares pursuant to the International Offering will be effected in accordance with the "book-building" process described in "Pricing and allocation" and based on a number of factors, including the level and timing of demand, the total size of the relevant investor's invested assets or equity assets in the relevant sector and whether or not it is expected that the relevant investor is likely to buy further Shares and/or hold or sell its Shares after the Listing. Such allocation is intended to result in a distribution of the Shares on a basis which would lead to the establishment of a solid professional and institutional shareholder base to the benefit of the Group and the Shareholders as a whole.

The Joint Representatives (for themselves and on behalf of the Underwriters) may require any investor who has been offered Offer Shares under the International Offering and who has made an application under the Hong Kong Public Offering to provide sufficient information to the Joint Representatives so as to allow them to identify the relevant applications under the Hong Kong Public Offering and to ensure that they are excluded from any allocation of Offer Shares under the Hong Kong Public Offering.

Reallocation

The total number of Offer Shares to be issued or sold pursuant to the International Offering may change as a result of the clawback arrangement described in "Hong Kong Public Offering – Reallocation," the exercise of the Over-allotment Option in whole or in part and/or any reallocation of unsubscribed Offer Shares originally included in the Hong Kong Public Offering.

Over-allotment Option

In connection with the Global Offering, we expect to grant the Over-allotment Option to the International Underwriters, exercisable by the Joint Representatives (for themselves and on behalf of the International Underwriters).

Pursuant to the Over-allotment Option, the International Underwriters will have the right, exercisable by the Joint Representatives (for themselves and on behalf of the International Underwriters) at any time from the Listing Date until 30 days after the last day for lodging applications under the Hong Kong Public Offering, to require us to issue up to an aggregate of 1,584,600 additional Shares, representing approximately 15% of the total number of Offer Shares initially available under the Global Offering, at the International Offer Price under the International Offering to cover over-allocations in the International Offering, if any. If the Over-allotment Option is exercised in full, the additional Offer Shares to be issued pursuant thereto will represent approximately 1.8% of the total Shares in issue immediately following the completion of the Global Offering without taking into account the Shares to be issued pursuant to the Equity Plans including pursuant to the exercise of share options or other awards that have been or may be granted from time to time. If the Over-allotment Option is exercised, an announcement will be made.

STABILIZATION

Underwriters use stabilization in some markets to facilitate the distribution of securities. To stabilize, the underwriters may bid for, or purchase, the securities in the secondary market during a specified period of time, to retard and, if possible, prevent a decline in the initial public market price of the securities below the offer price. Such transactions may be effected in all jurisdictions where it is permissible to do so, in each case in compliance with all applicable laws and regulatory requirements, including those of Hong Kong. In Hong Kong, the price at which the stabilization is effected is not permitted to exceed the Public Offer Price.

In connection with the Global Offering, the Stabilization Manager (or any person acting for it), on behalf of the Underwriters, may over-allocate or effect transactions with a view to stabilizing or supporting the market price of the Shares at a level higher than that which might otherwise prevail for a limited period after the Listing Date in the Hong Kong market.

However, there is no obligation on the Stabilization Manager (or any person acting for it) to conduct any such stabilizing action. Such stabilizing action, if taken: (a) will be conducted at the absolute discretion of the Stabilization Manager (or any person acting for it) and in what the Stabilization Manager reasonably regards as our best interest; (b) may be discontinued at any time; and (c) is required to be brought to an end within 30 days after the last day for lodging applications under the Hong Kong Public Offering. The Company will not, and will cause its affiliates or any of its or its affiliates' respective directors, officers, employees, or any person acting on its behalf or on behalf of any of the foregoing persons not to conduct any stabilizing action.

Stabilization action permitted in Hong Kong pursuant to the Securities and Futures (Price Stabilizing) Rules of the SFO includes: (a) over-allocating for the purpose of preventing or minimizing any reduction in the market price of the Shares; (b) selling or agreeing to sell the Shares so as to establish a short position in them for the purpose of preventing or minimizing any reduction in the market price of the Shares; (c) purchasing, or agreeing to purchase, the Shares pursuant to the Over-allotment Option in order to close out any position established under Paragraphs (a) or (b) above; (d) purchasing, or agreeing to purchase, any of the Shares for the sole purpose of preventing or minimizing any reduction in the market price of the Shares; (e) selling or agreeing to sell any Shares in order to liquidate any position established as a result of those purchases; and (f) offering or attempting to do anything as described in paragraphs (b), (c), (d) or (e) above.

Specifically, prospective applicants for and investors in the Offer Shares should note that:

(a) the Stabilization Manager (or any person acting for it) may, in connection with the stabilizing action, maintain a long position in the Shares;

(b) there is no certainty as to the extent to which and the time or period for which the Stabilization Manager (or any person acting for it) will maintain such a long position;

(c) liquidation of any such long position by the Stabilization Manager (or any person acting for it) and selling in the open market may have an adverse impact on the market price of the Shares;

(d) no stabilizing action can be taken to support the price of the Shares for longer than the stabilization period, which will begin on the Listing Date, and is expected to expire on Thursday, October 22, 2020, being the 30th day after the last day for lodging applications under the Hong Kong Public Offering. After this date, when no further stabilizing action may be taken, demand for the Shares, and therefore the price of the Shares, could fall;

(e) the price of the Shares cannot be assured to stay at or above the Public Offer Price by the taking of any stabilizing action; and

(f) stabilizing bids or transactions effected in the course of the stabilizing action may be made at any price at or below the Public Offer Price and can, therefore, be done at a price below the price paid by applicants for, or investors in, the Offer Shares.

We will ensure or procure that an announcement in compliance with the Securities and Futures (Price Stabilizing) Rules of the SFO will be made within seven days of the expiration of the stabilization period.

In addition, stabilization transactions with respect to the ADSs may be effected by one of the Underwriters or its affiliates before the listing of the Shares on the Hong Kong Stock Exchange in accordance with applicable laws and regulations.

Over-allocation

Following any over-allocation of Shares in connection with the Global Offering, the Stabilization Manager (or any person acting for it) may cover such over-allocations by exercising the Over-allotment Option in full or in part or by using Shares purchased by the Stabilization Manager (or any person acting for it) in the secondary market at prices that do not exceed the Public Offer Price or through the Stock Borrowing Agreement as detailed below, or through a combination of these means.

Stock Borrowing Agreement

To cover any over-allocation of Shares in connection with the Global Offering, the Stabilization Manager may choose to borrow up to 1,584,600 Shares (being the maximum number of Shares which may be issued pursuant to the exercise of the Over-allotment Option) from QM11 Limited, pursuant to the Stock Borrowing Agreement, which is expected to be entered into between the Stabilization Manager and QM11 Limited on or about the Price Determination Date.

The same number of Shares so borrowed must be returned to QM11 Limited, on or before the fifth business day or in the event that the Stabilization Manager conducts stabilizing action by purchasing ADSs in the U.S. market, the seventh business day, following the earlier of (a) the last day on which the Over-allotment Option may be exercised and (b) the day on which the Over-allotment Option is exercised in full, or such earlier time as agreed in writing between the Stabilization Manager and QM11 Limited.

The Shares borrowing arrangement described above will be effected in compliance with all applicable laws, rules and regulatory requirements in Hong Kong. No payment will be made to QM11 Limited by the Stabilization Manager (or any person acting for it) in relation to such Shares borrowing arrangement.

Pricing and allocation

Determining the Offer Price

We will determine the pricing for the Offer Shares for the purpose of the various offerings under the Global Offering on the Price Determination Date, which is expected to be on or about Tuesday, September 22, 2020 and, in any event, no later than Friday, September 25, 2020, by agreement with the Joint Representatives (for themselves and on behalf of the Underwriters), and the number of Offer Shares to be allocated under the various offerings will be determined shortly thereafter.

We will determine the Public Offer Price by reference to, among other factors, the closing price of the ADSs on Nasdaq on the last trading day on or before the Price Determination Date, and the Public Offer Price will not be more than HK$648.00 per Hong Kong Offer Share. The historical prices of our ADSs and trading volume on Nasdaq are set out below.

Period	High	Low	ADTV
	US$	*US$*	*ADSs*[(1)]
Fiscal year ended December 31, 2019	43.06	21.71	190,849
Fiscal year of 2020 (up to the Latest Practicable Date)	89.48	39.10	451,089

Note:

(1) Average daily trading volume ("ADTV") represents daily average number of our ADSs traded over the relevant period.

Applicants under the Hong Kong Public Offering must pay, on application, the maximum Public Offer Price of HK$648.00 per Offer Share plus brokerage of 1.0%, SFC transaction levy of 0.0027% and Hong Kong Stock Exchange trading fee of 0.005%, amounting to a total of HK$32,726.49 for one board lot of 50 Shares.

We may set the International Offer Price at a level higher than the maximum Public Offer Price if (a) the Hong Kong dollar equivalent of the closing trading price of the ADSs on the Nasdaq on the last trading day on or before the Price Determination Date (on a per-Share converted basis) were to exceed the maximum Public Offer Price as stated in this prospectus and/or (b) we believe that it is in its best interest as a listed company to set the International Offer Price at a level higher than the maximum Public Offer Price based on the level of interest expressed by professional and institutional investors during the book-building process.

If the International Offer Price is set at or lower than the maximum Public Offer Price, the Public Offer Price must be set at such price which is equal to the International Offer Price. In no circumstances will we set the Public Offer Price above the maximum Public Offer Price as stated in this prospectus or the International Offer Price.

We reserve the right not to proceed with the Hong Kong Public Offering or the International Offering on or at any time until the Price Determination Date if, for any reason, including as a result of volatility in the price of our ADSs or other changes in market conditions, we do not agree with the Joint Representatives (for themselves and on behalf of the Underwriters) on the pricing of the Offer Shares by Friday, September 25, 2020.

The International Underwriters will be soliciting from prospective investors' indications of interest in acquiring Offer Shares in the International Offering. Prospective professional and institutional investors will be required to specify the number of Offer Shares under the International Offering they would be prepared to acquire either at different prices or at a particular price. This process, known as "book-building," is expected to continue up to, and to cease on or about, the last day for lodging applications under the Hong Kong Public Offering.

The Joint Representatives (for themselves and on behalf of the Underwriters) may, where they deem appropriate, based on the level of interest expressed by prospective investors during the book-building process in respect of the International Offering, and with our consent, reduce the number of Offer Shares offered below as stated in this prospectus at any time on or prior to the morning of the last day for lodging applications under the Hong Kong Public Offering.

In such a case, we will, as soon as practicable following the decision to make such reduction, and in any event not later than the morning of the last day for lodging applications under the Hong Kong Public Offering, cause to be published on our website and the website of the Hong Kong Stock Exchange at **http://www.zailaboratory.com** and **www.hkexnews.hk**, respectively, notices of the reduction.

Upon the issue of such a notice, the revised number of Offer Shares will be final. If the number of Offer Shares is reduced, applicants under the Hong Kong Public Offering will be entitled to withdraw their applications, unless positive confirmations from the applicants to proceed are received.

Before submitting applications for the Hong Kong Offer Shares, applicants should have regard to the possibility that any announcement of a reduction in the number of Offer Shares may not be made until the last day for lodging applications under the Hong Kong Public Offering. Such notice will also include confirmation or revision, as appropriate, of the working capital statement and the Global Offering statistics as currently set out in this prospectus, and any other financial information which may change as a result of any such reduction. In the absence of any such notice so published, the number of Offer Shares will not be reduced.

The final pricing of the Offer Shares, the level of indications of interest in the International Offering, the level of applications in the Hong Kong Public Offering, the basis of allocations of the Hong Kong Offer Shares and the results of allocations in the Hong Kong Public Offering are expected to be made available through a variety of channels in the manner described in "How to Apply for Hong Kong Offer Shares – Publication of Results."

UNDERWRITING

The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters under the terms and conditions of the Hong Kong Underwriting Agreement and is subject to, among other things, our agreeing with the Joint Representatives (for themselves and on behalf of the Underwriters) on the pricing of the Offer Shares.

We expect to enter into the International Underwriting Agreement relating to the International Offering on the Price Determination Date.

These underwriting arrangements, including the Underwriting Agreements, are summarized in "Underwriting."

CONDITIONS OF THE GLOBAL OFFERING

Acceptance of all applications for Offer Shares will be conditional on:

(a) the Hong Kong Stock Exchange granting approval for the listing of, and permission to deal in, the Shares in issue and to be issued pursuant to the Global Offering (including the Shares which may be issued pursuant to the exercise of the Over-allotment Option) and the Shares to be issued pursuant to the Equity Plans, on the Main Board of the Hong Kong Stock Exchange and such approval not subsequently having been withdrawn or revoked prior to the Listing Date;

(b) the pricing of the Offer Shares having been agreed between the Joint Representatives (for themselves and on behalf of the Underwriters) and us;

(c) the execution and delivery of the International Underwriting Agreement on or around the Price Determination Date; and

(d) the obligations of the Hong Kong Underwriters under the Hong Kong Underwriting Agreement and the obligations of the International Underwriters under the International Underwriting Agreement becoming and remaining unconditional and not having been terminated in accordance with the terms of the respective agreements,

in each case on or before the dates and times specified in the respective Underwriting Agreements (unless and to the extent such conditions are validly waived on or before such dates and times) and, in any event, not later than the date which is 30 days from the date of this prospectus.

If, for any reason, we do not agree with the Joint Representatives (for themselves and on behalf of the Underwriters) on the pricing of the Offer Shares on or before Friday, September 25, 2020, the Global Offering will not proceed and will lapse.

The consummation of each of the Hong Kong Public Offering and the International Offering is conditional upon, among other things, the other offering becoming unconditional and not having been terminated in accordance with its terms.

If the above conditions are not fulfilled or waived prior to the dates and times specified, the Global Offering will lapse and the Hong Kong Stock Exchange will be notified immediately. Notice of the lapse of the Hong Kong Public Offering will be published by us on our website and the website of the Hong Kong Stock Exchange at **http://www.zailaboratory.com** and **www.hkexnews.hk**, respectively, on the next day following such lapse. In such a situation, all application monies will be returned, without interest, on the terms set out in "How to Apply for Hong Kong Offer Shares – Refund of

application monies." In the meantime, all application monies will be held in separate bank account(s) with the receiving bank or other bank(s) in Hong Kong licensed under the Banking Ordinance (Chapter 155 of the Laws of Hong Kong).

Share certificates for the Offer Shares will only become valid at 8:00 a.m. on Monday, September 28, 2020, provided that the Global Offering has become unconditional in all respects at or before that time.

DEALINGS IN THE SHARES

Assuming that the Hong Kong Public Offering becomes unconditional at or before 8:00 a.m. in Hong Kong on Monday, September 28, 2020, it is expected that dealings in the Shares on the Hong Kong Stock Exchange will commence at 9:00 a.m. on Monday, September 28, 2020.

The Shares will be traded in board lots of 50 Shares each and the stock code of the Shares will be 9688.

IMPORTANT NOTICE TO INVESTORS:

FULLY ELECTRONIC APPLICATION PROCESS

We have adopted a fully electronic application process for the Hong Kong Public Offering. We will not provide any printed copies of this prospectus or any printed copies of any application forms for use by the public.

*This prospectus is available at the website of the Hong Kong Stock Exchange at **www.hkexnews.hk** under the "HKEXnews > New Listings > New Listing Information" section, and our website at **http://www.zailaboratory.com**. If you require a printed copy of this prospectus, you may download and print from the website addresses above.*

The contents of the electronic version of the prospectus are identical to the printed prospectus as registered with the Registrar of Companies in Hong Kong pursuant to Section 342C of the Companies (WUMP) Ordinance.

Set out below are procedures through which you can apply for the Hong Kong Offer Shares electronically. We will not provide any physical channels to accept any application for the Hong Kong Offer Shares by the public.

If you are an intermediary, broker or agent, please remind your customers, clients or principals, as applicable, that this prospectus is available online at the website addresses above.

*If you have any questions about the application for the Hong Kong Offer Shares, you may call the enquiry hotline of our Hong Kong Share Registrar and **White Form eIPO** Service Provider, Computershare Hong Kong Investor Services Limited, at +852 2862 8648 from 9:00 a.m. to 9:00 p.m. on Thursday, September 17, 2020, Friday, September 18, 2020 and Monday, September 21, 2020, from 9:00 a.m. to 6:00 p.m. on Saturday, September 19, 2020 and Sunday, September 20, 2020 and from 9:00 a.m. to 12:00 noon on Tuesday, September 22, 2020.*

APPLICATIONS FOR THE HONG KONG OFFER SHARES

How to Apply

We will not provide any printed application forms for use by the public.

To apply for the Hong Kong Offer Shares, you may:

(1) apply online through the **White Form eIPO** service at **www.eipo.com.hk**; or

(2) apply through **CCASS EIPO** service to electronically cause HKSCC Nominees to apply on your behalf, including by:

(a) instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf; or

(b) (if you are an existing **CCASS Investor Participant**) giving **electronic application instructions** through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System by calling +852 2979 7888 (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input **electronic application instructions** for CCASS Investor Participants through HKSCC's Customer Service Centre at 1/F, One & Two Exchange Square, 8 Connaught Place, Central, Hong Kong by completing an input request.

If you apply through channel (1) above, the Hong Kong Offer Shares successfully applied for will be issued in your own name.

If you apply through channels (2)(a) or (2)(b) above, the Hong Kong Offer Shares successfully applied for will be issued in the name of HKSCC Nominees and deposited directly into CCASS to be credited to your or a designated CCASS Participant's stock account.

None of you or your joint applicant(s) may make more than one application, except where you are a nominee and provide the required information in your application.

We, the Joint Representatives, the **White Form eIPO** Service Provider and their respective agents may reject or accept any application, in full or in part, for any reason at their discretion.

Who can Apply

Eligibility for the Application

You can apply for the Hong Kong Offer Shares if you or any person(s) for whose benefit you are applying:

(a) are 18 years of age or older; and

(b) have a Hong Kong address.

If an application is made by a person under a power of attorney, we and the Joint Representatives may accept it at their discretion, and on any conditions we think fit, including requiring evidence of the attorney's authority.

The number of joint applicants may not exceed four and they may not apply by means of the **White Form eIPO** service for the Hong Kong Offer Shares.

Unless permitted by the Listing Rules or any relevant waivers that have been granted by the Hong Kong Stock Exchange (details of the relevant waivers are set out in "Waivers and Exemptions – Subscription For Shares By Existing Shareholders," you cannot apply for any Hong Kong Offer Shares if:

(a) you are an existing beneficial owner of Shares and/or a substantial shareholder of any of the Company's subsidiaries;

(b) you are the Company's director or chief executive and/or a director or chief executive officer of its subsidiaries;

(c) you are a close associate of any of the above persons;

(d) you are a core connected person of the Company or a person who will become a core connected person of the Company immediately upon the completion of the Global Offering; or

(e) you have been allocated or have applied for any International Offer Shares or otherwise participate in the International Offering.

Items Required for the Application

If you apply for the Hong Kong Offer Shares online through the **White Form eIPO** service, you must:

(a) have a valid Hong Kong identity card number; and

(b) provide a valid e-mail address and a contact telephone number.

If you are applying for the Hong Kong Offer Shares online by instructing your broker or custodian who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals, please contact them for the items required for the application.

Terms and Conditions of an Application

By applying through the application channels specified in this prospectus you:

(a) undertake to execute all relevant documents and instruct and authorize the Company and/or the Joint Representatives (or their agents or nominees), as their agents, to execute any documents for you and to do on your behalf all things necessary to register any Hong Kong Offer Shares allocated to you in your name or in the name of HKSCC Nominees as required by the Articles of Association;

(b) agree to comply with the Company's Memorandum and Articles of Association, the Companies (WUMP) Ordinance and the Cayman Companies Law;

(c) confirm that you have read the terms and conditions and application procedures set out in this prospectus and agree to be bound by them;

(d) confirm that you have received and read this prospectus and have relied only on the information and representations in this prospectus in making your application and will not rely on any other information or representations, except those in any supplement to this prospectus;

(e) confirm that you are aware of the restrictions on the Global Offering set out in this prospectus;

(f) agree that none of the Company, the Relevant Persons and the **White Form eIPO** Service Provider is or will be liable for any information and representations not in this prospectus (and any supplement to this prospectus);

(g) undertake and confirm that you or the person(s) for whose benefit you have made the application have not applied for or taken up, or indicated an interest for, and will not apply for or take up, or indicate an interest for, any International Offer Shares nor participated in the International Offering;

(h) agree to disclose to the Company, the Hong Kong Share Registrar, the receiving bank and the Relevant Persons any personal data that any of them may require about you and the person(s) for whose benefit you have made the application;

(i) if the laws of any place outside Hong Kong apply to your application, agree and warrant that you have complied with all such laws and neither the Company nor the Relevant Persons will breach any laws outside Hong Kong as a result of the acceptance of your offer to purchase, or any action arising from your rights and obligations under the terms and conditions in this prospectus;

(j) agree that once your application has been accepted, you may not rescind it because of an innocent misrepresentation;

(k) agree that your application, any acceptance of it and the resulting contract will be governed by, and construed in accordance with the laws of Hong Kong;

(l) warrant that the information you have provided is true and accurate;

(m) agree to accept the Hong Kong Offer Shares applied for or any lesser number allocated to you under the application;

(n) authorize (i) the Company to place your name(s) or the name of HKSCC Nominees on the Company's register of members as the holder(s) of any Hong Kong Offer Shares allocated to you and such other registers as required under the Company's Memorandum and Articles of Association and (ii) the Company and/or its agents to send any Share certificate(s) and/or any e-Refund payment instructions and/or any refund check(s) to you or the first-named applicant for joint applications by ordinary post at your own risk to the address stated on the application, unless you have fulfilled the criteria mentioned in "-Personal Collection" below to collect the Share certificate(s) and/or refund check(s) in person;

(o) declare and represent that this is the only application made and the only application intended by you to be made to benefit you or the person for whose benefit you are applying;

(p) understand that the Company, its directors and the Joint Representatives will rely on your declarations and representations in deciding whether or not to allocate any of the Hong Kong Offer Shares to you and that you may be prosecuted for making a false declaration;

(q) (if the application is made for your own benefit) warrant that no other application has been or will be made for your benefit by giving **electronic application instructions** to HKSCC directly or indirectly or through the **White Form eIPO** service or by any one as your agent or by any other person; and

(r) (if you are making the application as an agent for the benefit of another person) warrant that (i) no other application has been or will be made by you as agent for or for the benefit of that person or by that person or by any other person as agent for that person by giving **electronic application instructions** to HKSCC and (ii) you have due authority to give **electronic application instructions** on behalf of that other person as its agent.

For the avoidance of doubt, the Company and all other parties involved in the preparation of this prospectus acknowledge that each applicant and CCASS Participant who gives or causes to give **electronic application instructions** is a person who may be entitled to compensation under Section 40 of the Companies (WUMP) Ordinance (as applied by Section 342E of the Companies (WUMP) Ordinance).

Minimum Application Amount and Permitted Numbers

Your application through the **White Form eIPO** service or the **CCASS EIPO** service must be for a minimum of 50 Hong Kong Offer Shares and in one of the numbers set out in the table. You are required to pay the amount next to the number you select.

No. of Hong Kong Offer Shares applied for	Amount payable on application HK$	No. of Hong Kong Offer Shares applied for	Amount payable on application HK$	No. of Hong Kong Offer Shares applied for	Amount payable on application HK$	No. of Hong Kong Offer Shares applied for	Amount payable on application HK$
50	32,726.49	1,000	654,529.90	8,000	5,236,239.17	200,000	130,905,979.20
100	65,452.99	1,500	981,794.84	8,500	5,563,504.12	300,000	196,358,968.80
150	98,179.48	2,000	1,309,059.79	9,000	5,890,769.06	385,850[(1)]	252,550,360.37
200	130,905.98	2,500	1,636,324.74	9,500	6,218,034.01		
250	163,632.47	3,000	1,963,589.69	10,000	6,545,298.96		
300	196,358.97	3,500	2,290,854.64	20,000	13,090,597.92		
350	229,085.46	4,000	2,618,119.58	30,000	19,635,896.88		
400	261,811.96	4,500	2,945,384.53	40,000	26,181,195.84		
450	294,538.45	5,000	3,272,649.48	50,000	32,726,494.80		
500	327,264.95	5,500	3,599,914.43	60,000	39,271,793.76		
600	392,717.94	6,000	3,927,179.38	70,000	45,817,092.72		
700	458,170.93	6,500	4,254,444.32	80,000	52,362,391.68		
800	523,623.92	7,000	4,581,709.27	90,000	58,907,690.64		
900	589,076.91	7,500	4,908,974.22	100,000	65,452,989.60		

Note:

(1) Maximum number of Hong Kong Offer Shares you may apply for.

No application for any other number of the Hong Kong Offer Shares will be considered and any such application is liable to be rejected.

Applying through the White Form eIPO Service

General

Individuals who meet the criteria in "– Who can apply" above may apply through the **White Form eIPO** service for the Offer Shares to be allocated and registered in their own names through the designated website at **www.eipo.com.hk**.

Detailed instructions for application through the **White Form eIPO** service are set out on the designated website. If you do not follow the instructions, your application may be rejected and may not be submitted to the Company. If you apply through the designated website, you authorize the **White Form eIPO** Service Provider to apply on the terms and conditions in this prospectus, as supplemented and amended by the terms and conditions of the **White Form eIPO** Service Provider.

If you have any questions on how to apply through the **White Form eIPO** service for the Hong Kong Offer Shares, please contact the telephone enquiry line of the **White Form eIPO** Service Provider, Computershare Hong Kong Investor Services Limited at +852 2862 8648 which is available from 9:00 a.m. to 9:00 p.m. on Thursday, September 17, 2020, Friday, September 18, 2020 and Monday, September 21, 2020, from 9:00 a.m. to 6:00 p.m. on Saturday, September 19, 2020 and Sunday, September 20, 2020 and from 9:00 a.m. to 12:00 noon on Tuesday, September 22, 2020.

Time for Submitting Applications under the White Form eIPO Service

You may submit your application through the **White Form eIPO** service through the designated website at **www.eipo.com.hk** (24 hours daily, except on the last day for applications) from 9:00 a.m. on Thursday, September 17, 2020 until 11:30 a.m. on Tuesday, September 22, 2020 and the latest time for completing full payment of application monies in respect of such applications will be 12:00 noon on Tuesday, September 22, 2020, the last day for applications, or such later time as described in "Effect of Bad Weather and Extreme Conditions on the Opening and Closing of the Application Lists" below.

Commitment to Sustainability

The obvious advantage of **White Form eIPO** service is to save the use of paper via the self-serviced and electronic application process. Computershare Hong Kong Investor Services Limited, being the designated **White Form eIPO** Service Provider, will contribute HK$2 for each "Zai Lab Limited" **White Form eIPO** application submitted via **www.eipo.com.hk** to support sustainability.

Applying through CCASS EIPO Service

General

You may instruct your broker or custodian who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf. CCASS Participants may give **electronic application instructions** to apply for the Hong Kong Offer Shares and to arrange payment of the money due on application and payment of refunds under their participant agreements with HKSCC and the General Rules of CCASS and the CCASS Operational Procedures.

If you are a **CCASS Investor Participant**, you may give these **electronic application instructions** through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System by calling +852 2979 7888 (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input **electronic application instructions** for CCASS Investor Participants through HKSCC's Customer Service Centre at 1/F, One & Two Exchange Square, 8 Connaught Place, Central, Hong Kong by completing an input request.

You will be deemed to have authorized HKSCC and/or HKSCC Nominees to transfer the details of your application to the Company, the Joint Sponsors, the Joint Representatives, the Joint Global Coordinators and the Hong Kong Share Registrar.

Applying through CCASS EIPO Service

Where you have applied through **CCASS EIPO** service (either indirectly through a **broker or custodian** or directly) and an application is made by HKSCC Nominees on your behalf:

(a) HKSCC Nominees will only be acting as a nominee for you and is not liable for any breach of the terms and conditions of this prospectus; and

(b) HKSCC Nominees will do the following things on your behalf:

- agree that the Hong Kong Offer Shares to be allocated shall be registered in the name of HKSCC Nominees and deposited directly into CCASS for the credit of the CCASS Participant's stock account on your behalf or your CCASS Investor Participant's stock account;
- agree to accept the Hong Kong Offer Shares applied for or any lesser number allocated;
- undertake and confirm that you have not applied for or taken up, or indicated an interest for, and will not apply for or take up, or indicate an interest for, any International Offer Shares nor participated in the International Offering;
- *(if the electronic application instructions are given for your benefit)* declare that only one set of **electronic application instructions** has been given for your benefit;
- (if you are an agent for another person) declare that you have only given one set of **electronic application instructions** for the other person's benefit and are duly authorized to give those instructions as its agent;
- confirm that you understand that the Company, its directors and the Joint Representatives will rely on your declarations and representations in deciding whether or not to allocate any of the Hong Kong Offer Shares to you and that you may be prosecuted for making a false declaration;
- authorize the Company to place HKSCC Nominees' name on its register of members as the holder of the Hong Kong Offer Shares allocated to you, and despatch Share certificate(s) and/or refund monies in accordance with the arrangements separately agreed between the Company and HKSCC;

- confirm that you have read the terms and conditions and application procedures set out in this prospectus and agree to be bound by them;

- confirm that you have received and read this prospectus and have relied only on the information and representations in this prospectus in causing the application to be made and will not rely on any other information or representations, except those in any supplement to this prospectus;

- agree that neither the Company nor any of the Relevant Persons is or will be liable for any information and representations not in this prospectus (and any supplement to this prospectus);

- agree to disclose to the Company, the Hong Kong Share Registrar, the receiving bank and the Relevant Persons any personal data which they may require about you;

- agree (without prejudice to any other rights which you may have) that once HKSCC Nominees' application has been accepted, it cannot be rescinded for innocent misrepresentation;

- agree that any application made by HKSCC Nominees on your behalf is irrevocable on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong), such agreement to take effect as a collateral contract with the Company, and to become binding when you give the instructions and such collateral contract to be in consideration of the Company's agreement that it will not offer any Hong Kong Offer Shares to any person on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong) except by means of one of the procedures referred to in this prospectus. However, HKSCC Nominees may revoke the application on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong) if a person responsible for this prospectus under Section 40 of the Companies (WUMP) Ordinance (as applied by Section 342E of the Companies (WUMP) Ordinance) gives a public notice under that section on or before the fifth day after the time of the opening of the application lists (excluding any day which is a Saturday, Sunday or public holiday in Hong Kong) which excludes or limits that person's responsibility for this prospectus;

- agree that once HKSCC Nominees' application is accepted, neither that application nor your **electronic application instructions** can be revoked, and that acceptance of that application will be evidenced by the Company's announcement of the results of the Hong Kong Public Offering;

- agree to the arrangements, undertakings and warranties under the participant agreement between you and HKSCC, read with the General Rules of CCASS and the CCASS Operational Procedures, for giving **electronic application instructions** to apply for the Hong Kong Offer Shares;

- agree with the Company, for itself and for the benefit of each shareholder (and so that the Company will be deemed by its acceptance in whole or in part of the application by HKSCC Nominees to have agreed, for the Company and on behalf of each shareholder, with each CCASS Participant giving **electronic application instructions**) to observe and comply with its Memorandum and Articles of Association, the Companies (WUMP) Ordinance and the Cayman Companies Law; and

- agree that your application, any acceptance of it and the resulting contract will be governed by, and construed in accordance with the laws of Hong Kong.

Effect of Applying through CCASS EIPO Service

By applying through **CCASS EIPO** service, you (and, if you are joint applicants, each of you jointly and severally) are deemed to have done the following things. Neither HKSCC nor HKSCC Nominees will be liable to the Company or any other person in respect of the things mentioned below:

(a) instructed and authorized HKSCC to cause HKSCC Nominees (acting as nominee for the relevant CCASS Participants) to apply for the Hong Kong Offer Shares on your behalf;

(b) instructed and authorized HKSCC to arrange payment of the maximum Public Offer Price, brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee by debiting your designated bank account and, in the case of a wholly or partially unsuccessful application and/or if the Public Offer Price is less than the maximum Public Offer Price initially paid on application, refund of the application monies (including brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee) by crediting your designated bank account; and

(c) instructed and authorized HKSCC to cause HKSCC Nominees to do on your behalf all the things stated in this prospectus.

Time for Inputting Electronic Application Instructions[(1)]

CCASS Clearing/Custodian Participants can input **electronic application instructions** at the following times on the following dates:

Thursday, September 17, 2020	–	9:00 a.m. to 8:30 p.m.
Friday, September 18, 2020	–	8:00 a.m. to 8:30 p.m.
Saturday, September 19, 2020	–	8:00 a.m. to 1:00 p.m.
Monday, September 21, 2020	–	8:00 a.m. to 8:30 p.m.
Tuesday, September 22, 2020	–	8:00 a.m. to 12:00 noon

CCASS Investor Participants can input **electronic application instructions** from 9:00 a.m. on Thursday, September 17, 2020 until 12:00 noon on Tuesday, September 22, 2020 (24 hours daily, except on Tuesday, September 22, 2020, the last day for applications).

The latest time for inputting your **electronic application instructions** will be 12:00 noon on Tuesday, September 22, 2020, the last day for applications, or such later time as described in "Effect of Bad Weather and Extreme Conditions on the Opening and Closing of the Application Lists" below.

If you are instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, you are advised to contact your **broker** or **custodian** for the latest time for giving such instructions which may be different from the latest time as stated above.

Note:

(1) The times in this subsection are subject to change as HKSCC may determine from time to time with prior notification to CCASS Clearing Participants, CCASS Custodian Participants and/or CCASS Investor Participants.

Personal Data

The following Personal Information Collection Statement applies to any personal data held by the Company, the Hong Kong Share Registrar, the receiving bank and the Relevant Persons about you in the same way as it applies to personal data about applicants other than HKSCC Nominees. By applying through **CCASS EIPO** service, you agree to all of the terms of the Personal Information Collection Statement below.

Personal Information Collection Statement

This Personal Information Collection Statement informs applicant for, and holder of, the Hong Kong Offer Shares, of the policies and practices of the Company and its Hong Kong Share Registrar in relation to personal data and the Personal Data (Privacy) Ordinance (Chapter 486 of the Laws of Hong Kong).

Reasons for the Collection of your Personal Data

It is necessary for applicants and registered holders of the Hong Kong Offer Shares to supply correct personal data to the Company or its agents and the Hong Kong Share Registrar when applying for the Hong Kong Offer Shares or transferring the Hong Kong Offer Shares into or out of their names or in procuring the services of the Hong Kong Share Registrar.

Failure to supply the requested data may result in your application for the Hong Kong Offer Shares being rejected, or in delay or the inability of the Company or its Hong Kong Share Registrar to effect transfers or otherwise render their services. It may also prevent or delay registration or transfers of the Hong Kong Offer Shares which you have successfully applied for and/or the dispatch of share certificate(s) to which you are entitled.

It is important that the holders of the Hong Kong Offer Shares inform the Company and the Hong Kong Share Registrar immediately of any inaccuracies in the personal data supplied.

Purposes

Your personal data may be used, held, processed, and/or stored (by whatever means) for the following purposes:

(a) processing your application and refund check, where applicable, verification of compliance with the terms and application procedures set out in this prospectus and announcing results of allocation of the Hong Kong Offer Shares;

(b) compliance with applicable laws and regulations in Hong Kong and elsewhere;

(c) registering new issues or transfers into or out of the names of the holders of the Company's Shares including, where applicable, HKSCC Nominees;

(d) maintaining or updating the Company's Register of Members;

(e) verifying identities of the holders of the Company's Shares;

(f) establishing benefit entitlements of holders of the Company's Shares, such as dividends, rights issues, bonus issues, etc.;

(g) distributing communications from the Company and its subsidiaries;

(h) compiling statistical information and profiles of the holder of the Company's Shares;

(i) disclosing relevant information to facilitate claims on entitlements; and

(j) any other incidental or associated purposes relating to the above and/or to enable the Company and the Hong Kong Share Registrar to discharge their obligations to holders of the Company's Shares and/or regulators and/or any other purposes to which the securities' holders may from time to time agree.

Transfer of Personal Data

Personal data held by the Company and its Hong Kong Share Registrar relating to the holders of the Hong Kong Offer Shares will be kept confidential but the Company and its Hong Kong Share Registrar may, to the extent necessary for achieving any of the above purposes, disclose, obtain or transfer (whether within or outside Hong Kong) the personal data to, from or with any of the following:

(a) the Company's appointed agents such as financial advisers, receiving bankers and overseas principal share registrar;

(b) where applicants for the Hong Kong Offer Shares request a deposit into CCASS, HKSCC or HKSCC Nominees, who will use the personal data for the purposes of operating CCASS;

(c) any agents, contractors or third-party service providers who offer administrative, telecommunications, computer, payment or other services to the Company or the Hong Kong Share Registrar in connection with their respective business operation;

(d) the Hong Kong Stock Exchange, the SFC and any other statutory regulatory or governmental bodies or otherwise as required by laws, rules or regulations; and

(e) any persons or institutions with which the holders of the Hong Kong Offer Shares have or propose to have dealings, such as their bankers, solicitors, accountants or stockbrokers etc.

Retention of Personal Data

The Company and its Hong Kong Share Registrar will keep the personal data of the applicants and holders of the Hong Kong Offer Shares for as long as necessary to fulfil the purposes for which the personal data were collected. Personal data which is no longer required will be destroyed or dealt with in accordance with the Personal Data (Privacy) Ordinance.

Access to and Correction of Personal Data

Holders of the Hong Kong Offer Shares have the right to ascertain whether the Company or the Hong Kong Share Registrar hold their personal data, to obtain a copy of that data, and to correct any data that is inaccurate. The Company and the Hong Kong Share Registrar have the right to charge a reasonable fee for the processing of such requests. All requests for access

to data or correction of data should be addressed to the Company, at the Company's registered address disclosed in "Corporate Information" or as notified from time to time, for the attention of the secretary, or the Company's Hong Kong Share Registrar for the attention of the privacy compliance officer.

Warning for Electronic Applications

The application for the Hong Kong Offer Shares by **CCASS EIPO** service (directly or indirectly through your **broker** or **custodian**) is only a facility provided to CCASS Participants. Similarly, the application for the Hong Kong Offer Shares through the **White Form eIPO** service is only a facility provided by the **White Form eIPO** Service Provider to public investors. Such facilities are subject to capacity limitations and potential service interruptions and you are advised not to wait until the last day for applications to make your electronic application. The Company, the Relevant Persons, the **White Form eIPO** Service Provider take no responsibility for such applications and provide no assurance that any CCASS Participant applying through **CCASS EIPO** service or person applying through the **White Form eIPO** service will be allocated any Hong Kong Offer Shares.

To ensure that CCASS Investor Participants can give their **electronic application instructions**, they are advised not to wait until the last minute to input their instructions to the systems. In the event that CCASS Investor Participants have problems in the connection to CCASS Phone System/CCASS internet System for submission of **electronic application instructions**, they should go to HKSCC's Customer Service Centre to complete an input request form for **electronic application instructions** before 12:00 noon on Tuesday, September 22, 2020.

How many Applications can you Make

Multiple applications for the Hong Kong Offer Shares are not allowed except by nominees.

All of your applications will be rejected if more than one application through the **CCASS EIPO** service (directly or indirectly through your **broker** or **custodian**) or through the **White Form eIPO** service is made for your benefit (including the part of the application made by HKSCC Nominees acting on **electronic application instructions**), and the number of Hong Kong Offer Shares applied by HKSCC Nominees will be automatically reduced by the number of Hong Kong Offer Shares for which you have given such instructions and/or for which such instructions have been given for your behalf.

For the avoidance of doubt, giving an **electronic application instruction** under the **White Form eIPO** service more than once and obtaining different application reference numbers without effecting full payment in respect of a particular reference number will not

constitute an actual application. However, any **electronic application instructions** to make an application for the Hong Kong Offer Shares given by you or for your behalf to HKSCC will be deemed to be an actual application for the purposes of considering whether multiple applications have been made.

If an unlisted company makes an application and:

(a) the principal business of that company is dealing in securities; and

(b) you exercise statutory control over that company,

then the application will be treated as being made for your benefit.

"**Unlisted company**" means a company with no equity securities listed on the Hong Kong Stock Exchange.

"**Statutory control**" means you:

(a) control the composition of the board of directors of the company;

(b) control more than half of the voting power of the company; or

(c) hold more than half of the issued share capital of the company (not counting any part of it which carries no right to participate beyond a specified amount in a distribution of either profits or capital).

How much are the Hong Kong Offer Shares

The maximum Public Offer Price is HK$648.00 per Offer Share. You must also pay brokerage of 1.0%, SFC transaction levy of 0.0027% and Hong Kong Stock Exchange trading fee of 0.005%. This means that for one board lot of 50 Hong Kong Offer Shares, you will pay HK$32,726.49.

You must pay the maximum Public Offer Price, together with brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee, in full upon application for the Hong Kong Offer Shares.

You may submit an application through the **White Form eIPO** service or the **CCASS EIPO** service in respect of a minimum of 50 Hong Kong Offer Shares. If you make an **electronic application instruction** for more than 50 Hong Kong Offer Shares, the number of Hong Kong Offer Shares you apply for must be in one of the specified numbers set out in "How To Apply for Hong Kong Offer Shares – Applications for the Hong Kong Offer Shares – Minimum application amount and permitted numbers."

If your application is successful, brokerage will be paid to the Exchange Participants (as defined in the Listing Rules), and the SFC transaction levy and the Hong Kong Stock Exchange trading fee will be paid to the Hong Kong Stock Exchange (in the case of the SFC transaction levy, collected by the Hong Kong Stock Exchange on behalf of the SFC).

For further details on the Public Offer Price, see "Structure of the Global Offering – Pricing and allocation."

Effect of Bad Weather and Extreme Conditions on the Opening and Closing of the Application Lists

The application lists will not open or close if there is/are:

- a tropical cyclone warning signal number 8 or above;
- a "black" rainstorm warning; and/or
- Extreme Conditions

in force in Hong Kong at any time between 9:00 a.m. and 12:00 noon on Tuesday, September 22, 2020. Instead, they will open between 11:45 a.m. and 12:00 noon on the next business day which does not have any of those warnings or Extreme Conditions in force in Hong Kong at any time between 9:00 a.m. and 12:00 noon.

If the application lists do not open and close on Tuesday, September 22, 2020 or if there is/are a tropical cyclone warning signal number 8 or above, a "black" rainstorm warning signal and/or Extreme Conditions in force in Hong Kong that may affect the dates mentioned in "Expected Timetable," the Company will make an announcement on its website at **http://www.zailaboratory.com** and the website of the Hong Kong Stock Exchange at **www.hkexnews.hk**.

Publication of results

The Company expects to announce the pricing of the Offer Shares on Friday, September 25, 2020 on its website at **http://www.zailaboratory.com** and on the website of the Hong Kong Stock Exchange at **www.hkexnews.hk**.

The Company expects to announce the level of indications of interest in the International Offering, the level of applications in the Hong Kong Public Offering and the basis of allocations of the Hong Kong Offer Shares on Friday, September 25, 2020 on its website at **http://www.zailaboratory.com** and the website of the Hong Kong Stock Exchange at **www.hkexnews.hk**.

The results of allocations and the Hong Kong identity card/passport/Hong Kong business registration numbers of successful applicants under the Hong Kong Public Offering will be available at the times and dates and in the manner set out below:

(a) in the announcement to be posted on the Company's website and the website of the Hong Kong Stock Exchange at **http://www.zailaboratory.com** and **www.hkexnews.hk**, respectively, by no later than Friday, September 25, 2020;

(b) from the designated results of allocations website at **www.iporesults.com.hk** (alternatively: English **https://www.eipo.com.hk/en/Allotment**; Chinese **https://www.eipo.com.hk/zh-hk/Allotment**) with a "search by ID function" on a 24 hour basis from 8:00 a.m. on Friday, September 25, 2020 to 12:00 midnight on Thursday, October 1, 2020; and

(c) from the allocation results telephone enquiry line by calling +852 2862 8555 between 9:00 a.m. and 6:00 p.m. on Friday, September 25, 2020, and from Monday, September 28, 2020 to Wednesday, September 30, 2020.

If the Company accepts your offer to purchase (in whole or in part), which the Company may do by announcing the basis of allocations and/or making available the results of allocations publicly, there will be a binding contract under which you will be required to purchase the Hong Kong Offer Shares if the conditions of the Global Offering are satisfied and the Global Offering is not otherwise terminated. Further details are set out in "Structure of the Global Offering."

You will not be entitled to exercise any remedy of rescission for innocent misrepresentation at any time after acceptance of your application. This does not affect any other right you may have.

Circumstances in which you will not be Allocated the Hong Kong Offer Shares

You should note the following situations in which the Hong Kong Offer Shares will not be allocated to you:

If your Application is Revoked:

By applying through the **CCASS EIPO** service or through the **White Form eIPO** service, you agree that your application or the application made by HKSCC Nominees on your behalf cannot be revoked on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong). This agreement will take effect as a collateral contract with the Company.

Your application or the application made by HKSCC Nominees on your behalf may only be revoked on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong) in the following circumstances:

(a) if a person responsible for this prospectus under Section 40 of the Companies (WUMP) Ordinance (as applied by Section 342E of the Companies (WUMP) Ordinance) gives a public notice under that section on or before the fifth day after the time of the opening of the application lists (excluding any day which is a Saturday, Sunday or public holiday in Hong Kong) which excludes or limits that person's responsibility for this prospectus; or

(b) if any supplement to this prospectus is issued, in which case the Company will notify applicants who have already submitted an application that they are required to confirm their applications. If applicants have been so notified but have not confirmed their applications in accordance with the procedure to be notified, all unconfirmed applications will be deemed revoked.

If your application or the application made by HKSCC Nominees on your behalf has been accepted, it cannot be revoked. For this purpose, acceptance of applications which are not rejected will be constituted by notification in the press of the results of allocation, and where such basis of allocation is subject to certain conditions or provides for allocation by ballot, such acceptance will be subject to the satisfaction of such conditions or results of the ballot, respectively.

If the Company or its Agents Exercise their Discretion to Reject your Application:

The Company, the Joint Representatives, the **White Form eIPO** Service Provider and their respective agents or nominees have full discretion to reject or accept any application, or to accept only part of any application, without giving any reasons.

If:

(a) you make multiple applications or are suspected of making multiple applications;

(b) you or the person for whose benefit you apply for, have applied for or taken up, or indicated an interest for, or have been or will be placed or allocated (including conditionally and/or provisionally) the Hong Kong Offer Shares and the International Offer Shares;

(c) your payment is not made correctly;

(d) your **electronic application instructions** through the **White Form eIPO** service are not completed in accordance with the instructions, terms and conditions on the designated website at **www.eipo.com.hk**;

(e) you apply for more than 385,850 Hong Kong Offer Shares, being 50% of the 771,700 Hong Kong Offer Shares initially available under the Hong Kong Public Offering;

(f) the Company or the Joint Representatives believe that by accepting your application, a violation of applicable securities or other laws, rules or regulations would result; or

(g) the Underwriting Agreements do not become unconditional or are terminated.

Refund of Application Monies

If an application is rejected, not accepted or accepted in part only, or if the Public Offer Price as finally determined is less than the maximum Public Offer Price per Offer Share (excluding brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee payable thereon) paid on application, or if the conditions of the Global Offering as set out in "Structure of the Global Offering – Conditions of the Global Offering" are not satisfied or if any application is revoked, the application monies, or the appropriate portion thereof, together with the related brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee, will be refunded, without interest.

Any refund of your application monies will be made on or before Friday, September 25, 2020.

Despatch/Collection of Share Certificates/e-Refund Payment Instructions/Refund Checks

You will receive one Share certificate for all Hong Kong Offer Shares allocated to you under the Hong Kong Public Offering (except pursuant to applications made through the **CCASS EIPO** service where the Share certificates will be deposited into CCASS as described below).

The Company will not issue temporary document of title in respect of the Offer Shares. The Company will not issue receipt for sums paid on application.

Subject to arrangement on despatch/collection of Share certificates and refund checks as mentioned below, any refund checks and Share certificate(s) are expected to be posted on or before Friday, September 25, 2020. The right is reserved to retain any Share certificate(s) and any surplus application monies pending clearance of check(s) or banker's cashier order(s).

Share certificates will only become valid at 8:00 a.m. on Monday, September 28, 2020, provided that the Global Offering has become unconditional in all respects at or before that time and the right of termination described in "Underwriting" has not been exercised.

Investors who trade Shares on the basis of publicly available allocation details or prior to the receipt of the Share certificates or prior to the Share certificates becoming valid do so entirely at their own risk.

Personal Collection

If you apply through **White Form eIPO** service:

(a) If you apply for 300,000 Hong Kong Offer Shares or more through the **White Form eIPO** service and your application is wholly or partially successful, you may collect your Share certificate(s) (where applicable) in person from the Hong Kong Share Registrar, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wan Chai, Hong Kong, from 9:00 a.m. to 1:00 p.m. on Friday, September 25, 2020, or any other place or date notified by the Company.

(b) If you do not personally collect your Share certificate(s) within the time specified for collection, they will be sent to the address specified in your application instructions by ordinary post and at your own risk.

(c) If you apply for less than 300,000 Hong Kong Offer Shares through the **White Form eIPO** service, your Share certificate(s) (where applicable) will be sent to the address specified in your application instructions on or before Friday, September 25, 2020 by ordinary post and at your own risk.

(d) If you apply and pay the application monies from a single bank account, any refund monies will be despatched to that bank account in the form of e-Refund payment instructions. If you apply and pay the application monies from multiple bank accounts, any refund monies will be despatched to the address specified in your application instructions in the form of refund check(s) by ordinary post and at your own risk.

If you apply through CCASS EIPO service:

Allocation of the Hong Kong Offer Shares

(a) For the purposes of allocating the Hong Kong Offer Shares, HKSCC Nominees will not be treated as an applicant. Instead, each CCASS Participant who gives **electronic application instructions** or each person for whose benefit instructions are given will be treated as an applicant.

Deposit of Share Certificates into CCASS and Refund of Application Monies

(a) If your application is wholly or partially successful, your Share certificate(s) will be issued in the name of HKSCC Nominees and deposited into CCASS for the credit of your designated CCASS Participant's stock account or your CCASS Investor Participant stock account on Friday, September 25, 2020 or on any other date determined by HKSCC or HKSCC Nominees.

(b) The Company expects to publish the application results of CCASS Participants (and where the CCASS Participant is a broker or custodian, the Company will include information relating to the relevant beneficial owner), your Hong Kong identity card/passport/Hong Kong business registration number or other identification code (Hong Kong business registration number for corporations) and the basis of allocations of the Hong Kong Offer Shares in the manner as described in "– Publication of results" above on Friday, September 25, 2020. You should check the announcement published by the Company and report any discrepancies to HKSCC before 5:00 p.m. on Friday, September 25, 2020 or such other date as determined by HKSCC or HKSCC Nominees.

(c) If you have instructed your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, you can also check the number of the Hong Kong Offer Shares allocated to you and the amount of refund monies (if any) payable to you with that **broker** or **custodian**.

(d) If you have applied as a CCASS Investor Participant, you can also check the number of the Hong Kong Offer Shares allocated to you and the amount of refund monies (if any) payable to you via the CCASS Phone System and the CCASS Internet System (under the procedures contained in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time) on Friday, September 25, 2020. Immediately following the credit of the Hong Kong Offer Shares to your stock account and the credit of the refund monies to your bank account, HKSCC will also make available to you an activity statement showing the number of the Hong Kong Offer Shares credited to your CCASS Investor Participant stock account and the amount of refund monies (if any) credited to your designated bank account.

(e) Refund of your application monies (if any) in respect of wholly and partially unsuccessful applications and/or difference between the Public Offer Price and the maximum Public Offer Price per Offer Share initially paid on application (including brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee but without interest) will be credited to your designated bank account or the designated bank account of your broker or custodian on Friday, September 25, 2020.

Admission of the Shares into CCASS

If the Hong Kong Stock Exchange grants the listing of, and permission to deal in, the Shares and the Company complies with the stock admission requirements of HKSCC, the Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with effect from the date of commencement of dealings in the Shares on the Hong Kong Stock Exchange or any other date HKSCC chooses. Settlement of transactions between Exchange Participants (as defined in the Listing Rules) is required to take place in CCASS on the second business day after any trading day.

All activities under CCASS are subject to the General Rules of CCASS and CCASS Operational Procedures in effect from time to time.

Investors should seek the advice of their stockbroker or other professional adviser for details of the settlement arrangements as such arrangements may affect their rights and interests.

The Company has made all necessary arrangements to enable the Shares to be admitted into CCASS.

The following is the text of a report set out on pages I-1 to I-53, received from the Company's reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this prospectus.

Deloitte. 德勤

ACCOUNTANTS' REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF ZAI LAB LIMITED AND J.P. MORGAN SECURITIES (FAR EAST) LIMITED, GOLDMAN SACHS (ASIA) L.L.C. AND CITIGROUP GLOBAL MARKETS ASIA LIMITED

Introduction

We report on the historical financial information of Zai Lab Limited (the "Company") and its subsidiaries (together, the "Group") set out on pages I-4 to I-53, which comprises the consolidated balance sheets of the Group as at December 31, 2018 and 2019 and June 30, 2020 and the consolidated statements of operations and other comprehensive loss, the consolidated statements of shareholders' equity and the consolidated statements of cash flows of the Group for each of the two years ended December 31, 2019 and the six months ended June 30, 2020 (the "Track Record Period") and a summary of significant accounting policies and other explanatory information (together, the "Historical Financial Information"). The Historical Financial Information set out on pages I-4 to I-53 forms an integral part of this report, which has been prepared for inclusion in the prospectus of the Company dated September 17, 2020 (the "Prospectus") in connection with the listing of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the "Stock Exchange").

Directors' responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2(a) to the Historical Financial Information, and for such internal control as the directors of the Company determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants' responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 "Accountants' Reports on Historical Financial Information in Investment Circulars" issued by the Hong Kong Institute of Certified Public Accountants (the "HKICPA"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants' judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity's preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2(a) to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors of the Company, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants' report, a true and fair view of the Group's financial position as at December 31, 2018 and 2019 and June 30, 2020 and of the Group's financial performance and cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 2(a) to the Historical Financial Information.

Review of stub period comparative financial information

We have reviewed the stub period comparative financial information of the Group which comprises the consolidated statement of operations and other comprehensive loss, the consolidated statement of shareholders' equity and the consolidated statement of cash flows of the Group for the six months ended June 30, 2019 and other explanatory information (the "Stub Period Comparative Financial Information"). The directors of the Company are responsible for preparation of the Stub Period Comparative Financial Information in accordance with the basis of preparation set out in Note 2(a) to the Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has

come to our attention that causes us to believe that the Stub Period Comparative Financial Information, for the purpose of accountants' report, is not prepared, in all material respects, in accordance with the basis of preparation set out in Note 2(a) to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to Note 23 to the Historical Financial Information which states that no dividend was declared or paid by the Company in respect of the Track Record Period.

Deloitte Touche Tohmatsu
Certified Public Accountants
Hong Kong
September 17, 2020

I. HISTORICAL FINANCIAL INFORMATION OF THE COMPANY

Set out below is the Historical Financial Information which forms an integral part of this accountants' report.

The Historical Financial Information in this report was prepared based on previously issued consolidated financial statements of the Group for the years ended December 31, 2018 and 2019 and the consolidated financial statements of the Group for the six months ended June 30, 2020 (collectively referred as "Underlying Financial Statements"). The Underlying Financial Statements have been prepared in accordance with the accounting policies which conform with the accounting principles generally accepted in the United States of America ("U.S. GAAP"). The previously issued consolidated financial statements for the years ended December 31, 2018 and 2019 were audited by Deloitte Touche Tohmatsu Certified Public Accountants LLP in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB") relating to the consolidated financial statements and the effectiveness of internal control over financial reporting. The consolidated financial statements for the six months ended June 30, 2020 were audited by Deloitte Touche Tohmatsu Certified Public Accountants LLP in accordance with the standards of PCAOB relating to the consolidated financial statements only.

The Historical Financial Information is presented in United States Dollars and all values are rounded to the nearest thousand except when otherwise indicated.

Consolidated balance sheets
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

		As of		
		December 31, 2018	December 31, 2019	June 30, 2020
	Notes	*$*	*$*	*$*
Assets				
Current assets:				
Cash and cash equivalents	*3*	62,952	75,932	258,604
Short-term investments	*5*	200,350	200,000	205,000
Accounts receivable (net of allowance of nil, nil and $2 as of Dec 31, 2018 and 2019 and June 30, 2020)	*6*	90	3,791	7,024
Inventories	*7*	4	6,005	6,569
Prepayments and other current assets		5,749	6,736	7,684
Total current assets		269,145	292,464	484,881
Restricted cash, non-current	*4*	—	510	510
Investments in equity investees	*8*	3,150	2,398	1,991
Prepayments for equipment		276	440	383
Property and equipment, net	*9*	20,494	21,353	21,017
Operating lease right-of-use assets	*10*	—	15,071	13,929
Land use rights		—	7,655	7,416
Intangible assets, net		321	1,148	1,216
Long term deposits		557	377	712
Value added tax recoverable		8,044	13,737	16,159
Total assets		**301,987**	**355,153**	**548,214**

	Notes	As of December 31, 2018	As of December 31, 2019	As of June 30, 2020
		$	$	$
Liabilities and shareholders' equity				
Current liabilities:				
Short-term borrowings	*13*	3,643	6,450	4,238
Accounts payable		37,432	22,660	32,392
Current operating lease liabilities	*10*	—	4,351	4,175
Other current liabilities	*14*	7,767	13,174	15,750
Total current liabilities		48,842	46,635	56,555
Deferred income		2,064	2,881	15,736
Non-current operating lease liabilities	*10*	—	10,977	10,457
Total liabilities		**50,906**	**60,493**	**82,748**
Commitments and contingencies (Note 21)				
Shareholders' equity				
Ordinary shares (par value of US$0.00006 per share; 83,333,333 shares authorized, 58,006,967, 68,237,247 and 74,882,338 shares issued and outstanding as of December 31, 2018, December 31, 2019 and June 30, 2020, respectively)		3	4	4
Additional paid-in capital		498,043	734,734	1,031,791
Accumulated deficit		(249,627)	(444,698)	(573,315)
Accumulated other comprehensive income		2,662	4,620	6,986
Total shareholders' equity		**251,081**	**294,660**	**465,466**
Total liabilities and shareholders' equity		**301,987**	**355,153**	**548,214**

Consolidated statements of operations and other comprehensive loss
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

		Year ended December 31,		Six months ended June 30,	
		2018	2019	2019	2020
	Notes	*$*	*$*	*$*	*$*
				(Unaudited)	
Revenue	*11*	129	12,985	3,420	19,213
Expenses:					
Cost of sales		(43)	(3,749)	(882)	(4,980)
Research and development		(120,278)	(142,221)	(58,928)	(102,049)
Selling, general and administrative		(21,576)	(70,211)	(29,489)	(42,472)
Loss from operations		(141,768)	(203,196)	(85,879)	(130,288)
Interest income		3,261	8,232	3,365	2,882
Interest expense		(40)	(293)	(137)	(114)
Other income (expense), net		59	938	(307)	(691)
Loss before income tax and share of loss from equity method investment		(138,488)	(194,319)	(82,958)	(128,211)
Income tax expense	*12*	—	—	—	—
Share of loss from equity method investment		(587)	(752)	(316)	(406)
Net loss		(139,075)	(195,071)	(83,274)	(128,617)
Net loss attributable to ordinary shareholders		(139,075)	(195,071)	(83,274)	(128,617)
Net loss		(139,075)	(195,071)	(83,274)	(128,617)
Other comprehensive income, net of tax of nil:					
Foreign currency translation adjustments		2,212	1,958	563	2,366
Comprehensive loss attributable to ordinary shareholders		(136,863)	(193,113)	(82,711)	(126,251)
Loss per share – basic and diluted	*15*	(2.64)	(3.03)	(1.37)	(1.74)
Weighted-average shares used in calculating net loss per ordinary share – basic and diluted		52,609,810	64,369,490	60,919,842	73,847,551

Consolidated statements of shareholders' equity
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Ordinary shares					Accumulated other	
	Number of Shares	Amount	Additional paid in capital	Subscription receivable	Accumulated deficit	comprehensive income	Total
		$	$	$	$	$	$
Balance at December 31, 2017	49,912,570	3	345,270	0	(110,552)	450	235,171
Issuance of ordinary shares upon vesting of restricted shares	338,332	0	0	0	—	—	—
Exercise of shares option	256,065	0	196	—	—	—	196
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $652	7,500,000	0	140,348	—	—	—	140,348
Share-based compensation	—	—	12,229	—	—	—	12,229
Net loss	—	—	—	—	(139,075)	—	(139,075)
Foreign currency translation	—	—	—	—	—	2,212	2,212
Balance at December 31, 2018	58,006,967	3	498,043	—	(249,627)	2,662	251,081
Issuance of ordinary shares upon vesting of restricted shares	539,733	0	0	—	—	—	—
Exercise of shares option	670,939	0	1,055	—	—	—	1,055
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $854	9,019,608	1	215,345	—	—	—	215,346
Share-based compensation	—	—	20,291	—	—	—	20,291
Net loss	—	—	—	—	(195,071)	—	(195,071)
Foreign currency translation	—	—	—	—	—	1,958	1,958
Balance at December 31, 2019	68,237,247	4	734,734	—	(444,698)	4,620	294,660

	Ordinary shares					Accumulated other	
	Number of Shares	Amount	Additional paid in capital	Subscription receivable	Accumulated deficit	comprehensive income	Total
		$	$	$	$	$	$
Balance at December 31, 2018	58,006,967	3	498,043	—	(249,627)	2,662	251,081
Issuance of ordinary shares upon vesting of restricted shares (unaudited)	404,167	0	0	—	—	—	—
Exercise of shares option (unaudited)	137,177	0	304	—	—	—	304
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $839 (unaudited)	9,019,608	1	215,361	—	—	—	215,362
Share-based compensation (unaudited)	—	—	9,294	—	—	—	9,294
Net loss (unaudited)	—	—	—	—	(83,274)	—	(83,274)
Foreign currency translation (unaudited)	—	—	—	—	—	563	563
Balance at June 30, 2019 (unaudited)	67,567,919	4	723,002	—	(332,901)	3,225	393,330
Balance at December 31, 2019	68,237,247	4	734,734	—	(444,698)	4,620	294,660
Issuance of ordinary shares upon vesting of restricted shares	116,200	0	0	—	—	—	—
Exercise of shares option	228,891	0	3,075	—	—	—	3,075
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $740	6,300,000	0	280,555	—	—	—	280,555
Share-based compensation	—	—	13,427	—	—	—	13,427
Net loss	—	—	—	—	(128,617)	—	(128,617)
Foreign currency translation	—	—	—	—	—	2,366	2,366
Balance at June 30, 2020	74,882,338	4	1,031,791	—	(573,315)	6,986	465,466

"0" in above table mean less than 1,000 dollars.

Consolidated statements of cash flows
(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	$	$	$
			(Unaudited)	
Operating activities:				
Net loss	(139,075)	(195,071)	(83,274)	(128,617)
Adjustments to reconcile net loss to net cash provided by operating activities:				
Provision for expected credit losses	—	—	—	2
Inventory write-down	—	—	—	7
Depreciation and amortization expenses	1,650	3,766	1,563	2,107
Amortization of deferred income	(312)	(312)	(156)	(156)
Share-based compensation	12,229	20,291	9,294	13,427
Share of loss from equity method investment	587	752	316	406
Loss on disposal of property and equipment	1	15	10	1
Noncash lease expenses	—	2,831	1,037	2,114
Changes in operating assets and liabilities:				
Accounts receivable	(90)	(3,701)	(2,393)	(3,235)
Inventories	(4)	(6,001)	(137)	(571)
Prepayments and other current assets	(4,794)	(1,125)	(361)	(948)
Long term deposits	(250)	180	167	(335)
Value added tax recoverable	(2,982)	(5,693)	(3,126)	(2,422)
Accounts payable	28,464	(14,772)	(9,707)	9,732
Other current liabilities	7,056	9,136	4,027	4,697
Operating lease liabilities	—	(2,436)	(1,051)	(1,539)
Deferred income	(18)	1,129	607	13,011
Net cash used in operating activities	(97,538)	(191,011)	(83,184)	(92,319)
Cash flows from investing activities:				
Purchases of short-term investments	(200,350)	(277,640)	(201,600)	(205,000)
Proceeds from maturity of short-term investments	—	277,990	100,350	200,000
Purchase of equity method investment	(2,086)	—	—	—
Purchase of property and equipment	(10,015)	(6,035)	(4,077)	(1,303)
Purchase of land use right	—	(7,836)	—	—
Purchase of intangible assets	(103)	(1,371)	(690)	(218)
Net cash used in investing activities	(212,554)	(14,892)	(106,017)	(6,521)

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	$	$	$
			(Unaudited)	
Cash flows from financing activities:				
Proceeds from short-term borrowings	3,643	7,252	2,954	—
Repayment of short-term bank borrowings	—	(4,351)	(739)	(2,130)
Proceeds from exercises of share options	196	1,055	304	3,075
Proceeds from issuance of ordinary shares upon public offerings	141,000	216,200	216,200	281,295
Payment of public offering costs	(692)	(854)	(839)	(740)
Net cash provided by financing activities	144,147	219,302	217,880	281,500
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(763)	91	(28)	12
Net (decrease) increase in cash, cash equivalents and restricted cash	(166,708)	13,490	28,651	182,672
Cash, cash equivalents and restricted cash – beginning of the year/period	229,660	62,952	62,952	76,442
Cash, cash equivalents and restricted cash – end of the year/period	62,952	76,442	91,603	259,114
Supplemental disclosure on non-cash investing and financing activities:				
Payables for purchase of property and equipment	1,709	416	268	984
Payables for intangible assets	225	—	—	—
Payables for public offering costs	—	—	150	—
Supplemental disclosure of cash flow information:				
Cash and cash equivalents	62,952	75,932	91,603	258,604
Restricted cash, non-current	—	510	—	510
Total cash and cash equivalents and restricted cash	62,952	76,442	91,603	259,114
Interest expense paid	36	288	137	122

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

1. Organization and principal activities

Zai Lab Limited (the "Company") was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands. The Company and its subsidiaries (collectively referred to as the "Group") are principally engaged in discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical needs in the China market and the global markets, including in the fields of oncology, infectious and autoimmune diseases.

The Group's principal operations and geographic markets are in the People's Republic of China ("PRC" or "China"). The accompanying consolidated financial statements include the financial statements of the Company and its subsidiaries.

As of June 30, 2020, the Group's significant operating subsidiaries are as follows:

Name of company	Place of incorporation	Date of incorporation	Percentage of ownership	Principal activities
Zai Lab (Hong Kong) Limited.	Hong Kong S.A.R	April 29, 2013	100%	Operating company for business development and R&D activities and commercialisation of innovative medicines and device
Zai Lab (Shanghai) Co., Ltd..	PRC	January 6, 2014	100%	Development and commercialisation of innovative medicines and devices
Zai Lab (AUST) Pty., Ltd..	Australia	December 10, 2014	100%	Clinical trial activities
Zai Lab (Suzhou) Co., Ltd..	PRC	November 30, 2015	100%	Development and commercialisation of innovative medicines
Zai Biopharmaceutical (Suzhou) Co., Ltd. . .	PRC	June 15, 2017	100%	Development and commercialisation of innovative medicines

Name of company	Place of incorporation	Date of incorporation	Percentage of ownership	Principal activities
Zai Lab (US) LLC . . .	U.S.	April 21, 2017	100%	Operating company for business development and R&D activities
Zai Lab International Trading (Shanghai) Co., Ltd.	PRC	November 6, 2019	100%	Commercialisation of innovative medicines and devices

2. Summary of significant accounting policies

(a) Basis of presentation

The Historical Financial Information has been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). Significant accounting policies followed by the Group in the preparation of the accompanying consolidated financial statements are summarized below.

(b) Principles of consolidation

The Historical Financial Information includes the financial statements of the Company and its subsidiaries. All intercompany transactions and balances among the Group and its subsidiaries are eliminated upon consolidation.

(c) Use of estimates

The preparation of the Historical Financial Information in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, assessing the impairment of long-lived assets, discount rate of operating lease liabilities, revenue recognition, allocation of the research and development service expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets and the fair value of the financial instruments. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

(d) Foreign currency translation

The functional currency of Zai Lab Limited and Zai Lab (Hong Kong) Limited are the United States dollar ("$"). The Group's PRC subsidiaries determined their functional currency to be Chinese Renminbi ("RMB"). The Group's Australia subsidiary determined its functional currency to be Australia dollar ("A$"). The determination of the respective functional currency is based on the criteria of Accounting Standard Codification ("ASC") 830, *Foreign Currency Matters*. The Group uses the United States dollar as its reporting currency.

Assets and liabilities are translated from each entity's functional currency to the reporting currency at the exchange rate on the balance sheet date. Equity amounts are translated at historical exchange rates, and expenses, gains and losses are translated using the average rate for the period. Translation adjustments are reported as cumulative translation adjustments and are shown as a separate component of other comprehensive loss in the consolidated statements of changes in shareholders' equity and comprehensive loss.

Monetary assets and liabilities denominated in currencies other than the applicable functional currencies are translated into the functional currencies at the prevailing rates of exchange at the balance sheet date. Non-monetary assets and liabilities are translated into the applicable functional currencies at historical exchange rates. Transactions in currencies other than the applicable functional currencies during the period are converted into the functional currencies at the applicable rates of exchange prevailing at the transaction dates. Transaction gains and losses are recognized in the consolidated statements of operations.

(e) Cash, cash equivalents and restricted cash

Cash and cash equivalents

The Group considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash on hand, demand deposits and highly liquid investments with maturity of less than three months and are stated at cost plus interests earned, which approximates fair value.

Restricted cash

Restricted cash mainly consists of the bank deposits held as collateral for issuance of letters of credit.

(f) Short-term investments

Short-term investments are time deposits with original maturities more than three months. Short-term investments are stated at cost, which approximates fair value. Interest earned is included in interest income.

(g) Accounts receivable

Before January 1, 2020, accounts receivable are recorded at the amounts due from customers and net of allowances for doubtful accounts. An allowance for doubtful accounts is recorded when the collection of the full amount is no longer probable. In evaluating the collectability of accounts receivable, the Group considers many factors including aging of the receivable due, the customer's payment history, creditworthiness, financial conditions, and current economic trends. Credit losses of accounts receivable, which may be for all or part of a particular accounts receivable, shall be deducted from the allowance. The related accounts receivable balance shall be charged off in the period in which the accounts receivable are deemed uncollectible. Recoveries of accounts receivable previously charged written off shall be recorded when received. The Group regularly reviews the adequacy and appropriateness of any allowance for doubtful accounts.

From January 1, 2020, the Group adopted the ASU 2016-13, *Credit Losses, Measurement of Credit Losses on Financial Instruments*. Accounts receivable are recorded at the amounts due from customers and net of allowances for credit losses. The allowance for credit losses reflects the Group's current estimate of credit losses expected to be incurred over the life of the receivables. The Group considers various factors in establishing, monitoring, and adjusting its allowance for credit losses including the aging of receivables and aging trends, customer creditworthiness and specific exposures related to particular customers. The Group also monitors other risk factors and forward-looking information, such as country specific risks and economic factors that may affect a customer's ability to pay in establishing and adjusting its allowance for credit losses. Accounts receivable are written off when deemed uncollectible.

(h) Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a weighted average basis. The Group periodically reviews the composition of inventory and shelf life of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. The Group will record a write-down to its net realizable value in cost of sales in the period that the decline in value is first identified. Nil, nil and $7 inventory write-down was recorded as of December 31, 2018 and 2019, and June 30, 2020.

(i) Investments in equity investees

The Group uses the equity method to account for an equity investment over which it has significant influence but does not own a majority equity interest or otherwise control. The Group records equity method adjustments in share of earnings and losses. Equity method adjustments include the Group's proportionate share of investee income or loss, adjustments to recognize certain differences between the Group's carrying value and its equity in net assets of the investee at the date of investment, impairments, and other adjustments required by the equity method. Dividends received are recorded as a reduction of carrying amount of the investment. Cumulative distributions that do not exceed the Group's cumulative equity in earnings of the investee are considered as a return on investment and classified as cash inflows

from operating activities. Cumulative distributions in excess of the Group's cumulative equity in the investee's earnings are considered as a return of investment and classified as cash inflows from investing activities.

The Group is required to perform an impairment assessment of its investments whenever events or changes in business circumstances indicate that the carrying value of the investment may not be fully recoverable. An impairment loss is recorded when there has been a loss in value of the investment that is other than temporary. No impairment was recorded for the years ended December 31, 2018 and 2019, and six months ended June 30, 2020.

(j) Prepayments for equipment

The prepayments for equipment purchase are recorded in long term prepayments considering the prepayments are all related to property and equipment.

(k) Property and equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	Useful life
Office equipment	3 years
Electronic equipment	3 years
Vehicle	4 years
Laboratory equipment	5 years
Manufacturing equipment	10 years
Leasehold improvements	lesser of useful life or lease term

Construction in progress represents property and equipment under construction and pending installation and is stated at cost less impairment losses if any.

(l) Lease

Before January 1, 2019, the Group applied the ASC Topic 840, *Leases*. Each lease is classified at the inception date as either a capital lease or an operating lease. the Group assesses a lease to be a capital lease if any of the following conditions exist: (1) ownership is transferred to the lessee by the end of the lease term, (2) there is a bargain purchase option, (3) the lease term is at least 75% of the property's estimated remaining economic life or (4) the present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date. A capital lease is accounted for as if there was an acquisition of an asset and an incurrence of an obligation at the inception

of the lease. All the Group's leases were classified as operating lease under ASC Topic 840. The Group's reporting for periods prior to January 1, 2019 continued to be reported in accordance with *Leases* (Topic 840).

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over the periods of their respective lease terms. The Group leases office space and employee accommodation under operating lease agreements. Certain of the lease agreements contain rent holidays. Rent holidays are considered in determining the straight-line rent expense to be recorded over the lease term. The lease term begins on the date of initial possession of the lease property for purposes of recognizing lease expense on straight-line basis over the term of the lease.

From January 1, 2019, the Group adopted the ASC Topic 842, *Leases* ("ASC 842"). The Group adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The Group determines if an arrangement is a lease at inception. The Group classifies the lease as a finance lease if it meets certain criteria or as an operating lease when it does not. The Group has lease agreements with lease and non-lease components, which the Group has elected to account for the components as a single lease component. The Group leases facilities for office, research and development center, and manufacturing facilities in mainland China, Hong Kong and U.S, which are all classified as operating leases with fixed lease payments, or minimum payments, as contractually stated in the lease agreements. The Group's leases do not contain any material residual value guarantees or material restrictive covenants.

At the commencement date of a lease, the Group recognizes a lease liability for future fixed lease payments and a right-of-use ("ROU") asset representing the right to use the underlying asset during the lease term. The lease liability is initially measured as the present value of the future fixed lease payments that will be made over the lease term. The lease term includes periods for which it's reasonably certain that the renewal options will be exercised and periods for which it's reasonably certain that the termination options will not be exercised. The future fixed lease payments are discounted using the rate implicit in the lease, if available, or the incremental borrowing rate ("IBR"). Upon adoption of ASU 2016-02, the Group elected to use the remaining lease term as of January 1, 2019 in the Group's estimation of the applicable discount rate for leases that were in place at adoption. For the initial measurement of the lease liability for leases commencing after January 1, 2019, the Group uses the discount rate as of the commencement date of the lease, incorporating the entire lease term. Additionally, the Group elected not to recognize leases with lease terms of 12 months or less at the commencement date in the consolidated balance sheets.

The ROU asset is measured at the amount of the lease liability with adjustments, if applicable, for lease prepayments made prior to or at lease commencement, initial direct costs incurred by the Group and lease incentives. Under ASC 842, land use rights agreements are also considered to be operating lease contracts. The Group will evaluate the carrying value of ROU assets if there are indicators of impairment and review the recoverability of the related

asset group. If the carrying value of the asset group is determined to not be recoverable and is in excess of the estimated fair value, the Group will record an impairment loss in other expenses in the consolidated statements of operations. ROU assets for operating leases are included in operating lease right-of-use assets in the consolidated balance sheets.

Operating leases are included in operating lease right-of-use assets and operating lease liabilities in the consolidated balance sheets. Operating lease liabilities that become due within one year of the balance sheet date are classified as current operating lease liabilities.

Lease expense is recognized on a straight-line basis over the lease term.

(m) Land use rights

All land in the PRC is owned by the PRC government. The PRC government may sell land use rights for a specified period of time. The purchase price of land use rights represents the operating lease prepayments for the rights to use the land in the PRC under ASC 842 and is recorded as land use rights on the balance sheet, which is amortized over the remaining lease term.

In 2019, the Group acquired land use rights from the local Bureau of Land and Resources in Suzhou for the purpose of constructing and operating the research center and biologics manufacturing facility in Suzhou. The land use rights are being amortized over the respective lease terms, which are 30 years.

(n) Long term deposits

Long term deposits represent amounts paid in connection with the Group's long-term lease agreements.

(o) Value added tax recoverable

Value added tax recoverable represent amounts paid by the Group for purchases. The amounts were recorded as long-term assets considering they are expected to be deducted from future value added tax payables arising on the Group's revenues which it expects to generate in the future.

(p) Intangible assets

Intangible assets mainly consist of externally purchased software which are amortized over one to five years on a straight-line basis. Amortization expenses for the years ended December 31, 2018 and 2019 were $15 and $305, respectively. Amortization expenses for the six months ended June 30, 2019 and 2020 were $118 (unaudited) and $127, respectively. Amortization expenses of the Group's intangible assets are expected to be approximately $151, $301, $299, $286, $178 and $1 for the remainder of 2020, the years ended December 31, 2021, 2022, 2023, and 2024 and thereafter, respectively.

(q) Impairment of long-lived assets

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2018 and 2019, and for six months ended June 30, 2020, there was no impairment of the value of the Group's long-lived assets.

(r) Fair value measurements

The Group applies ASC topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 – Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Group primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities. As of December 31, 2018 and 2019, and June 30, 2020, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximates its fair value based on the nature and the assessment of the ability to recover these amounts.

(s) Revenue recognition

In 2018, the Group adopted of ASC Topic 606 ("ASC 606"), *Revenue from Contracts with Customers,* in recognition of revenue. Under ASC 606, the Group recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Group determines are within the scope of ASC 606, the Group performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Group satisfies a performance obligation. The Group only applies the five-step model to contracts when it is probable that the Group will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Group reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Group recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

The Group's revenue is all from product sales. The Group recognizes revenue from product sales when the Group has satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the consumers. Cost of sales mainly consists of the acquisition cost of products and royalty fee.

The Group has applied the practical expedients under ASC 606 with regard to assessment of financing component and concluded that there is no significant financing component given that the period between delivery of goods and payment is generally one year or less.

The Group started to generate product sales revenue since 2018. For the year ended December 31, 2018, the Group's product revenues were generated from the sale of ZEJULA (niraparib) to customers. For the year ended December 31, 2019 and six months ended June 30, 2020, the Group's product revenues were generated from the sale of ZEJULA (niraparib) and OPTUNE (Tumor Treating Fields) to customers.

In mainland China, the Group sells the products to distributors, who ultimately sell the products to health care providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the products delivery to distributors. Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates are recorded as a reduction of revenue if any. Estimated rebates are determined based on contracted rates, sales volumes and distributor inventories. The Group regularly reviews the information related to these estimates and adjusts the amount accordingly.

In Hong Kong S.A.R, the Group sells the products to customers, which are typically healthcare providers such as oncology centers. The Group utilizes a third party for warehousing services. Based on the nature of the arrangement, the Group has determined that it is a principal in the transaction since the Group is primarily responsible for fulfilling the promise to provide the products to the customers, maintains inventory risk until delivery to the customers and has latitude in establishing the price. Revenue was recognized at the amount to which the Group expected to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the third party is recognized in operating expenses.

The Group didn't recognize any contract assets and contract liabilities as of December 31, 2018 and 2019, and June 30, 2020.

(t) Research and development expenses

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

The Group has acquired rights to develop and commercialize drug candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval which meet the capitalization criteria would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. If the conditions enabling capitalization of development costs as an asset have not yet been met, all development expenditures are recognized in profit or loss when incurred.

(u) Deferred income

Deferred income mainly consists of deferred income from government grants, American Depositary Receipts (the "ADR") Program Agreement with ADR depositary bank (the "DB") in July 2017 and the upfront payments received from Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd. ("Hanhui").

Government grants consist of cash subsidies received by the Group's subsidiaries in the PRC from local governments. Grants received as incentives for conducting business in certain local districts with no performance obligation or other restriction as to the use are recognized when cash is received. Cash grants of $1,332 and $2,151 were included in other income for the years ended December 31, 2018 and 2019, respectively. Cash grants of $193 (unaudited) and $2,024 were included in other income for the six months ended June 30, 2019 and 2020, respectively. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Group may be required to refund the subsidy. Cash grants of $894, $2,023 and $2,321 were recorded in deferred income as of December 31, 2018 and 2019, and June 30, 2020, respectively, which will be recognized when the government specified performance obligation is satisfied.

According to the ADR program agreement, the Group has the right to receive reimbursements for using DB's services, subject to the compliance by the Group with the terms of the agreement. The Group performed a detail assessment of the requirements and recognizes the reimbursements it expects to be entitled to over the five-year contract term as other income. For the years ended December 31, 2018 and 2019, $312 and $312 were recorded in other income, respectively. For the six months ended June 30, 2019 and 2020, $156 (unaudited) and $156 were recorded in other income, respectively. And $1,170, $858 and $702 were recorded in deferred income as of December 31, 2018, 2019, and June 30, 2020, respectively.

In March 2020, the Group entered into an Exclusive Promotion Agreement with Hanhui. Under the terms of the agreement, the Group will leverage Hanhui's existing infrastructure to optimize an anticipated future commercial launch of omadacycline in China given that omadacycline is a broad spectrum antibiotic in both the hospital and community settings. In exchange for the exclusive promotion rights in mainland China, Hanhui shall pay the Group a non-creditable, upfront payment in the amount of RMB230,000, among which RMB90,000 was received in April 2020. The Group assessed and determined that the income recognition criteria was not met, and recorded the upfront payment as deferred income. As of June 30, 2020, a total amount of $12,713 was recorded in deferred income.

(v) Comprehensive loss

Comprehensive loss is defined as the changes in equity of the Group during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income*, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Group's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

(w) Stock-based compensation

The Group grants share options and non-vested restricted shares to eligible employees, management and directors and accounts for these share based awards in accordance with ASC 718, *Compensation—Stock Compensation*.

Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

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

The Group determined the fair value of the stock options granted to employees. Before 2018, the Group applied binomial option pricing model in determining the estimated fair value of the options granted to employees. In 2018, the Group changed to use the Black-Scholes option valuation model. A change in the valuation technique is a change in accounting estimate for the purposes of applying ASC 250, and shall be applied prospectively to new awards.

Awards Granted to Non-Employees

Prior to the adoption of Accounting Standard Update 2018-07 Compensation—Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019,

The Group has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 505, *Equity-Based Payments to Non-Employees*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if the Group had paid cash for the services provided by the non-employees in accordance with ASC 505.

After the adoption of Accounting Standard Update 2018-07 Compensation—Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019,

The Group grants share options to eligible Non-Employees and accounts for these share based awards in accordance with ASC 718, *Compensation—Stock Compensation*. Non-Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. The Group determined the fair value of the stock options granted to Non-Employees using the Black-Scholes option valuation model.

(x) Income taxes

Income tax expense includes (a) deferred tax expense, which generally represents the net change in the deferred tax asset or liability balance during the year plus any change in valuation allowances; (b) current tax expense, which represents the amount of tax currently payable to or receivable from a taxing authority; and (c) non-current tax expense, which represents the increases and decreases in amounts related to uncertain tax positions from prior periods and not settled with cash or other tax attributes.

The Group recognizes deferred tax assets and liabilities for temporary differences between the financial statement and income tax bases of assets and liabilities, which are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Group evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. It is the Group's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

(y) Earnings (loss) per share

Basic earnings (loss) per ordinary share is computed by dividing net income (loss) attributable to ordinary shareholders by weighted average number of ordinary shares outstanding during the period.

Diluted earnings (loss) per ordinary share reflects the potential dilution that could occur if securities were exercised or converted into ordinary shares. The Group had stock options and non-vested restricted shares, which could potentially dilute basic earnings (loss) per share in the future. To calculate the number of shares for diluted earnings (loss) per share, the effect of the stock options and non-vested restricted shares is computed using the treasury stock method. The computation of diluted earnings (loss) per share does not assume exercise or conversion of securities that would have an anti-dilutive effect.

(z) Segment information

In accordance with ASC 280, *Segment Reporting*, the Group's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment. The Group does not distinguish between markets or segments for the purpose of internal reporting. As the Group's long-lived assets are substantially located in and derived from China, no geographical segments are presented.

(aa) Concentration of risks

Concentration of customers

The following customers accounted for 10% or more of revenue for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	$	$	$
			(Unaudited)	
A	51	5,397	920	*
B	34	*	*	*
C	14	*	*	*
D	*	4,682	1,102	*
E	*	*	*	3,236

* Represents less than 10% of revenue for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020.

Concentration of suppliers

The following suppliers accounted for 10% or more of research and development expenses and the inventory purchases for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	*$*	*$*	*$*
			(Unaudited)	
A	25,515	*	*	*
B	14,664	*	*	12,313
C	*	27,966	22,625	*
D	*	18,362	*	*
E	*	*	*	31,022

* Represents less than 10% of research and development expenses and the inventory purchases for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020.

Concentration of credit risk

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, short-term investments. The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2018 and 2019, and June 30, 2020, all of the Group's cash and cash equivalents and short-term investments were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which management believes are of high credit quality and continually monitors the credit worthiness of these financial institutions.

Foreign currency risk

RMB is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Group included aggregated amounts of RMB26,878, RMB47,168 and RMB165,488 which were denominated in RMB, as of December 31, 2018 and 2019, and June 30, 2020, respectively, representing 6%, 9% and 9% of the cash, cash equivalents as of December 31, 2018 and 2019, and June 30, 2020, respectively.

(ab) Recent accounting pronouncements

Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09 "*Revenue from Contracts with Customers (Topic 606)*", or ASC 606, a comprehensive new standard which amends revenue recognition principles. The Group adopted ASC 606 beginning January 1, 2018 using the modified retrospective transition method. Given there was no revenue for the periods before January 1, 2018, there were no transition adjustments.

In February 2016, the FASB issued ASC 842 which supersedes the lease recognition requirements in ASC 840, *Leases*, ("ASC 840"). The most prominent of the changes in ASC 842 is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases. Consistent with ASC 840, leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. In July 2018, the FASB issued an accounting standard update which amended ASC 842 and offered an additional (and optional) transition method by which entities could elect not to recast the comparative periods presented in financial statements in the period of adoption.

The Group adopted the new standard on January 1, 2019, using the optional adoption method whereby the Group did not adjust comparative period financial statements. Consequently, prior period balances and disclosures have not been restated. The Group elected the package of transition provisions available for expired or existing contracts, which allowed the Group to carry forward its historical assessments of (i) whether contracts are or contain leases, (ii) lease classification and (iii) initial direct costs. For leases in place upon adoption, the Group used the remaining lease term as of January 1, 2019 in determining the incremental borrowing rate ("IBR"). For the initial measurement of the lease liabilities for leases commencing on or after January 1, 2019, the IBR at the lease commencement date was applied.

The Group's lease portfolio consists entirely of operating leases, the adoption of ASU 2016-02 resulted in the initial recognition of ROU assets of $7,093 and related lease liabilities of $6,955 on the consolidated balance sheet at January 1, 2019. Upon adoption, the Group reclassified $138 prepaid rent to operating ROU assets. The Group's leases do not contain any material residual value guarantees or material restrictive covenants. Additionally, the adoption of ASU 2016-02 did not materially affect the consolidated statements of operations and other comprehensive loss or the consolidated statements of cash flows.

In June 2018, the FASB issued ASU 2018-07*, Compensation—Stock Compensation (Topic 718)*: Improvements to Nonemployee Share-Based Payment Accounting, which intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718, *Compensation—Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. The Group

adopted this ASU on January 1, 2019 using the modified retrospective method. The adoption of this new standard generally requires the accounting for equity-based payments to nonemployees to be consistent with the accounting for employees. As a result, the Group recognized the cost of services received from a nonemployee in exchange for an equity instrument based on the award's grant-date fair value. Unvested equity-based payments to nonemployees have been remeasured at fair value as of the adoption date. The adoption did not have a material effect on the consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Credit Losses, Measurement of Credit Losses on Financial Instruments*, which has subsequently been amended by ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-10, ASU 2019-11 and ASU 2020-03. This ASU significantly changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The standard has replaced incurred loss approach with an expected loss model for instruments measured at amortized cost. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standards are to be applied using a modified retrospective approach and are effective for interim periods and fiscal years beginning after December 15, 2019, with early adoption permitted.

The Group adopted the standard on January 1, 2020. Based on the composition of the Group's trade receivables and investment portfolio, the adoption of this standard did not have a material impact on the Group's financial position or results of operations upon adoption. The Group has updated its accounting policy for accounts receivable and is providing additional disclosure about its allowance for credit losses, as required by the standard, upon adoption.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)*: Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance is effective for interim periods and fiscal years beginning after December 15, 2019, with early adoption permitted. The Group adopted this standard on January 1, 2020. There was no impact to the Group's financial position or results of operations upon adoption as the Group did not have any financial instruments that are measured as level 3.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)*: Clarifying the Interaction between Topic 808 and Topic 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting

consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The update is effective in fiscal years beginning after December 15, 2019, and interim periods therein, and early adoption is permitted for entities that have adopted ASC 606. The Group adopted this standard on January 1, 2020. There was no material impact to the Group's financial position or results of operations upon adoption.

Future Adoption of Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Income Taxes* (Topic 740): Simplifying the Accounting for Income Taxes. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, Income taxes, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group is currently evaluating the impact on its financial statements of adopting this guidance.

3. Cash and cash equivalents

	As of		
	December 31, 2018	**December 31, 2019**	**June 30, 2020**
	$	*$*	*$*
Cash at bank and in hand	36,778	75,111	257,775
Cash equivalents	26,174	821	829
	62,952	75,932	258,604
Denominated in:			
US$	58,254	62,478	225,709
RMB (note (i))	3,916	6,761	23,375
Hong Kong dollar ("HK$")	20	5,948	9,151
Australia dollar ("A$")	762	745	369
	62,952	75,932	258,604

Note:

(i) Certain cash and bank balances denominated in RMB were deposited with banks in the PRC. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

4. Restricted cash, non-current

The Group's restricted cash balance is $510 and $510 as of December 31, 2019 and June 30, 2020, respectively. It was mainly long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Group.

5. Short-term investments

Short-term investments primarily comprise of the time deposits with original maturities between three months and one year. For the years ended December 31, 2018 and 2019, the Group recorded the interest income of $2,359 and $7,778 from the short-term investments in the consolidated statements of operations, respectively. For the six months ended June 30, 2019 and 2020, the Group recorded the interest income of $3,306 (unaudited) and $2,512 from the short-term investments in the consolidated statements of operations and other comprehensive loss.

As of June 30, 2020, the Group's short-term investments consisted entirely of short-term held to maturity debt instruments with highest credit rating, which were determined to have no risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of June 30, 2020.

6. Accounts receivable

The roll-forward of the allowance for credit losses related to accounts receivable for the six months ended June 30, 2020 consists of the following activity:

	Allowance for Credit Losses
	$
Balance as of December 31, 2019	—
Current period provision for expected credit losses	2
Amounts written-off	—
Recoveries of amounts previously written-off	—
Balance as of June 30, 2020	2

The Group did not have any allowance for credit losses for the years ended December 31, 2018 and 2019.

7. Inventories

The Group's inventory balance of $4, $6,005 and $6,569 as of December 31, 2018 and 2019, and June 30, 2020, respectively, mainly consisted of finished goods purchased from Tesaro Inc. ("Tesaro") and Novocure Limited ("Novocure") for distribution in Hong Kong and Macau, as well as certain raw materials purchased for ZEJULA commercialization in the PRC.

	As of		
	December 31, 2018	**December 31, 2019**	**June 30, 2020**
	$	*$*	*$*
Finished goods	4	593	838
Raw materials	—	5,412	5,738
Inventories	4	6,005	6,576
Inventory write-down:			
Balance at beginning of the year	—	—	—
Additions	—	—	(7)
Write-offs	—	—	—
Inventories	4	6,005	6,569

8. Investments in equity investees

In June 2017, the Group entered into an agreement with three third-parties to establish JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which provides services for drug discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Group was RMB26,250 in cash, representing 20% of the equity interest of JING, which was fully paid by the Group in 2017 and 2018. The Group recorded its share of loss in this investee of $587 and $752 for the years ended December 31, 2018 and 2019, respectively. And the Group recorded its share of loss in this investee of $316 (unaudited) and $406 for the six months ended June 30, 2019 and 2020, respectively.

9. Property and equipment, net

Property and equipment consist of the following:

	As of		
	December 31, 2018	**December 31, 2019**	**June 30, 2020**
	$	*$*	*$*
Office equipment	384	397	391
Electronic equipment	599	1,482	1,858
Vehicle	77	76	75
Laboratory equipment	3,917	5,854	7,279
Manufacturing equipment	9,369	11,049	11,016
Leasehold improvements	4,608	7,528	7,478
Construction in progress	3,748	428	267
	22,702	26,814	28,364
Less: accumulated depreciation	(2,208)	(5,461)	(7,347)
Property and equipment, net	20,494	21,353	21,017

Depreciation expenses for the years ended December 31, 2018 and 2019 were $1,634 and $3,372, respectively. And depreciation expenses for the six months ended June 30, 2019 and 2020 were $1,447 (unaudited) and $1,974, respectively.

10. Lease

The Group leases facilities for office, research and development center, and manufacturing facilities in mainland China, Hong Kong and U.S. Lease terms vary based on the nature of operations and the market dynamics, however, all leased facilities are classified as operating leases with remaining lease terms between one and six years.

The total lease expenses under operating leases which included the short-term lease expenses for the years ended December 31, 2018 were $1,494. The Group only has one short-term lease with insignificant lease expense for which the contract expired on June 30, 2019.

Supplemental information related to leases is as follows:

	Year ended December 31,	Six months ended June 30,	
	2019	2019	2020
	$	*$*	*$*
		(Unaudited)	
Operating fixed lease cost	3,245	1,406	2,463

Supplemental cash flow information related to leases was as follows:

	Year ended December 31,	Six months ended June 30,	
	2019	2019	2020
	$	*$*	*$*
		(Unaudited)	
Cash paid for amounts included in measurement of lease liabilities . . .	2,778	1,060	1,986
Non-cash operating lease liabilities arising from obtaining operating right-of-use assets	10,876	1,666	1,036

The maturities of lease liabilities in accordance with *Leases (Topic 842)* in each of the next five years and thereafter as of December 31, 2019 were as follows:

	Year ended December 31
	$
2020	4,595
2021	3,910
2022	3,039
2023	1,333
2024	1,379
Thereafter	1,787
Total lease payments	16,043
Less: imputed interest	(715)
Present value of minimum operating lease payments	15,328

The maturities of lease liabilities in accordance with *Leases (Topic 842)* in each of the next five years and thereafter as of June 30, 2020 were as follows:

	Year ended December 31
	$
Remainder 2020	2,665
2021	4,229
2022	3,293
2023	1,641
2024	1,474
Thereafter	2,135
Total lease payments	15,437
Less: imputed interest	(805)
Present value of minimum operating lease payments	14,632

Weighted-average remaining lease terms and discount rates are as follows:

	Year ended December 31,	Six months ended June 30,	
	2019	2019	2020
		(Unaudited)	
Weighted-average remaining lease term	4.4 years	2.9 years	4.2 years
Weighted-average discount rate	3.1%	4.4%	3.2%

The undiscounted future minimum payments under non-cancellable operating leases as of December 31, 2018, prior to the adoption of *Leases (Topic 842)* was as follows:

	Year ended December 31
	$
2019	2,169
2020	1,007
2021	164
2022 and thereafter	—
Total lease commitment	3,340

11. Revenue

The Group's revenue are primarily derived from the sale of ZEJULA and OPTUNE in mainland China and Hong Kong. The table below presents the Group's net product sales for the years ended December 31, 2018 and 2019 and the six months ended June 30, 2019 and 2020.

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	*$*	*$*	*$*
			(Unaudited)	
Product revenue – gross	129	12,985	3,420	20,415
Less: Rebate and sales return	—	—	—	(1,202)
Product revenue – net	129	12,985	3,420	19,213

Sales rebates are offered to distributors in mainland China and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes and distributor inventories.

The following table disaggregates net revenue by product for the years ended December 31, 2018 and 2019, and the six months ended June 30, 2019 and 2020:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	$	$	$
			(Unaudited)	
ZEJULA	129	6,625	1,925	13,791
OPTUNE	—	6,360	1,495	5,422
Total product revenue – net	129	12,985	3,420	19,213

12. Income Tax

Cayman Islands ("Cayman")

Zai Lab Limited and ZLIP Holding Limited are incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, Zai Lab Limited and ZLIP Holding Limited are not subject to tax on income or capital gains. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

British Virgin Islands Taxation ("BVI")

ZL Capital Limited is incorporated in the British Virgin Islands. Under the current laws of the British Virgin Islands, ZL Capital Limited is not subject to income tax.

Australia ("AUST")

Zai Lab (AUST) Pty., Ltd. is incorporated in Australia and is subject to corporate income tax at a rate of 30%. Zai Lab (AUST) Pty., Ltd. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

U.S. ("US")

Zai Lab (US) LLC. is incorporated in U.S. and is subject to U.S. federal corporate income tax at a rate of 21%. Zai Lab (US) LLC. is also subject to state income tax in Delaware. Zai Lab (US) LLC. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

Hong Kong S.A.R ("HK")

Zai Lab (Hong Kong) Limited is incorporated in Hong Kong S.A.R. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with relevant Hong Kong tax laws. Under the two-tiered profits tax rates regime in Hong Kong, the first HK$2 million of profits of the qualifying group entity will be taxed at 8.25%, and profits above HK$2 million will be taxed at 16.5%. For the years ended December 31, 2018 and 2019 and six months ended June 30, 2020, Zai Lab (Hong Kong) Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented. Under the Hong Kong tax law, Zai Lab (Hong Kong) Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

PRC

Under PRC's Enterprise Income Tax Law ("EIT Law"), the statutory income tax rate is 25%, and the EIT rate shall be reduced to 15% for state-encouraged High and New Technology Enterprises ("HNTE"). Zai Lab (Shanghai) Co., Ltd., first obtained a HNTE certificate in 2018 and began to enjoy the preferential tax rate of 15% from 2018 to 2020. Zai Lab International Trading (Shanghai) Co., Ltd., Zai Lab (Suzhou) Co., Ltd., and Zai Biopharmaceutical (Suzhou) Co., Ltd. are subject to the statutory rate of 25%.

No provision for income taxes has been required to be accrued because the Company and all of its subsidiaries are in cumulative loss positions for all the periods presented.

Loss (income) before income taxes consists of:

	Year ended December 31,		Six months ended June 30,	
	2018	**2019**	**2019**	**2020**
	$	*$*	*$*	*$*
			(Unaudited)	
Cayman	1,218	(3,241)	(189)	591
BVI	2	2	—	—
PRC	127,711	185,239	76,299	112,320
HK	7,778	3,271	3,109	4,983
US	2,351	9,786	4,047	10,336
AUST	15	14	8	387
	139,075	195,071	83,274	128,617

Reconciliations of the differences between the PRC statutory income tax rate and the Group's effective income tax rate for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020 are as follows:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
			(Unaudited)	
Statutory income tax rate	25%	25%	25%	25%
Share-based compensations	(1.93%)	(1.51%)	(1.11%)	(1.02%)
Non-deductible expenses	(0.38%)	(0.39%)	(0.13%)	(0.40%)
Prior year tax filing adjustment	1.55%	1.93%	1.50%	1.85%
Effect of different tax rate of subsidiary operation in other jurisdictions	(0.76%)	0.07%	(0.77%)	(0.52%)
Preferential tax rate	—	(9.14%)	(8.92%)	(8.72%)
Effect of change in tax rate	—	(9.15%)	(7.12%)	—
Changes in valuation allowance	(23.48%)	(6.81%)	(8.45%)	(16.19%)
Effective income tax rate	—	—	—	—

The principal components of the deferred tax assets and liabilities are as follows:

	Year ended December 31,		Six months ended June 30,
	2018	2019	2020
	$	*$*	*$*
Deferred tax assets:			
Depreciation of property and equipment, net	15	57	69
Government grants	187	325	372
Deferred revenue	—	—	1,907
Net operating loss forwards	49,726	62,833	102,579
Less: valuation allowance	(49,928)	(63,215)	(104,927)
Deferred tax assets, net	—	—	—

The Group considers positive and negative evidence to determine whether some portion or all of the deferred tax assets will be more likely than not realized. This assessment considers, among other matters, the nature, frequency and severity of recent losses and forecasts of future profitability. These assumptions require significant judgment and the forecasts of future taxable income are consistent with the plans and estimates the Group is using to manage the underlying businesses. Valuation allowances are established for deferred tax assets based on a more likely than not threshold. The Group's ability to realize deferred tax assets depends on its ability to generate sufficient taxable income within the carry forward periods provided for in the tax law. In 2018, 2019 and 2020, the Group has determined that the deferred tax assets on temporary differences and net operating loss carry forwards are related to certain subsidiaries, for which the Group is not able to conclude that the future realization of those net operating loss carry forwards and other deferred tax assets are more likely than not. As such, it has fully provided valuation allowance for the deferred tax assets as of December 31, 2018, December 31, 2019 and June 30, 2020. Amounts of operating loss carry forwards were $204,693, $403,460 for the years ended December 31, 2018, and 2019, respectively, which are expected to expire from 2020 to 2029.

Movement of the valuation allowance is as follows:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	*$*	*$*	*$*
			(Unaudited)	
Balance as of January 1	(17,269)	(49,928)	(49,928)	(63,215)
Additions	(32,659)	(13,287)	(16,471)	(41,712)
Balance as of December 31/June 30	(49,928)	(63,215)	(66,399)	(104,927)

Uncertainties exist with respect to how the current income tax law in the PRC applies to the Group's overall operations, and more specifically, with regard to tax residency status. The EIT Law includes a provision specifying that legal entities organized outside of the PRC will be considered residents for Chinese income tax purposes if the place of effective management or control is within the PRC. The implementation rules to the EIT Law provide that non-resident legal entities will be considered PRC residents if substantial and overall management and control over the manufacturing and business operations, personnel, accounting and properties, occurs within the PRC. Despite the present uncertainties resulting from the limited PRC tax guidance on the issue, the Group does not believe that the legal entities organized outside of the PRC within the Group should be treated as residents for EIT Law purposes. If the PRC tax authorities subsequently determine that the Company and its subsidiaries registered outside the PRC should be deemed resident enterprises, the Company and its subsidiaries registered outside the PRC will be subject to the PRC income taxes, at a rate of 25%. The Group is not subject to any other uncertain tax position.

13. Short-term borrowings

On June 25, 2018, Zai Lab (Suzhou) Co., Ltd. entered into a three-year revolving loan facility agreement of RMB25,000 with a local commercial bank, and the outstanding borrowing under this agreement was RMB25,000 as of June 30, 2020, which will be due in remainder months of 2020. The borrowing is guaranteed by Zai Lab (Shanghai) Co., Ltd., with an average interest rate of 4.785%. The agreement does not contain any financial covenants or restrictions. For the year ended December 31, 2018, Zai Lab (Suzhou) Co., Ltd. drew down RMB20,000 of this loan. In the first half of 2019, Zai Lab (Suzhou) Co., Ltd. drew down RMB5,000 (unaudited) of this loan and repaid outstanding principal of RMB5,000 (unaudited). Zai Lab (Suzhou) Co., Ltd. further drew down RMB25,000 and repaid the outstanding principal of RMB20,000 during the second half of 2019.

For the six months ended June 30, 2020, there was no drawdown nor repayment.

On December 12, 2018, Zai Biopharmaceutical (Suzhou) Co., Ltd. entered into a three-year facility agreement for RMB40,000 with a local commercial bank, the outstanding borrowing under this agreement was RMB5,000 as of June 30, 2020, which will be due in 2020. The borrowing is guaranteed by Zai Lab (Shanghai) Co., Ltd., with average interest rate of 4.785%. The agreement does not contain any financial covenants or restrictions. For the year ended December 31, 2018, Zai Biopharmaceutical (Suzhou) Co., Ltd. drew down RMB5,000 of this loan. For the year ended December 31, 2019, Zai Biopharmaceutical (Suzhou) Co., Ltd. drew down RMB20,000 of this loan and repaid the outstanding principal of RMB5,000. For the six months ended June 30, 2019, Zai Biopharmaceutical (Suzhou) Co., Ltd. drew down RMB15,000 (unaudited) of this loan. For the six months ended June 30, 2020, Zai Biopharmaceutical (Suzhou) Co., Ltd. repaid RMB15,000 of this loan.

14. Other current liabilities

Other current liabilities consist of followings:

	As of		
	December 31, 2018	December 31, 2019	June 30, 2020
	$	*$*	*$*
Payroll	3,699	9,590	7,521
Professional service fee	1,564	774	1,510
Payables for purchase of property and equipment	1,709	416	984
Payables for purchase of intangible assets	225	—	—
Accrued rebate to distributors	—	—	812
Others *(note (i))*	570	2,394	4,923
	7,767	13,174	15,750

Note:

(i) Others are mainly payments from employees for exercising the share-based compensations and payables related to travel and business entertainment expenses and conference fee.

15. Loss per share

Basic and diluted net loss per share for each of the periods presented are calculated as follow:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
			(Unaudited)	
Numerator:				
Net loss attributable to ordinary shareholders	(139,075)	(195,071)	(83,274)	(128,617)
Denominator:				
Weighted average number of ordinary shares – basic and diluted	52,609,810	64,369,490	60,919,842	73,847,551
Net loss per share-basic and diluted	(2.64)	(3.03)	(1.37)	(1.74)

As a result of the Group's net loss for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	As of		
	December 31, 2018	December 31, 2019	June 30, 2020
Share options	8,761,735	9,122,980	9,808,561
Non-vested restricted shares	1,112,001	743,268	710,068

16. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of June 30, 2020:

Company Name	Relationship with the Group
MEDx (Suzhou) Translational Medicine Co., Ltd. (Formerly known as Qiagen (Suzhou) translational medicine Co., Ltd)	Significant influence held by Samantha Du's (Director, Chairwoman and Chief Executive Officer of the Company) immediate family

For the years ended December 31, 2018 and 2019, the Group incurred $126 and $234 research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for drug research and development services, respectively. And for the six months ended June 30, 2019 and 2020, the Group incurred $62 (unaudited) and $184 research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for drug research and development services, respectively. All of the transactions are carried out with normal business terms and are on arms' length basis.

17. Share-based compensation

Share options

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan") which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group ("Option Pool"). Subsequently, the Board of Directors approved the increase in the Option Pool to 7,369,767 ordinary shares.

In connection with the completion of the initial public offering (the "IPO"), the Board of Directors has approved the 2017 Equity Incentive Plan (the "2017 Plan") and all equity-based awards subsequent to the IPO would be granted under the 2017 Plan.

In 2018, the Group granted 2,759,750 share options to certain management and employees of the Company at the exercise price ranging from $17.60 to $24.58 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

In 2019, the Group granted 1,067,385 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from $27.23 to $41.59 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five or three years period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

For the six months ended June 30, 2020, the Group granted 960,878 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from $44.94 to $82.13 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five or three years period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

Before 2018, the binomial option-pricing model was applied in determining the estimated fair value of the options granted. From 2018, the Group changed to use the Black-Scholes option valuation model going forward in determining the estimated fair value of the options granted. The change in valuation technique is accounted for as a change in accounting estimate under ASC 250 and applied prospectively to new awards.

The following table presents the assumptions used to estimate the fair values of the share options granted in the periods presented:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
			(Unaudited)	
Risk-free rate of return	2.7%-3.2%	1.6%-2.5%	1.8%-2.5%	0.4%-0.8%
Contractual life of option	10 years	10 years	10 years	10 years
Expected term	6.5 years	6 or 6.5 years	6 or 6.5 years	6 or 6.5 years
Estimated volatility rate	70%	70%	70%	70%
Expected dividend yield	0%	0%	0%	0%

A summary of option activity under the Plan during the years ended December 31, 2018 and 2019, and six months ended June 30, 2020 is presented below:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
		$	*Years*	*$*
Outstanding at January 1, 2018	6,548,377	1.28	8.06	130,668,851
Granted	2,759,750	21.15	—	—
Exercised	(256,065)	0.76	—	—
Forfeited	(290,327)	3.73	—	—
Outstanding at December 31, 2018	8,761,735	7.47	7.80	138,009,758
Granted	1,067,385	32.22	—	—
Exercised	(670,939)	1.57	—	—
Forfeited	(35,201)	25.99	—	—
Outstanding at December 31, 2019	9,122,980	10.73	7.16	281,562,301

	Number of options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
		$	*Years*	*$*
Outstanding at December 31, 2018	8,761,735	7.47	7.80	138,009,758
Granted (unaudited)	649,193	28.40	—	—
Exercised (unaudited)	(137,177)	2.21	—	—
Forfeited (unaudited)	(18,141)	23.73	—	—
Outstanding at June 30, 2019 (unaudited)	9,255,610	8.97	7.49	189,991,245
Outstanding at December 31, 2019	9,122,980	10.73	7.16	281,562,301
Granted	960,878	52.80	—	—
Exercised	(228,891)	13.44	—	—
Forfeited	(46,406)	31.73	—	—
Outstanding at June 30, 2020	9,808,561	14.69	6.95	661,528,948
Vested and Exercisable as of June 30, 2020	5,079,377	4.51	5.86	394,282,051
Vested or expected to vest as of June 30, 2020	9,808,561	14.69	6.95	661,528,948

The weighted-average grant-date fair value of the options granted in 2018 and 2019, and the six months ended June 30, 2019 and 2020 were $14.03, $20.98, $18.56 (unaudited) and $33.51 per share respectively. The following table summarizes the compensation cost related to the options recorded for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	*$*	*$*	*$*
			(Unaudited)	
Selling, general and administrative	4,428	6,931	3,030	5,548
Research and development	4,975	7,994	3,617	4,807
Total	9,403	14,925	6,647	10,355

As of June 30, 2020, there was $73,809 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 1.9 years.

Non-vested restricted shares

In 2018, 62,500 ordinary shares were authorized for grant to the independent directors, respectively. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2018, 694,500 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2019, 50,000 ordinary shares were authorized for grant to the independent directors, respectively. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2019, 121,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

During the six months ended June 30, 2020, 50,000 ordinary shares were authorized for grant to the independent directors. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

During the six months ended June 30, 2020, 45,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

The Group measured the fair value of the non-vested restricted shares as of respective grant dates, and recognizes the amount as compensation expense over the deemed service period using a graded vesting attribution model on a straight-line basis.

The following table summarized the Group's non-vested restricted share activity during the years ended December 31, 2018 and 2019, and six months ended June 30, 2020:

	Numbers of non-vested restricted shares	Weighted average grant date fair value
		$
Non-vested as of January 1, 2018	693,333	2.57
Granted	757,000	20.73
Vested	(338,332)	1.95
Non-vested as of December 31, 2018	1,112,001	15.13
Granted	171,000	27.55
Vested	(539,733)	8.97
Non-vested as of December 31, 2019	743,268	22.45
Granted	95,000	57.12
Vested	(116,200)	24.43
Forfeited	(12,000)	20.98
Non-vested as of June 30, 2020	710,068	26.79

As of June 30, 2020, there was $15,833 of total unrecognized compensation expense related to non-vested restricted shares. The following table summarizes the compensation cost related to the restricted shares recorded for the years ended December 31, 2018 and 2019, and six months ended June 30, 2019 and 2020:

	Year ended December 31,		Six months ended June 30,	
	2018	2019	2019	2020
	$	*$*	*$*	*$*
			(Unaudited)	
Selling, general and administrative	2,206	3,643	1,843	2,114
Research and development	620	1,723	804	958
Total	2,826	5,366	2,647	3,072

18. Licenses and collaborative arrangement

The following is a description of the Group's significant ongoing collaboration agreements for the years ended December 31, 2018 and 2019, and six months ended June 30, 2020.

License and collaboration agreement with Tesaro (Now: GSK)

In September 2016, the Group entered into a collaboration, development and license agreement with Tesaro, under which the Group obtained an exclusive license for certain patents and know-how that Tesaro licensed from Merck, Sharp & Dohme Corp. (a subsidiary of Merck & Co. Inc.), or Merck Corp., and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize Tesaro's proprietary PARP inhibitor, ZEJULA, in mainland China, Hong Kong and Macau, or the licensed territory, in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). In February 2018, the Group entered into an amendment with GSK to eliminate GSK's option to co-market ZEJULA in the licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $15,000 and accrued two development milestone payments in total of $4,500 to Tesaro. On top of those, if the Group achieves other specified regulatory, development and commercialization milestones, the Group may be additionally required to pay further milestone payments up to $36,000 to Tesaro. In addition, if the Group successfully develops and commercializes the licensed products, the Group will pay Tesaro tiered royalties on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Tesaro.

License and collaboration agreement with Paratek Bermuda Ltd. ("Paratek")

In April 2017, the Group entered into a license and collaboration agreement with Paratek, under which the Group obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, use, sell, import and commercialize omadacycline in mainland China, Hong Kong, Macau and Taiwan, or licensed territory, in the field of all human therapeutic and preventative uses other than biodefense, or the licensed field. Paratek retains the right to manufacture the licensed product in the licensed territory for use outside the licensed territory. The Group also granted to Paratek a non-exclusive license to certain of intellectual property for Paratek to develop and commercialize the licensed products outside of licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $7,500 and two milestone payment in total of $8,000 to Paratek and the Group may be required to pay further milestone payments of up to an aggregate of $46,500 to Paratek for the achievement of certain development and sales milestone events. In addition, the Group will pay to Paratek tiered royalties on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Paratek.

License and collaboration agreement with Five Prime Therapeutics, Inc. ("Five Prime")

In December 2017, the Group entered into a collaboration and license agreement with Five Prime, under which the Group obtained exclusive rights to develop and commercialize Five Prime's proprietary afucosylated FGFR2b antibody known as bemarituzumab, and all fragments, conjugates, derivatives and modifications thereof in China, Hong Kong, Macau and Taiwan, or the licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $5,000 and a milestone payment of $2,000 to Five Prime. Additionally, the Group may be required to pay further development and regulatory milestone payments of up to an aggregate of $37,000 to Five Prime. The Group is also be obligated to pay Five Prime a royalty, on a licensed product-by-licensed product and region-by-region basis, depending on the number of patients the Group enrolls in the bemarituzumab study, subject to reduction in certain circumstances, on net sales of each licensed product in the licensed territory until the latest of (i) the 11th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Five Prime.

License and collaboration agreement with Entasis Therapeutics Holdings Inc. ("Entasis")

In April 2018, the Group entered into a collaboration and license agreement with Entasis, under which the Group obtained an exclusive right to develop and commercialize Entasis's proprietary compounds known as durlobactam and SUL-DUR, with the possibility of developing and commercializing a combination of such compounds with Imipenem, in mainland China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan, or the territory.

Under the terms of the agreement, the Group made an upfront payment of $5,000 and two development milestone payments in total of $7,000 to Entasis. Additionally, the Group may be required to pay Entasis development, regulatory and research milestone payments (other than existing ones) and commercial milestone payments of up to an aggregate of $91,600. The Group is also responsible for a portion of the costs of the global pivotal Phase III clinical trial of SUL-DUR outside of the territory. The Group is also obligated to pay Entasis a royalty based on a percentage of net sales of licensed products, depending on the amount of net sales of licensed products in the territory, subject to reduction in certain circumstances, until, with respect to a licensed product in a region in the territory, the latest of (i) the 10th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Entasis.

License and collaboration agreement with Crescendo Biologics Ltd. ("Crescendo")

In May 2018, the Group and Crescendo entered into an exclusive, worldwide licensing agreement, under which the Group will develop, commercialize, and manufacture a topical, innovative antibody VH domain therapeutic for potential application in inflammatory indications.

Under the terms of the agreement, Crescendo granted to the Group a worldwide exclusive license to develop and commercialize its drug candidate for all indications. The Group will be responsible for conducting all regulatory filings, clinical studies, and commercialization activities, with both companies participating in a Joint Development Committee.

The Group paid upfront fee of $2,000 and a milestone payment of $1,000 to Crescendo. And the Group will provide development, regulatory, and commercial milestones for multiple indications up to an aggregate of $168,575. Crescendo will also be eligible to receive tiered royalties on global sales.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Crescendo.

License and collaboration agreement with Novocure Limited ("Novocure")

In September 2018, the Group entered a license and collaboration agreement with Novocure. Under the terms of the agreement, Novocure exclusively licensed to the Group the rights to perform clinical studies, sublicenseable to affiliates and third parties, sell, offer for sale and import Tumor Treating Fields products in the field of oncology, in mainland China, Hong Kong, Macau and Taiwan, or the territory.

Under the terms of the agreement, the Group paid an upfront license fee in the amount of $15,000 and a milestone payment of $2,000 to Novocure. In addition, the Group accrued a milestone payment of $8,000. The Group also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $68,000, and tiered royalties at percentage rates on the net sales of the Licensed Products in the Territory. The Group will purchase licensed products exclusively from Novocure at Novocure's fully burdened manufacturing cost.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Novocure.

License and collaboration agreement with MacroGenics Inc. ("MacroGenics")

In November 2018, the Group entered into a collaboration agreement with MacroGenics. Under the terms of collaboration agreement, MacroGenics exclusively licensed to the Group regional development and commercialization rights to margetuximab, tebotelimab and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, or the TRIDENT molecule, and, together with margetuximab and tebotelimab, each, a licensed product, in mainland China, Hong Kong, Macau and Taiwan, or the territory.

Under the terms of the agreement, the Group paid an upfront license fee of $25,000 and two milestone payments in total of $4,000 to MacroGenics. The Group also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of $136,000, and tiered royalties at percentage rates for net sales of Margetuximab, tebotelimab and TRIDENT molecule in the territory.

The Group has the right to terminate this agreement at any time by providing written notice of termination to MacroGenics.

Collaboration agreement with Deciphera Pharmaceuticals, LLC ("Deciphera")

In June 2019, the Group entered into a license agreement with Deciphera. Under the terms of the agreement, Deciphera exclusively licensed to the Group the rights to perform clinical studies, sublicenseable to affiliates without Deciphera's consent and third parties, sell, offer for sale and import ripretinib, in the field of the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in mainland China, Hong Kong, Macau and Taiwan.

Under the terms of the agreement, the Group paid Deciphera an upfront license fee of $20,000 and a milestone payment of $5,000. In addition, the Group accrued a milestone payment of $2,000. The Group also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of $178,000, and tiered royalties on the net sales of the licensed products in the territory.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Deciphera.

License and collaboration agreement with Incyte Corporation ("Incyte")

In July 2019, the Group entered into a collaboration and license agreement with Incyte. Under the terms of the agreement, Incyte exclusively licensed to the Group the rights to perform clinical studies, sublicenseable to affiliates in mainland China, Hong Kong, Macau and Taiwan without Incyte's consent and other affiliates and third parties, sell, offer for sale and import retifanlimab in the field of the treatment, palliation, diagnosis or prevention of diseases in the fields of haematology or oncology in humans in mainland China, Hong Kong, Macau and Taiwan.

Under the terms of agreement, the Group paid Incyte an upfront license fee of $17,500. The Group also agreed to pay certain development, regulatory and commercial milestone payments of up to an aggregate of $60,000, and tiered royalties at percentage rates on the net sales of retifanlimab in mainland China, Hong Kong, Macau and Taiwan.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Incyte.

Collaboration agreement with Regeneron Pharmaceuticals, Inc ("Regeneron")

In April 2020, the Group entered into a collaboration agreement with Regeneron. Under the terms of the agreement, the Group paid an upfront payment of $30,000 to Regeneron. Regeneron is also eligible to receive up to $160,000 in additional regulatory and sales milestones. The Group will contribute to the global development costs for odronextamab for certain trials and will receive the rights to develop and exclusively commercialize odronextamab in oncology in mainland China, Hong Kong, Taiwan and Macau. Additionally, the Group will make payments to Regeneron based on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron will be responsible for the manufacture and supply of odronextamab for the Group's development and commercialization in the region.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Regeneron.

As noted above, the Group has entered into various license and collaboration agreements with third party licensors to develop and commercialize drug candidates. Based on the terms of these agreements the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management's evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Group up to an aggregate of approximately $1,533,344 in future milestone payments upon the achievement of contractually specified development milestones, such as regulatory approval for the drug candidates, which may be before the Group has commercialized the drug or received any revenue from sales of such drug candidate, which may never occur.

19. Restricted net assets

The Group's ability to pay dividends may depend on the Group receiving distributions of funds from its PRC subsidiary. Relevant PRC statutory laws and regulations permit payments of dividends by the Group's PRC subsidiary only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Group's PRC subsidiary.

In accordance with the Company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group's PRC subsidiaries were established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2018 and 2019, no appropriation to statutory reserves was made because the PRC subsidiaries had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Group's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulation in the PRC may further restrict the Group's PRC subsidiaries from transferring funds to the Group in the form of dividends, loans and advances. As of December 31, 2018 and 2019, and June 30, 2020 amounts restricted are in the paid-in capital of the Group's PRC subsidiaries, which amounted to $90,952, $155,858 and $205,858, respectively.

20. Employee defined contribution plan

Full time employees of the Group in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that the Group's PRC subsidiaries make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Group has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were $1,425 and $5,406 for the years ended December 31, 2018 and 2019, respectively, and $2,299 and $2,419 for the six months ended June 30, 2019 and 2020, respectively.

21. Commitments and Contingencies

(a) Purchase commitments

As of June 30, 2020, the Group's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statement was $3,971 which is expected to be incurred within one year.

(b) Contingencies

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 18).

22. Subsequent events

In July 2020, the Group entered into a license agreement with Turning Point Therapeutics, Inc. ("Turning Point"), pursuant to which Turning Point granted the Group exclusive rights to develop and commercialize products containing Turning Point's drug candidate, repotrectinib, in Mainland China, Hong Kong, Macau and Taiwan (the "Territory"). Turning Point retains exclusive rights to, among other things, develop, manufacture and commercialize the Products outside the Territory. Pursuant to the terms of agreement, Turning Point will receive an upfront cash payment of $25,000 and will be eligible to receive up to $151,000 in development and sales milestone payments. In addition, the Group will pay Turning Point tiered percentage royalties on annual net sales of the products in the Territory, subject to adjustments in specified circumstances.

23. Dividends

No dividends have been paid or declared by the Company during the Track Record Period.

III. SUBSEQUENT FINANCIAL STATEMENTS

No audited consolidated financial statements have been prepared by the Group in respect of any period subsequent to June 30, 2020 and up to the date of this report.

The following information does not form part of the accountants' report on the historical financial information for the two years ended December 31, 2019 and the six months ended June 30, 2020 of the Group (the "Accountants' Report") from Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, the reporting accountants of the Company, as set forth in Appendix I to this prospectus, and is included herein for information only. The unaudited pro forma financial information should be read in conjunction with the section headed "Financial Information" in this prospectus and the Accountants' Report set forth in Appendix I to this prospectus.

A. UNAUDITED PRO FORMA ADJUSTED NET TANGIBLE ASSETS

The following unaudited pro forma adjusted net tangible assets of the Group attributable to ordinary shareholders of the Company prepared in accordance with Rule 4.29 of the Hong Kong Listing Rules is set out to illustrate the effect of the Global Offering on the consolidated net tangible assets attributable to ordinary shareholders of the Company as at June 30, 2020 as if the Global Offering had taken place on such date.

This unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group, had the Global Offering been completed as of June 30, 2020 or at any further dates. It is prepared based on the audited consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as at June 30, 2020 as derived from the Accountants' Report, the text of which is set out in Appendix I to this prospectus and adjusted as described below.

	Audited consolidated net tangible assets attributable to ordinary shareholders of the Company as of June 30, 2020	Estimated net proceeds from the Global Offering	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as of June 30, 2020	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per Share	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per ADS	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per Share	Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per ADS
	US$'000 *(Note 1)*	*US$'000* *(Note 2)*	*US$'000*	*US$* *(Note 3)*	*US$* *(Note 4)*	*HK$* *(Note 5)*	*HK$* *(Note 5)*
Based on the indicative offer price of HK$648.00 per Offer Share	464,250	853,378	1,317,628	15.42	15.42	119.51	119.51

Notes:

(1) The audited consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as of June 30, 2020 is derived from the Accountants' Report set out in Appendix I to this prospectus, which is based on the audited consolidated net assets of the Group attributable to ordinary shareholders of the Company as of June 30, 2020 of US$465,466,000 with adjustments for intangible assets attributable to the ordinary shareholders of the Company of US$1,216,000.

(2) The estimated net proceeds from the Global Offering are based on 10,564,050 Offer Shares at the indicative offer price of HK$648.00 per Offer Share after deduction of the estimated listing expenses and share issue costs (including underwriting fees and other related expenses) expected to be incurred by the Company subsequent to June 30, 2020 and without taking into account any allotment and issuance of any Shares upon the exercise of the Over-allotment Option, the Shares to be issued pursuant to the Share Incentive Plans and other compensation programs, including pursuant to the exercise of options or the vesting of restricted shares or other awards that have been or may be granted from time to time and any issuance or repurchase of Shares and/or ADSs by the Company. For the purpose of calculating the estimated net proceeds from the Global Offering, the translation of Hong Kong dollars into U.S. Dollars was made at the exchange rate of HK$7.7501 to US$1.00, which is derived from the exchange rate of Hong Kong dollars against U.S. Dollars on June 30, 2020 set forth in the Exchange Rate Conversion section of the Prospectus. No representation is made that Hong Kong dollars have been, could have been or may be converted to U.S. Dollars, or vice versa, at that rate or at any other rates or at all.

(3) The unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per Share is arrived at after the adjustments referred to in the preceding paragraphs and on the basis that 85,446,388 Shares were in issue assuming that the Global Offering had been completed on June 30, 2020 without taking into account any allotment and issuance of any Shares upon the exercise of the Over-allotment Option, the Shares to be issued pursuant to the Share Incentive Plans and other compensation programs, including pursuant to the exercise of options or the vesting of restricted shares or other awards that have been or may be granted from time to time and any issuance or repurchase of Shares and/or ADSs by the Company.

(4) The unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company per ADS is arrived at after the adjustments referred to in the preceding paragraphs and on the basis that one ADS represents one Share.

(5) For the purpose of this unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company, the balances stated in U.S. Dollars are converted into Hong Kong dollars at the exchange rate of US$1.00 to HK$7.7501. No representation is made that U.S. Dollars amounts have been, could have been or may be converted into Hong Kong dollars, or vice versa, at that rate or at any other rates or at all.

(6) No adjustments have been made to the unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to the ordinary shareholders of the Company to reflect any trading results or other transactions of the Group entered into subsequent to June 30, 2020.

B. REPORT FROM THE REPORTING ACCOUNTANTS ON UNAUDITED PRO FORMA FINANCIAL INFORMATION

The following is the text of the independent reporting accountants' assurance report received from Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, the reporting accountants of the Company, in respect of the Group's unaudited pro forma financial information prepared for the purpose of incorporation in this prospectus.

Deloitte.

INDEPENDENT REPORTING ACCOUNTANTS' ASSURANCE REPORT ON THE COMPILATION OF UNAUDITED PRO FORMA FINANCIAL INFORMATION

To the Directors of Zai Lab Limited

We have completed our assurance engagement to report on the compilation of unaudited pro forma financial information of Zai Lab Limited (the "Company") and its subsidiaries (hereinafter collectively referred to as the "Group") by the directors of the Company (the "Directors") for illustrative purposes only. The unaudited pro forma financial information consists of the unaudited pro forma statement of adjusted consolidated net tangible assets of the Group attributable to ordinary shareholders of the Company as at June 30, 2020 and related notes as set out on pages II-1 to II-2 of Appendix II to the prospectus issued by the Company dated September 17, 2020 (the "Prospectus"). The applicable criteria on the basis of which the Directors have compiled the unaudited pro forma financial information are described on pages II-1 to II-2 of Appendix II to the Prospectus.

The unaudited pro forma financial information has been compiled by the Directors to illustrate the impact of the proposed Global Offering (as defined in the Prospectus) on the Group's financial position as at June 30, 2020 as if the proposed Global Offering had taken place at June 30, 2020. As part of this process, information about the Group's financial position has been extracted by the Directors from the Group's historical financial information for each of the two years ended December 31, 2019 and the six months ended June 30, 2020, on which an accountants' report set out in Appendix I to the Prospectus has been published.

Directors' Responsibilities for the Unaudited Pro Forma Financial Information

The Directors are responsible for compiling the unaudited pro forma financial information in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") and with reference to Accounting Guideline 7 "Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars" ("AG 7") issued by the Hong Kong Institute of Certified Public Accountants (the "HKICPA").

Our Independence and Quality Control

We have complied with the independence and other ethical requirements of the "Code of Ethics for Professional Accountants" issued by the HKICPA, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies Hong Kong Standard on Quality Control 1 "Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and Other Assurance and Related Services Engagements" issued by the HKICPA and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Reporting Accountants' Responsibilities

Our responsibility is to express an opinion, as required by paragraph 4.29(7) of the Listing Rules, on the unaudited pro forma financial information and to report our opinion to you. We do not accept any responsibility for any reports previously given by us on any financial information used in the compilation of the unaudited pro forma financial information beyond that owed to those to whom those reports were addressed by us at the dates of their issue.

We conducted our engagement in accordance with Hong Kong Standard on Assurance Engagements 3420 "Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus" issued by the HKICPA. This standard requires that the reporting accountants plan and perform procedures to obtain reasonable assurance about whether the Directors have compiled the unaudited pro forma financial information in accordance with paragraph 4.29 of the Listing Rules and with reference to AG 7 issued by the HKICPA.

For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the unaudited pro forma financial information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the unaudited pro forma financial information.

The purpose of unaudited pro forma financial information included in an investment circular is solely to illustrate the impact of a significant event or transaction on unadjusted financial information of the Group as if the event had occurred or the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the event or transaction at June 30, 2020 would have been as presented.

A reasonable assurance engagement to report on whether the unaudited pro forma financial information has been properly compiled on the basis of the applicable criteria involves performing procedures to assess whether the applicable criteria used by the Directors in the compilation of the unaudited pro forma financial information provide a reasonable basis for presenting the significant effects directly attributable to the event or transaction, and to obtain sufficient appropriate evidence about whether:

- the related pro forma adjustments give appropriate effect to those criteria; and
- the unaudited pro forma financial information reflects the proper application of those adjustments to the unadjusted financial information.

The procedures selected depend on the reporting accountants' judgment, having regard to the reporting accountants' understanding of the nature of the Group, the event or transaction in respect of which the unaudited pro forma financial information has been compiled, and other relevant engagement circumstances.

The engagement also involves evaluating the overall presentation of the unaudited pro forma financial information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion:

(a) the unaudited pro forma financial information has been properly compiled on the basis stated;

(b) such basis is consistent with the accounting policies of the Group; and

(c) the adjustments are appropriate for the purposes of the unaudited pro forma financial information as disclosed pursuant to paragraph 4.29(1) of the Listing Rules.

Deloitte Touche Tohmatsu
Certified Public Accountants
Hong Kong
September 17, 2020

We are an exempted company incorporated in the Cayman Islands on March 28, 2013 with limited liability and our affairs are governed by our Articles of Association, and the Companies Law (as amended) of the Cayman Islands, which we refer to as the Companies Law, and the common law of the Cayman Islands.

Set out below is a summary of certain provisions of the current Articles of Association of our Company and of certain aspects of the Cayman Companies Law. As the information contained below is in summary form, it does not contain all information that may be material to potential investors. A copy of the current memorandum and articles of association of our Company and the Companies Law is available for inspection as referred to in the section headed "Documents available for inspection" in Appendix V.

SUMMARY OF THE CONSTITUTION OF THE COMPANY

Memorandum of Association

The Memorandum of Association of the Company was adopted on September 4, 2020 and states, inter alia, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by the Companies Law or any other law of the Cayman Islands.

The Memorandum of Association is available for inspection at the address specified in Appendix V in the section headed "Documents Available for Inspection."

Articles of Association

The Articles of Association of the Company were adopted by special resolution passed on August 30, 2017, and effective on September 20, 2017 and include provisions to the following effect:

Shares

All of our issued and outstanding Shares are fully paid and non-assessable. Our Shares are issued in registered form. Shareholders who are non-residents of the Cayman Islands may freely hold and vote their Shares.

Dividends

The holders of Shares are entitled to such dividends as may be declared by the board of Directors. In addition, Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by the Directors. Under Cayman Islands law, dividends may be declared and paid only out of funds legally available therefor, namely out of

either profit or the Company's share premium account, and provided further that a dividend may not 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.

Any dividend unclaimed after a period of six years from the date of declaration of such dividend may be forfeited by the board of Directors and, if so forfeited, shall revert to the Company.

Voting Rights

Each Share is entitled to one vote on all matters upon which our Shares are entitled to vote, including the election of directors. Voting at any meeting of Shareholders is by show of hands unless a poll is demanded. A poll may be demanded by a Shareholder present in person or by proxy. A quorum required for a meeting of Shareholders consists of not less than an aggregate of one-third of all voting share capital of the Company in issue present in person or by proxy and entirely to vote.

An ordinary resolution to be passed by the Shareholders requires the affirmative vote of a simple majority of the votes cast by those Shareholders entitled to vote who are present in person or by proxy at a general meeting. Shareholders may, among other things, divide or consolidate their Shares by ordinary resolution. A special resolution requires the affirmative vote of no less than two-thirds of the votes cast by those Shareholders entitled to vote who are present in person or by proxy at a general meeting. A special resolution will be required for important matters such as a change of name or making changes to the Memorandum and Articles of Association. Both ordinary resolutions and special resolutions may also be passed by a unanimous written resolution signed by all the Shareholders of the Company, as permitted by the Companies Law and the Memorandum and Articles of Association.

The Company undertakes that (i) at the next annual general meeting, where any member is, under the Hong Kong Listing Rules, required to abstain from voting on any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement shall not be counted, and (ii) it will put forth a resolution at the next annual general meeting in the second quarter of 2021 to amend the Articles of Association such that where any member is, under the Hong Kong Listing Rules, required to abstain from voting on any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement shall not be counted. In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed.

Pending the amendment to our Articles of Association as mentioned above, we will stipulate in our proxy statement that a member with material interest in a transaction or arrangement will be required to abstain from voting on resolutions relating to such transaction or arrangement.

Transfer of Shares

Any of the Shareholders may transfer all or any of his or her Shares by an instrument of transfer in the usual or common form or any other form approved by the board of Directors.

However, the board of Directors may, in its absolute discretion, decline to register any transfer of any Share which is not fully paid up or on which the Company has a lien. The board of Directors may also decline to register any transfer of any Share unless:

(a) the instrument of transfer is lodged with the Company, accompanied by the certificate for the Shares to which it relates and such other evidence as the board of Directors may reasonably require to show the right of the transferor to make the transfer;

(b) the instrument of transfer is in respect of only one class of Shares;

(c) the instrument of transfer is properly stamped, if required;

(d) in the case of a transfer to joint holders, the transfer is not to more than four joint holders;

(e) the Shares transferred are free of any lien in favor of the Company; or

(f) any fee related to the transfer has been paid to the Company.

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

Liquidation

On a winding up of the Company, if the assets available for distribution among the Shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus will be distributed among the 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 the Company for unpaid calls or otherwise. If the assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that the losses are borne by the Shareholders in proportion to the par value of the Shares held by them.

Redemption, Repurchase and Surrender of Shares

The Company may issue Shares on terms that such Shares are subject to redemption, at the option of the Company or at the option of the holders thereof, on such terms and in such manner as may be determined, before the issue of such Shares, by the board of Directors or by a special resolution of the Shareholders. The Company may also repurchase any of the Company's Shares provided that the manner and terms of such purchase have been approved by the board of Directors or by ordinary resolution of the Shareholders, or are otherwise authorized by the Memorandum and Articles of Association. Under the Companies Law, the redemption or repurchase of any Share may be paid out of the Company's profits or out of the proceeds of a fresh 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 the 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 the Company has commenced liquidation. In addition, the Company may accept the surrender of any fully paid Share for no consideration.

Variation of Rights of Shares

The rights attaching to any class of Shares may, subject to any rights or restrictions for the time being attached to any class, be materially adversely varied with the consent in writing of the holders of a majority of the issued Shares of that class, or with the sanction of a special resolution passed at a separate meeting of the holders of the Shares of that class.

As of the date of this prospectus, the Company only has one class of shares. The Company undertakes that (i) after the Global Offering and until the following proposed amendment to its Articles of Association is passed, the Company will not seek to vary or abrogate any class right, and any request by shareholders to vary or abrogate any class right will require the written consent 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 general meeting of the holders of the shares of that class or series; and (ii) it will convene its next annual general meeting in the second quarter of 2021 and put forth a resolution at such annual general meeting, to revise its Articles of Association, so that the rights attaching to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may be varied or abrogated with the written consent 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 general meeting of the holders of the shares of that class or series.

In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed. We have been advised by our legal advisers as to Cayman Islands law that there is no legal impediment on

the adoption of the above-mentioned transitional arrangements, and that the adoption of such transitional arrangements is not in breach of our Articles of Association or any rules and regulations in the Cayman Islands.

General Meetings of Shareholders

Shareholders' general meetings may be held in such place as the board of Directors considers appropriate.

As a Cayman Islands exempted company, the Company is not obliged by the Companies Law to call Shareholders' annual general meetings. The Memorandum and Articles of Association provide that the Company may (but are not obliged to) in each year hold a general meeting as its annual general meeting. The Company undertakes to convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend its Articles of Association in accordance with the requirement under Rule 19C.07(4) of the Listing Rules such that its Articles of Association will require the Company to hold an annual general meeting each year and not more than 15 months should elapse between the date of one annual general meeting of our Company and the next. See "Waivers and Exemptions" and "Information about this Prospectus and the Global Offering – Our Articles of Association" for further details.

Following the Listing, we will continue to hold our annual general meeting each year. In the event that the proposed amendment of our Articles of Association as described above is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed.

Shareholders' annual general meetings and any other general meetings of the Shareholders may be convened by a majority of the board of Directors or the Chairman of the board. The board of Directors shall give not less than seven days' notice of a Shareholders' meeting to those persons whose names appear as members in the Company's register of members on the date the notice is given (or on any other date determined by the Directors to be the record date for such meeting) and who are entitled to vote at the meeting. The Company undertakes to (i) provide 14 calendar days-notice for any general meetings after the Listing, and (ii) convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend our Articles of Association in accordance with the requirement under Rule 19C.07(5) of the Listing Rules, such that our Articles of Association will require our Company to give at least 14 calendar days-notice for any general meeting.

Cayman Islands 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. The Memorandum and Articles of Association allow one or more Shareholders holding Shares representing not less than one-third of the share capital of the Company entitled

to vote at general meetings, to requisition an extraordinary general meeting, in which case the Directors are obliged to call such meeting and to put the resolutions so requisitioned to a vote at such meeting; however, the Memorandum and Articles of Association do not provide the Shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such Shareholders. The Company undertakes to convene the next annual general meeting in the second quarter of 2021 after the Global Offering to amend the Articles of Association in accordance with the requirement under Rule 19C.07(7) of the Listing Rules, such that (i) members holding not less than 10% of the total number of issued shares of our Company shall be able to convene an extraordinary general meeting and add resolutions to a meeting agenda, and (ii) the quorum for holding general meetings shall be members holding not less than 10% of our Company's total number of issued shares. In the event that the proposed amendment is not approved by our shareholders at the next annual general meeting, we will continue to put forth a resolution for the proposed amendment at each of the following annual general meetings until such resolution is passed; and

The Company will adopt transitional arrangements to ensure that (i) where after the Global Offering and before the above-mentioned proposed amendment to its Articles of Association is passed, if one or more members holding not less than 10% of the total number of issued shares of the Company raise requisition for an extraordinary general meeting or requests to add resolutions to a meeting agenda, such members will be permitted to do so, and (ii) one or more members holding not less than 10% of the Company's total number of issued shares will also be able to form a quorum at any general meeting which is held after the Global Offering and before the next annual general meeting. We have been advised by our legal advisers as to Cayman Islands law that there is no legal impediment on the adoption of such transitional arrangements, and that the adoption of such transactional arrangements is not in breach of our Articles of Association or any rules and regulations in the Cayman Islands. See "Waivers and Exemptions" and "Information about this Prospectus and the Global Offering – Our Articles of Association" for further details.

Appointment and Removal of Directors

The Articles of Association provide that unless otherwise determined by the Company in general meeting, the number of Directors shall not be less than one or more than ten Directors.

The Articles of Association provide that the Company may by ordinary resolution appoint any person to be a Director or remove any Director. Each Director shall hold office until the expiration of his term as provided in the written agreement relating to the Director's term, if any, and until his successor shall have been elected or appointed, vacates his office in accordance with the provisions of the Articles of Association, or is removed by the Shareholders. In addition, the board by the affirmative vote of a simple majority of the remaining Directors present and voting at a board meeting, may at any time and from time to time appoint any person nominated by a unanimous decision of the nominating committee of the Board as a Director to fill any vacancy on the Board or as an addition to the existing board.

The office of a Director shall be vacated if:

(a) he becomes bankrupt or makes any arrangement or composition with his creditors;

(b) he dies or is found to be or becomes of unsound mind;

(c) he resigns his office by notice in writing to the Company; or

(d) if he is removed from office pursuant to any other provision of the Articles or the Companies Law.

Proceedings of the Board

The quorum necessary for the transaction of the business of the Directors may be fixed by the Directors and unless so fixed shall be a majority of the then existing Directors. The Company will put forth a resolution at or before its next annual general meeting after the Listing which is expected to be held around mid-2021 to revise its Articles of Association, so that the quorum necessary for the transaction of the business of the Directors shall be a majority of the members of the board of Directors. See "Information about this Prospectus and the Global Offering – Our Articles of Association" for further details.

The Directors may regulate their meetings and proceedings as they think fit. Questions arising at any meeting shall be decided by a majority of votes.

Changes in Share Capital

The Company may by ordinary resolution:

(a) increase the share capital by such, to be divided into shares of such classes and amount, as the resolution shall prescribe;

(b) consolidate and divide all or any of its share capital into shares or larger amount than its existing shares;

(c) subdivide its existing Shares, or any of them into Shares of a smaller amount provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced Share shall be the same as it was in case of the Share from which the reduced Share is derived; and

(d) cancel any Shares that, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the Shares so cancelled.

Directors' Power to Issue Shares

Subject to the provisions, if any, in the Memorandum and Articles of Association and to any direction that may be given by the Company in a general meeting, the Directors may in their absolute discretion and without approval of the Shareholders, issue Shares, grant rights over existing Shares or issue other securities in one or more series as they deem necessary and appropriate and determine designations, powers, preferences, privileges and other rights, including dividend rights, conversion rights, terms of redemption and liquidation preferences, any or all of which may be greater than the powers and rights associated with the Shares held by existing Shareholders, at such times and on such other terms as they think proper.

Directors Borrowing Powers

The Directors may exercise all the powers of the Company to borrow money and to mortgage or charge its undertaking, property and uncalled capital or any part thereof and to issue debentures, debenture stock and other such securities whenever money is borrowed or as security for any debt, liability or obligation of the Company or of any third party.

Disclosure of Interest in Contracts with the Company or any of our Subsidiaries

A Director who is in any way, whether directly or indirectly, interested in a contract or transaction or proposed contract or transaction with the Company shall declare the nature of his interest at a meeting of the Directors. A general notice given to the Directors by any Director to the effect that he is a member of any specified company or firm and is to be regarded as interested in any contract which may thereafter be made with that company or firm shall be deemed a sufficient declaration of interest in regard to any contract so made.

A Director may vote in respect of any contract or proposed contract or arrangement notwithstanding that he may be interested therein and if he does so his vote shall be counted and he may be counted in the quorum at any meeting of the Directors at which any such contract or proposed contract or arrangement shall come before the meeting for consideration.

Remuneration of Directors

The Directors may receive such remuneration as the Board may from time to time determine.

The Directors may be entitled to be repaid all travelling, hotel and incidental expenses reasonably incurred or expected to be incurred by him in attending to meetings of the Board or committees of the Board or general meetings or separate meetings of any class of Shares or of debentures of the Company or otherwise in connection with the discharge of his duties as director.

Restriction on Ownership of Securities

There are no provisions in the Articles of Association relating to restrictions on ownership of the Company's Shares or securities.

SUMMARY OF CAYMAN ISLANDS COMPANY LAW AND TAXATION

Introduction

The Companies Law is derived, to a large extent, from the older Companies Acts of England and Wales, but does not follow recent United Kingdom statutory enactments, and accordingly there are significant differences between the Companies Law and the current Companies Act of England. Set out below is a summary of certain provisions of the Companies Law, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of corporate law and taxation which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

Incorporation

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on March 28, 2013 under the Companies Law. As such, its operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the size of its authorized share capital.

Share Capital

The Companies Law permits a company to issue ordinary shares, preference shares, redeemable shares or any combination thereof.

The Companies Law provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the share premium on those shares shall be transferred to an account called the "share premium account." At the option of a company, these provisions may not apply to share premium on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The Companies Law provides that the share premium account may be applied by a company, subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation:

(a) paying distributions or dividends to members;

(b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;

(c) in the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Law);

(d) writing-off the preliminary expenses of the company;

(e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company; and

(f) providing for the premium payable on redemption or purchase of any shares or debentures of the company.

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid the company will be able to pay its debts as they fall due in the ordinary course of business. The Companies Law provides that, subject to confirmation by the Grand Court of the Cayman Islands, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

Subject to the detailed provisions of the Companies Law, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a shareholder. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. The manner of such a purchase must be authorised either by the articles of association or by an ordinary resolution of the company.

The articles of association may provide that the manner of purchase may be determined by the directors of the company. At no time may a company redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any member of the company holding shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and to act in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

Dividends and Distributions

With the exception of section 34 of the Companies Law, there are no statutory provisions relating to the payment of dividends. Based upon English case law which is likely to be persuasive in the Cayman Islands in this area, dividends may be paid only out of profits. In addition, section 34 of the Companies Law permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account (see the paragraph named 'Share Capital' above for details).

Protection of Minorities

The Cayman Islands courts can be expected to follow English case law precedents. The rule in *Foss v. Harbottle* (and the exceptions thereto which permit a minority shareholder to commence a class action against or derivative actions in the name of the company to challenge (a) an act which is ultra vires the company or illegal, (b) an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company, and (c) an action which requires a resolution with a qualified (or special) majority which has not been obtained) has been applied and followed by the courts in the Cayman Islands.

In the case of a company (not being a bank) having a share capital divided into shares, the Grand Court of the Cayman Islands may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine into the affairs of the company and to report thereon in such manner as the Grand Court shall direct. Any shareholder of a company may petition the Grand Court of the Cayman Islands which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

Claims against a company by its shareholders must, as a general rule, be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

The English common law rule that the majority will not be permitted to commit a fraud on the minority has been applied and followed by the Courts of the Cayman Islands.

Disposal of Assets

The Companies Law contains no specific restrictions on the powers of directors to dispose of assets of a company. As a matter of general law, in the exercise of those powers, the directors must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the company.

Accounting and Auditing Requirements

The Companies Law requires that a company shall cause to be kept proper books of account with respect to:

- all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place;
- all sales and purchases of goods by the company; and
- the assets and liabilities of the company.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

Register of Members

An exempted company may, subject to the provisions of its articles of association, maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as its directors may from time to time think fit. There is no requirement under the Cayman Companies Law for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection.

Inspection of Books and Records

Members of a company will have no general right under the Companies Law to inspect or obtain copies of the register of members or corporate records of the company. They will, however, have such rights as may be set out in the company's articles of association.

Special Resolutions

The Cayman Companies Law provides that a resolution is a special resolution when it has been passed by a majority of at least two-thirds of such members as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given, except that a company may in its articles of association specify that the required majority shall be a number greater than two-thirds, and may additionally so provide that such majority (being not less than two-thirds) may differ as between matters required to be approved by a special resolution. Written resolutions signed by all the members entitled to vote for the time being of the company may take effect as special resolutions if this is authorized by the articles of association of the company.

Subsidiary Owning Shares in Parent

The Companies Law does not prohibit a Cayman Islands company acquiring and holding shares in its parent company provided its objects so permit. The directors of any subsidiary making such acquisition must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the subsidiary.

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, (1) "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 (2) 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 authorised by (1) a special resolution of the shareholders of each constituent company, and (2) such other authorisation, if any, as may be specified in such constituent company's articles of association. The plan must be filed with the Registrar of Companies 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. Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation effected in compliance with these statutory procedures.

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

- the statutory provisions as to the required majority vote have been met;

- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;

- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and

- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Law.

When a takeover offer is made and accepted by holders of 90% 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 on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction is thus approved, or if a takeover offer is made and accepted, a dissenting shareholder would have no rights comparable to appraisal rights.

Indemnification

The Companies 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 (e.g. for purporting to provide indemnification against the consequences of committing a crime).

Liquidation

A company may be placed in liquidation compulsorily by an order of the court, or voluntarily (a) by a special resolution of its members if the company is solvent, or (b) by an ordinary resolution of its members if the company is insolvent. The liquidator's duties are to collect the assets of the company (including the amount (if any) due from the contributories (shareholders)), settle the list of creditors and discharge the company's liability to them, rateably if insufficient assets exist to discharge the liabilities in full, and to settle the list of contributories and divide the surplus assets (if any) amongst them in accordance with the rights attaching to the shares.

Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

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 or withholding tax applicable to an exempted company or to any holder of shares. There are no other taxes likely to be material to the Company 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.

No stamp duty is payable in the Cayman Islands on the issue of shares by, or any transfers of shares of, Cayman Islands companies (except those which hold interests in land in the Cayman Islands). The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or from a Cayman company. There are no exchange control regulations or currency restrictions in the Cayman Islands. Payments of dividends and capital in respect of shares 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 shares, nor will gains derived from the disposal of shares be subject to Cayman Islands income or corporation tax.

Pursuant to section 6 of the Tax Concessions Law (as amended) of the Cayman Islands, the Company may apply for an undertaking from the Financial Secretary of the Cayman Islands that for twenty years from the date of such certificate no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to the Company or its operations; and in addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable (i) on or in respect of the shares, debentures or other obligations of the Company; or (ii) by way of the withholding in whole or in part of any relevant payment as defined in section 6(3) of the Tax Concessions Law (as amended).

Exchange Control

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

General

Travers Thorp Alberga, the Company's legal advisors on Cayman Islands law, have sent to the Company a letter of advice summarizing aspects of Cayman Islands company law. This letter, together with a copy of the Cayman Companies Law, is available for inspection as referred to in the section headed "Documents available for Inspection" in Appendix V. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he/she is more familiar is recommended to seek independent legal advice.

A. FURTHER INFORMATION ABOUT US

1. Incorporation

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Cayman Companies Law on March 28, 2013. Our registered office address is at Harbour Place 2nd Floor, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands. As our Company is incorporated in the Cayman Islands, our operation is subject to the relevant laws and regulations of the Cayman Islands, the Articles and the Memorandum. A summary of the relevant laws and regulations of the Cayman Islands and of our constitution is set out in the section headed "Appendix III – Summary of the Constitution of the Company and Cayman Companies Law" in this prospectus.

We have registered with the Registrar of Companies in Hong Kong as a non-Hong Kong company under Part 16 of the Companies Ordinance, with our principal place of business in Hong Kong at Room 2301, 23/F., Island Place Tower, 510 King's Road, North Point, Hong Kong. Li & Partners has been appointed as our authorized representative for the acceptance of service of process and notices in Hong Kong at 22/F., World-Wide House, 19 Des Voeux Road Central, Hong Kong.

2. Changes in our share capital

There has been no change in our share capital within the two years immediately preceding the date of this prospectus, other than Shares issued pursuant to the Equity Plans and:

(a) on September 10, 2018, we completed a follow-on public offering and sold 7,500,000 ADSs;

(b) on May 7, 2019, we completed a follow-on public offering and sold 7,843,138 ADSs. In addition, the underwriters exercised their option to purchase an additional 1,176,470 ADSs from the Company;

(c) on January 27, 2020, we completed a follow-on public offering and sold 5,500,000 ADSs. QM11 Limited, a shareholder of the Company, also offered 500,000 ADSs. In addition, the underwriters exercised their option to purchase an additional 800,000 ADSs and 100,000 ADSs from the Company and QM11 Limited, respectively; and

(d) on September 4, 2020, our Shareholders passed a resolution to, conditional upon Listing, increase the authorized share capital of our Company from US$5,000 divided into 83,333,333 Shares of a par value of US$0.00006 each to US$30,000 divided into 500,000,000 Shares of a par value of US$0.00006 each.

3. Changes in share capital of our subsidiaries

The following alterations in the share capital of our subsidiaries have taken place within the two years immediately preceding the date of this prospectus:

Zai Lab Shanghai

On January 28, 2019, the registered capital of Zai Lab Shanghai increased from US$66.5 million to US$116.5 million. On February 17, 2020, the registered capital of Zai Lab Shanghai increased from US$116.5 million to US$166.5 million.

Zai Lab Suzhou

On May 28, 2019, the registered capital of Zai Lab Suzhou increased from RMB63.97 million to RMB166.5 million.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of our material contract

The following contract (not being a contract entered into in the ordinary course of business) was entered into by members of our Group within the two years preceding the date of this prospectus which is or may be material:

(a) the Hong Kong Underwriting Agreement.

2. Intellectual property rights

(a) Trademarks

As at the Latest Practicable Date, we are the owner of the following material registered trademarks, details of which are as follows:

Trademark		Registered Owner	Place of Registration
再鼎医药	再鼎医药	The Company Zai Lab Shanghai	Hong Kong PRC
zai Lab	zaiLab	The Company Zai Lab Shanghai	Hong Kong PRC
ZAI LAB	ZAI LAB	The Company Zai Lab Shanghai	Hong Kong PRC

(b) Copyrights

As at the Latest Practicable Date, we had not registered any copyrights which we consider to be or may be material to our business.

(c) Domain names

As at the Latest Practicable Date, the following were the key domain name registration of our Group:

http://www.zailaboratory.com

(d) Patents

For a discussion of the details of our granted material patents and filed material patent applications in connection with our products and drug candidates, please refer to the section headed "Business – Intellectual Property – Patents – Summary of granted material patents and filed material patent applications of our products and drug candidates."

Save as aforesaid, as at the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our Group's business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS AND EXECUTIVE OFFICERS

1. Directors' service contracts

We have entered into employment agreements with each of our executive officers and our directors (other than our non-employee directors). See "Directors and Senior Management – B. Compensation – Employment Arrangements with Our Executive Officers."

2. Remuneration of Directors

See "Directors and Senior Management – B. Compensation" for a discussion of Directors' remuneration.

3. Disclosure of interests

See "Major Shareholders" for disclosure of interests of directors and executive officers.

4. Disclosure relating to Directors and Experts

Save as disclosed in this prospectus, as at the Latest Practicable Date:

(a) none of the Directors or experts referred to in the sub-section headed "E. Other Information – 7. Qualifications of Experts" in this Appendix has any direct or indirect interest in the promotion of our Company, or in any assets which have within the two years immediately preceding the date of this prospectus been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;

(b) none of the Directors or experts referred to in the sub-section headed "E. Other Information – 7. Qualifications of Experts" in this Appendix is materially interested in any contract or arrangement subsisting at the date of this prospectus which is significant in relation to the business of our Group taken as a whole; and

(c) none of the experts referred to under the section headed "E. Other Information – 7. Qualifications of Experts" in this prospectus has any shareholding in any member of our Group or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

D. SHARE INCENTIVE PLANS AND OTHER COMPENSATION PROGRAMS

2017 Equity Plan

The following summary describes the material terms of the Zai Lab Limited 2017 Equity Plan, which is the only equity plan under which our Company currently grants equity awards.

Purposes. The purposes of our 2017 Equity Plan are to attract, retain and reward key employees and directors of, and consultants and advisors to, our Company and our subsidiaries, to incentivize them to generate shareholder value, to enable them to participate in the growth of our Company and to align their interests with the interests of our shareholders.

Administration. Our 2017 Equity Plan is administered by our compensation committee, which has the discretionary authority to interpret our 2017 Equity Plan, determine eligibility for and grant awards, determine, modify and waive the terms and conditions of any award, determine the form of settlement of awards, designate whether an award will be over, or with respect to, ordinary shares or ADSs, prescribe forms, rules and procedures relating to our 2017 Equity Plan and awards and otherwise do all things necessary or desirable to carry out the purposes of our 2017 Equity Plan. Our compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board of directors and, to the extent permitted by law, officers of our Company, and may delegate to employees and other persons such ministerial tasks as it deems appropriate. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

Eligibility. Key employees, directors, consultants and advisors of our Company and our subsidiaries are eligible to participate in our 2017 Equity Plan. Eligibility for stock options intended to be incentive stock options, or ISOs, is limited to employees of our Company or certain affiliates. Eligibility for stock options, other than ISOs, and stock appreciation rights, or SARs, is limited to individuals who are providing direct services on the date of grant of the award to our Company or certain affiliates.

Authorized shares. Subject to adjustment as described below, the maximum number of shares that may be delivered in satisfaction of awards under our 2017 Equity Plan is 1,924,327 shares, plus an annual increase, to be added as of January 1st of each year from January 1, 2018 to January 1, 2027, equal to the lesser of (i) four percent (4%) of the number of shares outstanding as of the close of business on the immediately preceding December 31st; and (ii) the number of shares determined by our board of directors on or prior to such date for such year. For purposes of our 2017 Equity Plan, "share" means a share of our common stock (an "ordinary share"), unless there are ADSs representing ordinary shares available, in which case "share" means the number of ADSs equal to an ordinary share. If the ratio of ADSs to ordinary shares is not 1:1, then (a) the maximum number of shares that may be delivered under our 2017 Equity Plan, (b) all award adjustments made pursuant to our 2017 Equity Plan; and (c) all awards designated as awards over ordinary shares will automatically be adjusted to reflect the ratio of the ADSs to ordinary shares, as reasonably determined by the Administrator. Up to the total number of shares available for awards under the plan may be delivered in satisfaction of ISOs.

Subject to applicable laws, shares delivered under our 2017 Equity Plan may be newly issued ordinary shares, previously issued ordinary shares acquired by us or ADSs. Any shares underlying awards that are settled or that expire, become unexercisable, terminate or are forfeited or repurchased by us, in each case without the delivery of shares, will again be available for issuance under our 2017 Equity Plan. In addition, the number of shares delivered in satisfaction of awards will be determined net of shares withheld by us in payment of the exercise price or purchase price of an award or in satisfaction of tax withholding requirements with respect to an award.

Individual limits. The maximum number of shares subject to share options that may be granted to any participant in our 2017 Equity Plan in any calendar year is 577,298 shares and the maximum number of shares subject to SARs that may be granted to any participant in any calendar year is 288,649 shares. The maximum number of shares subject to awards other than share options and SARs that may be granted to any participant in any calendar year is 288,649 shares.

Director limits. In addition to the individual limits described above, the maximum grant date fair value of awards granted under our 2017 Equity Plan to any non-employee director of our Company in respect of his or her service as a director with respect to any calendar year may not exceed US$500,000, assuming maximum payout.

Types of awards. Our 2017 Equity Plan provides for the grant of share options, SARs, restricted and unrestricted shares and share units, performance awards, and other awards that are convertible into or otherwise based on our shares. Dividend equivalents may also be provided in connection with awards under our 2017 Equity Plan.

1. *Stock options and SARs*. The Administrator may grant share options, including ISOs, and SARs. A share option is a right entitling the holder to acquire shares upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price of each share option, and the base value of each SAR, granted under our 2017 Equity Plan shall be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, share options and SARs granted under our 2017 Equity Plan may not be repriced or substituted for with new share options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any share options or SARs that have a per share exercise or base price greater than the fair market value of a share on the date of such cancellation, in each case, without shareholder approval. Each share option and SAR will have a maximum term of not more than ten years from the date of grant (or five years, in the case of certain ISOs).

2. *Restricted and unrestricted shares and share units*. The Administrator may grant awards of shares, share units, restricted shares and restricted share units. A share unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted share unit is a share unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted shares are shares that are subject to restrictions requiring that they be redelivered or offered for sale to our Company if specified conditions are not satisfied.

3. *Performance awards*. The Administrator may grant performance awards, which are awards subject to performance criteria.

4. *Other stock-based awards*. The Administrator may grant other awards that are convertible into or otherwise based on shares, subject to such terms and conditions as it determines.

5. *Substitute awards*. The Administrator may grant substitute awards, which may have terms and conditions that are inconsistent with the terms and conditions of our 2017 Equity Plan.

Vesting; terms of awards. The Administrator determines the terms of all awards granted under our 2017 Equity Plan, including the time or times an award vests or becomes exercisable, the terms on which an award remains exercisable, and the effect of termination of a participant's employment or service on an award. The Administrator may at any time accelerate the vesting or exercisability of an award.

Transferability of awards. Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

Section 162(m). During a transition period following the completion of our initial public offering, the Administrator may grant awards under our 2017 Equity Plan that are exempt from Section 162(m) of the Code and its requirements under a special transition rule.

Effect of certain transactions. In the event of certain covered transactions (including the consummation of a merger, consolidation, or the sale of substantially all of our Company's assets or shares, a change in ownership of our Company's shares, or the dissolution or liquidation of our Company), the Administrator may, with respect to outstanding awards, provide for (in each case, on such terms and subject to such conditions as it deems appropriate):

1. The assumption, substitution or continuation of some or all awards (or any portion thereof) by the acquirer or surviving entity;

2. The acceleration of exercisability or delivery of shares in respect of any award, in full or in part; and/or

3. The cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the Administrator may otherwise determine, each award will automatically terminate immediately upon the consummation of the covered transaction, other than awards that are substituted for or assumed.

Adjustment provisions. In the event of certain corporate transactions, including an extraordinary cash dividend, share dividend, share split or combination of shares (including a reverse share split), recapitalization or other change in our capital structure, the Administrator shall make appropriate adjustments to the maximum number of shares that may be issued under our 2017 Equity Plan, the individual award limits, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of, outstanding awards, and any other provisions affected by such event.

Clawback. The Administrator may provide that any outstanding award or the proceeds of any award or shares acquired thereunder will be subject to forfeiture and disgorgement to our Company if the participant to whom the award was granted violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

Amendments and termination. The Administrator may at any time amend our 2017 Equity Plan or any outstanding award and may at any time terminate our 2017 Equity Plan as to future grants. However, except as expressly provided in our 2017 Equity Plan, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent (unless the Administrator expressly reserved the right to do so at the time the award was granted). Any amendments to our 2017 Equity Plan will be conditioned on shareholder approval to the extent required by law or applicable stock exchange requirements.

Outstanding awards. The following table summarizes the outstanding share options and restricted shares held by our directors and executive officers, as well as by their affiliates, as of the Latest Practicable Date.

Name	Ordinary shares underlying outstanding awards, which represent options unless otherwise indicated	Purchase price (US$/share)	Exercise price (US$/share)	Date of grant[1]
Samantha Du . .	4,092,392	N/A	$0.60 – $44.94	October 22, 2015 – March 12, 2020
Billy Cho	*	N/A	$21.84 – $44.94	March 2, 2018 – March 12, 2020
	*[2]	N/A	N/A	March 2, 2018
Tao Fu	*[2]	N/A	N/A	September 20, 2017 – September 24, 2018
	*	N/A	$18.92	September 24, 2018
Yongjiang Hei . .	*	N/A	$22.00	August 6, 2018
	*[2]	N/A	N/A	August 6, 2018
William Liang . .	*	N/A	$23.80 – $44.94	June 4, 2018 – March 12, 2020
	*[2]	N/A	N/A	June 4, 2018
Harald Reinhart .	*	N/A	$3.00 – $20.9	May 12, 2017 – November 16, 2018
Kai-Xian Chen .	*[2]	N/A	N/A	January 1, 2020
John Diekman . .	*[2]	N/A	N/A	September 20, 2017 – January 1, 2020
William Lis . . .	*[2]	N/A	N/A	January 1, 2020
Leon O. Moulder. Jr . .	*[2]	N/A	N/A	January 13, 2020
Peter Wirth . . .	*[2]	N/A	N/A	January 1, 2020
F. Ty Edmondson	*[2]	N/A	N/A	August 17, 2020
	*	N/A	$82.5	August 17, 2020

* Less than 1% of our outstanding Shares.

(1) Options expire on or before the 10-year anniversary of the grant date.

(2) Represents restricted shares.

Other Compensation Programs

2017 Cash Bonus Plan

Our board of directors has adopted and our shareholders have approved the Zai Lab Limited 2017 Cash Bonus Plan, or our Cash Plan. Annual award opportunities for executive officers and key employees of our Company and its subsidiaries are granted under our Cash Plan. The following summary describes the material terms of our Cash Plan. This summary is not a complete description of all provisions of our Cash Plan and is qualified in its entirety by reference to our Cash Plan, which is filed as an exhibit to this Annual Report on Form 20-F.

Administration. Our Cash Plan will be administered by our compensation committee and its delegates. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable. The Administrator will have the discretionary authority to interpret our Cash Plan, determine eligibility for and grant awards, determine, modify or waive the terms and conditions of any award, prescribe forms, rules and procedures relating to our Cash Plan and awards, and otherwise do all things necessary or appropriate to carry out the purposes of our Cash Plan.

Eligibility and participation. Executive officers and key employees of our Company and our subsidiaries will be eligible to participate in our Cash Plan and will be selected from time to time by the Administrator to participate in the plan.

Awards. For each award granted under our Cash Plan, the Administrator will establish the performance criteria applicable to the award, the amount or amounts payable if the performance criteria are achieved and such other terms and conditions as the Administrator deems appropriate.

Performance criteria. Awards under our Cash Plan will be made based on, and subject to achieving, specified criteria established by the Administrator, including measures of performance relating to any, or any combination of, the following (measured either absolutely or comparatively (including, without limitation, by reference to an index or indices or the performance of one or more companies) and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof and subject to such adjustments, if any, as the Administrator specifies): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; share or ADS price; shareholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or strategic business criteria, consisting of one or more objectives based on: meeting specified market penetration or value added, product development or introduction

(including, without limitation any clinical trial accomplishments, regulatory or other filings or approvals, or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, patent application or issuance goals.

Payments under an award; individual limits. A participant will be entitled to payment under an award only if all conditions to payment have been satisfied in accordance with our Cash Plan and the terms of the award. Following the end of a performance period, the Administrator will determine whether and to what extent the applicable performance criteria have been satisfied and will determine the amount payable under each award.

Recovery of compensation. Payments in respect of an award will be subject to forfeiture and disgorgement to our Company if the participant to whom the award was granted violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

Amendment and termination. The Administrator may amend or terminate our Cash Plan at any time, except that any amendment or termination that would materially and adversely affect a participant's rights under an award will require the consent of the affected participant, unless the Administrator expressly reserved the right to so amend the award at the time of grant.

2015 Equity Plan

On March 5, 2015, our board of directors approved the 2015 Equity Plan which is administered by our board. Under the 2015 Equity Plan, our board may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group ("Option Pool"). Subsequently, our board approved the increase in the Option Pool to 7,369,767 ordinary shares.

In May 2017, the Group granted 158,313 share options to certain management and employees of the Group at an exercise price of US$3.0 per share under the 2015 Equity Plan. These options granted have a contractual term of 10 years and generally vest over a four or five year period, with 25% or 20% of the awards vesting on each annual anniversary after the grant date.

In May 2017, the Group granted 4,583 share options to certain individual advisors of the Group at an exercise price of US$3.0 per share. These options granted have a contractual term of 10 years and generally vest over a three year period, with 33.33% of the awards vesting anniversary year after the grant date.

In connection with the completion of the listing of our ADSs on Nasdaq, our board approved the 2017 Equity Plan and all equity-based awards subsequent to the Nasdaq listing were granted under the 2017 Equity Plan.

E. OTHER INFORMATION

1. Litigation

See "Business – Legal Proceedings and Compliance" for further information.

2. Joint Sponsors

The Joint Sponsors have applied on behalf of our Company to the Hong Kong Stock Exchange for the listing of, and permission to deal in, the Shares in issue, the Shares to be issued pursuant to the Global Offering (including the additional Shares that may be issued pursuant to the exercise of the Over-allotment Option), and the Shares to be issued pursuant to the Equity Plans, including pursuant to the exercise of options or other awards that have been or may be granted from time to time. All necessary arrangements have been made to enable the Shares to be admitted into CCASS.

J.P. Morgan Securities (Far East) Limited, Goldman Sachs (Asia) L.L.C. and Citigroup Global Markets Asia Limited satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Hong Kong Listing Rules.

The sponsor fee payable to each of the Joint Sponsors is US$500,000 and is payable by our Company.

3. No material adverse change

Our Directors believe that there has been no material adverse change in the financial or trading position of our Group since June 30, 2020 (being the date on which the latest audited consolidated financial statements of our Group were made up).

4. Preliminary expenses

Our Company did not incur any material preliminary expenses.

5. Binding effect

This prospectus shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (WUMP) Ordinance so far as applicable.

6. Register of members

Our branch register of members will be maintained in Hong Kong by our Hong Kong Share Registrar, Computershare Hong Kong Investor Services Limited. Unless the directors otherwise agree, all transfers and other documents of title of Shares must be lodged for registration with and registered by our share register in Hong Kong and may not be lodged in the Cayman Islands. All necessary arrangements have been made to enable the Shares to be admitted to CCASS.

7. Qualifications of experts

The following are the qualifications of the experts (as defined under the Listing Rules and the Companies (WUMP) Ordinance) who have given opinion or advice which are contained in this prospectus:

Name	Qualification
J.P. Morgan Securities (Far East) Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities) and Type 6 (advising on corporate finance) of the regulated activities under the SFO
Goldman Sachs (Asia) L.L.C.	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities under the SFO
Citigroup Global Markets Asia Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 7 (providing automated trading services) of the regulated activities under the SFO
Deloitte Touche Tohmatsu	Certified Public Accountant and Registered Public Interest Entity Auditor registered in accordance with the Financial Reporting Council Ordinance (Cap. 588)
Zhong Lun Law Firm	Qualified PRC Lawyers
Travers Thorp Alberga	Cayman Islands attorneys-at-law
Frost & Sullivan Limited	Industry Consultant

8. Consents

Each of the experts set out in the section above in this Appendix has given and has not withdrawn their respective consents to the issue of this prospectus with the inclusion of its report and/or letter and/or opinion and/or legal opinion (as the case may be) and references to its name included in the form and context in which it appears.

As at the Latest Practicable Date, none of the experts named in the section headed "Qualifications of experts" in this Appendix had any shareholding interests in any member of our Group or the right or option (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

9. Promoter

Our Company has no promoter for the purpose of the Listing Rules. Within the two years preceding the date of this prospectus, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any promoter in connection with the Global Offering and the related transactions described in this prospectus.

10. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries.

11. Bilingual Prospectus

The English language and Chinese language versions of this prospectus are being published separately, in reliance upon the exemption provided in section 4 of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, Chapter 32L of the Laws of Hong Kong.

12. Miscellaneous

Save as disclosed in this prospectus, within the two years immediately preceding the date of this prospectus:

(i) no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries;

(ii) neither our Company nor any of our subsidiaries have issued or agreed to issue any founder shares, management shares or deferred shares;

(iii) no share or loan capital of our Company is under option or is agreed conditionally or unconditionally to be put under option; and

(iv) there is no arrangement under which future dividends are waived or agreed to be waived.

Our Directors confirm that:

(a) there has not been any interruption in our business that may have or has had a material adverse effect on our financial position in the 12 months immediately preceding the date of this prospectus; and

(b) we and our subsidiaries have no outstanding debentures or convertible debt securities.

The English version of this prospectus shall prevail over the Chinese version.

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to the copy of this prospectus and delivered to the Registrar of Companies in Hong Kong for registration were (i) a copy of the **GREEN** Application Form, (ii) the written consents referred to in paragraph headed "E. Other Information – 8. Consents" of Appendix IV to this prospectus, and (iii) copy of the material contract referred to in paragraph headed "B. Further Information About Our Business – 1. Summary of our material contract" of Appendix IV to this prospectus.

DOCUMENTS AVAILABLE FOR INSPECTION

Copies of the following documents will be available for inspection at the office of Davis Polk & Wardwell, at 18/F, The Hong Kong Club Building, 3A Chater Road, Central, Hong Kong, during normal business hours up to and including the date which is 14 days from the date of the prospectus:

(a) our Memorandum and the Articles;

(b) the Accountants' Report and the assurance report on the compilation of unaudited pro forma financial information of our Group prepared by Deloitte Touche Tohmatsu, the texts of which are set out in Appendices I and II;

(c) the audited consolidated financial statements of our Company for the two financial years ended December 31, 2018 and 2019 and for the six months ended June 30, 2020;

(d) the PRC legal opinion issued by Zhong Lun Law Firm, our PRC legal adviser, on certain aspects of our Group;

(e) the letter of advice prepared by Travers Thorp Alberga, our legal adviser on Cayman Islands law, summarising the constitution of our Company and certain aspects of the Cayman Companies Law referred to in Appendix III;

(f) copy of material contract referred to under the paragraph headed "Appendix IV – Statutory and General Information – B. Further Information About Our Business – 1. Summary of our material contract" in this prospectus;

(g) the written consents referred to under the paragraph headed "Appendix IV – Statutory and General Information – E. Other Information – 8. Consents" in this prospectus;

(h) the industry report prepared by Frost & Sullivan Limited referred to in the section headed "Industry Overview" in this prospectus; and

(i) the Cayman Companies Law.

ZAI LAB LIMITED