As confidentially submitted to the Securities and Exchange Commission on May 30, 2017
Registration No. 333-

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

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Zai Lab Limited

(Exact name of registrant as specified in its charter)

Not applicable
(Translation of Registrant's name into English)

Cayman Islands	**2834**	**98-1144595**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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

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Approximate date of commencement of proposed sale to public: As soon as practicable after this Registration Statement is declared effective.

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

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

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

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

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

Emerging growth company ☒

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

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered(1)			**Proposed maximum aggregate offering price(2)(3)**	**Amount of registration fee**
Ordinary Shares, $0.00001 par value			$	$

(1) American depositary shares issuable upon deposit of the ordinary shares registered hereby have been registered under a separate registration statement on Form F-6 (Registration No. 333-). Each American depositary share represents ordinary shares.

(2) Includes the ordinary shares represented by American depositary shares that may be sold upon exercise of the underwriters' option to purchase additional shares.

(3) Estimated solely for the purpose of determining the amount of registration fee in accordance with Rule 457(o) under the Securities Act.

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

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

Subject to completion
Preliminary prospectus dated , 2017

Prospectus

Zai Lab Limited

American depositary shares
Representing ordinary shares

We are offering American depositary shares, or ADSs. Each ADS represents ordinary shares.

This is our initial public offering in the United States, and no public market currently exists for our ADSs.

We currently expect the initial public offering price to be between $ and $ per ADS. After pricing of the offering, we expect that the shares will trade on the Nasdaq Stock Market under the symbol "ZLAB."

We are eligible to be treated as an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, and, as a result, are subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Foreign Private Issuer."

Investing in our ADSs involves risks that are described in the "Risk Factors" section beginning on page 12 of this prospectus.

	Per ADS	Total
Public offering price	$	$
Underwriting discount(1)	$	$
Proceeds to Zai Lab Limited before expenses	$	$

(1) See "Underwriting" for a detailed description of compensation payable to the underwriters.

To the extent that the underwriters sell more than ADSs, the underwriters have the option to purchase up to an aggregate of additional ADSs from us at the initial public offering price less the underwriting discounts and commissions for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission 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.

The underwriters expect to deliver the ADSs to the purchasers on or about , 2017.

J.P. Morgan **Citigroup** **Leerink Partners**

The date of this prospectus is , 2017

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

Through and including (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Industry and market data

Although we are responsible for all disclosure contained in this prospectus, in some cases we have relied on certain market and industry data obtained from third-party sources that we believe to be reliable. Market estimates are calculated by using independent industry publications, government publications and third-party forecasts in conjunction with our assumptions about our markets. While we are not aware of any misstatements regarding any market, industry or similar data presented herein, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the headings “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors” in this prospectus.

Trademarks and service marks

We own or have rights to trademarks and service marks for use in connection with the operation of our business, including, but not limited to, ZAI LAB and 再鼎医药 .. All other trademarks or service marks appearing in this prospectus that are not identified as marks owned by us are the property of their respective owners.

Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may be listed without the ®, (TM) and (sm) symbols, but we will assert, to the fullest extent under applicable law, our applicable rights in these trademarks, service marks and trade names.

Prospectus summary

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

Overview of our business

We are an innovative biopharmaceutical company based in Shanghai focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China market, including in the areas of oncology, autoimmune and infectious diseases. We believe there exists a significant opportunity to build an organization that not only addresses such unmet needs but leverages underutilized resources in China to foster innovation. As part of that effort, we have assembled a management team with global experience and an extensive track record in navigating the regulatory process to develop and commercialize innovative drugs in China. Our mission is to leverage our expertise and insight to address the expanding needs of Chinese patients in order to transform their lives and eventually utilize our China-based competencies to impact human health worldwide.

Furthermore, Zai Lab was built on the vision that, despite having a significant addressable market and sizable growth potential, China has historically lacked access to many innovative therapies available in other parts of the world and its drug development infrastructure has been underutilized. There remains the need to bring new and transformative therapies to China. In recent years, the Chinese government has focused on promoting local innovation through streamlining regulatory processes, improving drug quality standards and fostering a favorable environment, which we believe creates an attractive opportunity for the growth of China-based, innovation-focused companies.

Since our founding in 2014, we have assembled an innovative pipeline consisting of six drug candidates through partnerships with global biopharmaceutical companies. These include three late-stage assets targeting fast growing segments of China's pharmaceutical market, and three assets addressing global unmet medical needs. We believe that our management's extensive global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, opportunities to partner with global companies aiming to bring innovative products to market in China efficiently. Our lead drug candidate is niraparib, a PARP inhibitor licensed from Tesaro. We intend to develop niraparib for Chinese patients across multiple tumor types and anticipate beginning two Phase III studies of niraparib in patients with ovarian cancer, one in the second half of 2017 and the other in the first half of 2018. In addition, we intend to pursue niraparib in other indications.

In the longer term, we plan to build a premier, fully integrated drug discovery and development platform that brings both in-licensed and internally-discovered medicines to patients in China and globally. As our business grows, we plan to build our own commercial team to launch our portfolio of drug products. Part of our strategy is the ability to produce both large and small molecule therapeutics under global standard current Good Manufacturing Practice, or cGMP. To this end, in the first half of 2017 we built a small molecule drug product facility capable of supporting clinical and commercial production and have also begun construction of a large molecule facility, which is expected to be utilized for clinical production of our drug candidates. The completion of the large molecule facility is expected in the first half of 2018.

Our company is led by a management team with extensive pharmaceutical research, development and commercialization track record in both global and Chinese biopharmaceutical companies.

Since our founding, we have raised $134.5 million in equity financing from our dedicated group of investors, including global and China-based healthcare funds.

Our innovative pipeline

We have a broad pipeline of proprietary drug candidates that range from discovery stage to late-stage clinical programs. These include three drug candidates with greater China rights and three drug candidates with global rights. The following table summarizes our drug candidates and programs:

Program	Commercial rights	Indication	Zai Lab clinical stage	Partnerships	Partner clinical stage
ZL-2306 (Niraparib)	China	Ovarian cancer	Phase 3(1)	TESARO	Commercial
		Breast cancer	Phase 3(1)		Phase 3
		Lung cancer	Phase 2(1)		Phase 2
ZL-2401 (Omadacycline)	China	ABSSSI	Phase 3(2)	PARATEK	Phase 3
		CABP	Phase 3(2)		Phase 3
ZL-2301	China	HCC	Phase 2	Bristol-Myers Squibb	Phase 3
ZL-3101 (Fugan)	Global	Eczema, Psoriasis	Phase 2	gsk	
ZL-2302	Global	NSCLC	Pre-clinical	SANOFI	
ZL-1101	Global	GVHD, SLE	Pre-clinical	ucb	
Internal Discovery Programs	Global	Multiple (Immuno-oncology)	Pre-clinical		

(1) Pending clinical trial application, or CTA, approval from the China Food and Drug Administration, or CFDA, to initiate the clinical trials.

(2) Pending submission of CTA and approval from CFDA.

- **Niraparib (ZL-2306)** is a highly potent and selective oral, small molecule poly ADP ribose polymerase, or PARP 1/2, inhibitor with the potential to be a first-in-class drug for treatment across multiple solid tumor types in China including ovarian, certain types of breast and lung cancers. We have licensed niraparib from Tesaro, which in March 2017 received marketing approval for niraparib (Zejula®) from the U.S. Food and Drug Administration, or FDA, as maintenance treatment for women with recurrent platinum-sensitive epithelial ovarian cancer. Niraparib was commercially launched in the United States in April 2017. Niraparib does not require BRCA mutation or other biomarker testing as is necessary for other approved PARP inhibitors which,

we believe, significantly expands its availability to ovarian cancer patients in China. During the second half of 2018, we expect to commercialize niraparib for the treatment of ovarian cancer in Hong Kong and Macau where the drug will be eligible for an expedited registration process after being approved by the FDA and the European Medicines Agency, or EMA. In China, our CTA for niraparib has been accepted as a Category 1 drug by the CFDA. We anticipate initiating Phase III studies of niraparib in patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy in the second half of 2017, and as a first-line maintenance therapy in the first half of 2018. These studies are expected to be similar in design to Tesaro's clinical studies of niraparib. We also anticipate beginning a Phase III study in patients with gBRCA positive breast cancer in the first half of 2018. In addition, we intend to study niraparib in patients with triple negative breast cancer, squamous-type non-small cell lung cancer and small cell lung cancer in China. Niraparib has the potential to be the first PARP inhibitor marketed in China. In addition to niraparib monotherapy in the potential indications stated, we also intend to explore the combination of niraparib with other potential therapies such as immune-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

- **Omadacycline (ZL-2401)** is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. We have licensed omadacycline from Paratek which is primarily being developed for acute bacterial skin/skin structure infections, or ABSSSI, community-acquired bacterial pneumonia, or CABP, and urinary tract infections, or UTIs. Omadacycline is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. Omadacycline has been granted Qualified Infectious Disease Product, or QIDP, status in the United States and has been granted Fast Track status by the FDA. If approved, omadacycline is expected to be available in intravenous, or IV, and once-daily oral, or PO, formulations. Paratek has reported the results of two pivotal Phase III studies of omadacycline in ABSSSI and CABP. Both trials used an IV/oral sequential dosing design. Both of these studies achieved their primary endpoints. Paratek anticipates reporting top-line data from its oral-only Phase III ABSSSI study in mid-2017. We are in the technology transfer stage and plan to discuss our China development plan with key opinion leaders and the CFDA.
- **ZL-2301** is an oral, small molecule dual target tyrosine kinase inhibitor, or TKI, which blocks both vascular endothelial growth factor receptor, or VEGFR, and fibroblast growth factor receptor, or FGFR. ZL-2301 was studied by our partner Bristol-Myers Squibb mainly for the treatment of hepatocellular carcinoma, or HCC, the most common type of liver cancer. In these trials, ZL-2301 demonstrated anti-tumor activity and a generally well-established safety profile in HCC patients. In 2012, Bristol-Myers Squibb terminated its development program of ZL-2301 after it missed the primary endpoints in two Phase III trials with advanced HCC patients. Based on our review of the results from Bristol-Myers Squibb's development program for ZL-2301, our understanding of the etiology and current standard of care of HCC in Chinese patients and our ongoing research, we believe that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical trials. The CFDA has approved our CTA for ZL-2301 as a Category 1 drug, and in the second quarter of 2017 we initiated a Phase II trial of ZL-2301 as a second-line treatment for advanced HCC patients in China. Pending results from this Phase II trial, we plan to initiate a Phase III clinical trial shortly thereafter.
- **Fugan (ZL-3101)** is a novel steroid-sparing topical product for the treatment of eczema and psoriasis. We are developing fugan as a botanical formulation to offer patients with eczema and psoriasis a natural alternative to topical steroid treatments, which are currently the main forms of treatment and are known to have many side effects associated with long-term use. We licensed the exclusive worldwide rights to fugan from GSK in 2016. We initiated a Phase II study of fugan in patients with eczema in China in the second quarter of 2017. Pending results from this Phase II study, we plan to initiate a Phase III global, multi-center clinical trial.

- **ZL-2302** is a multi-targeted TKI with activity against both anaplastic lymphoma kinase, or ALK, mutation and crizotinib-resistant ALK mutations being developed for the treatment of patients with non-small cell lung cancer who have ALK mutations and who have developed crizotinib resistance and/or brain metastasis. We licensed the exclusive worldwide rights to ZL-2302 from Sanofi in 2015. Our preclinical studies demonstrated that ZL-2302 has ability to penetrate the blood-brain barrier, which could make ZL-2302 an effective therapy for a subset of patients who have non-small cell lung cancer with ALK mutations and brain metastasis. Such patients typically have limited treatment options, poor prognosis and low quality of life. Our CTA for ZL-2302 has been accepted as a Category 1 drug by the CFDA, and we expect to initiate a Phase I study of ZL-2302 in China in the first half of 2018.
- **ZL-1101** is an anti-OX40 antagonistic antibody with first-in-class potential for the treatment of a range of autoimmune diseases such as graft-versus-host disease or systemic lupus erythematosus. We licensed the exclusive worldwide rights to ZL-1101 from UCB in 2015. Its anti-inflammatory activities have been validated by a variety of inflammatory and autoimmune disease models. ZL-1101's bioactivities and functional potency have been investigated both *in vitro* and *in vivo* studies. In such studies, cellular proliferation and production of inflammatory cytokines was markedly suppressed, demonstrating that ZL-1101 effectively inhibits lymphocyte activation. ZL-1101 was also found to be highly potent. We intend to file an IND in 2018.

Industry

As an innovative biopharmaceutical company, we believe we are well positioned to take advantage of industry trends which are favorable to China-based innovation.

Evolution of China's emerging innovative pharmaceutical market

China's pharmaceutical market is the second largest pharmaceutical market in the world and is projected to grow from $115 billion in 2016 to $160 billion by 2021 and $237 billion by 2026, according to BMI Research. This growth is driven by strong fundamental demand for therapeutic treatments and the Chinese government's focus on providing better quality care to patients including by encouraging greater usage of innovative drugs. We believe that the significant market opportunities for innovative therapies in the China market are due to several trends, including demographics and disease incidence, improving access to healthcare, increasing affordability and demand for healthcare and focusing on innovation.

Historically, China's pharmaceutical market was dominated by mature and generic products. In recent years, the Chinese government has focused on promoting innovation especially in areas of high unmet medical need through streamlining regulatory processes, improving drug quality standards and fostering a favorable environment for innovation. Going forward, innovative patented therapeutics are projected to grow at over 10% annually until 2020, which is expected to surpass the growth rate of generic products.

CFDA regulatory outlook—CFDA reform to accelerate innovation

In August 2015 China's State Council released its circular *Opinions Concerning the Reform of the Review and Approval System for Drugs and Medical Devices*, or Circular No. 44, which sets forth the government's clear determination to encourage transformation and upgrade the pharmaceutical industry.

More recently, on May 11, 2017, the CFDA issued three new draft policies regarding innovation for public comments. The three draft policies aim to accelerate the review and approval of new drug and medical device applications (Circular No. 52), deregulate the conduct of clinical trials to encourage innovation (Circular No. 53), and enhance post-market supervision throughout a product's entire life cycle (Circular No. 54).

If the draft polices are adopted, the regulatory process will be further streamlined and speed-to-market of new products is expected to accelerate. Furthermore, these circulars appear to demonstrate the CFDA's direction of gradually conforming to ICH guidelines. Consequently, we believe that not only will this benefit pharmaceutical innovation in China but will also be especially advantageous for China based companies that are experienced with global standards of innovative drug development.

Medical insurance and drug spending outlook—multiple engines for improving affordability for innovation

Over the past decade, the Chinese national government has been working on alleviating the burden on individuals by expanding health insurance coverage from approximately 30% in 2003 to over 95% in 2013 with a goal of achieving universal coverage by 2020. At the same time, medical insurance plans at the provincial level have been introduced to complement the basic insurance programs. This increase in health insurance coverage has had a dramatic impact on drug reimbursement and affordability in China.

Aside from the Chinese government's efforts to improve public reimbursement, a large part of China's population has become increasingly affluent and has demonstrated an ability and willingness to pay out-of-pocket for innovative efficacious drugs.

In addition to government health insurance and self-pay, there is also growing government support for the development of commercial private health insurance to provide support for China's growing middle and upper classes. Favorable industry policies such as tax incentives to consumers have been issued.

The advantages of being a China-based, innovation-focused biopharmaceutical platform

China has undertaken significant efforts to encourage innovation and stimulate greater productivity in its economy to transform the competitive landscape of the domestic pharmaceutical market, with incentives which include grants, tax incentives and supporting greater investment and global talent recruitment. We expect that this multi-pronged approach will support the emergence of innovative, globally competitive China-based biopharmaceutical companies.

Some of the key advantages of being a fully integrated, China-based and innovation-focused biopharmaceutical development and manufacturing platform include:

- Accelerated time to market;
- Market exclusivity for up to five years for Category 1 drugs;
- Customized development programs which are tailored to Chinese patients' specific unmet medical needs, and higher efficiency in executing clinical development programs; and
- Commercialization of innovative therapies.

Our vision and strategy

Our vision is to become a leading global innovative biopharmaceutical company based in China and deliver transformative medicines to patients in China and around the world. We intend to utilize our strengths to pursue the following strategies:

- ***Rapidly advance and commercialize our in-licensed late stage clinical drug candidates.*** We have built a broad and sustainable drug pipeline for the greater China and global market and will focus on rapidly advancing and commercializing our in-licensed drug candidates.

- ***Capitalize on our location in China, our management team's domestic and international drug development experience and our track record of licensing to further solidify our position as a strategic gateway partner into China for biopharmaceutical companies outside of China.*** We believe the combination of our management's experience and knowledge, the changing regulatory landscape in China, our manufacturing capabilities, the commercial capabilities we are developing and the global pharmaceutical industry's current approach to the China market makes us an ideal gateway partner for global biopharmaceutical companies seeking to access the China market.
- ***Continue to license promising programs for global rights.*** We have a track record of in-licensing the global rights of drug candidates from leading global biopharmaceutical companies such as GSK, Sanofi and UCB. We will continue to seek new in-licensing opportunities which grant us the global rights for differentiated drug candidates for which we can utilize the advantages of development in China to establish proof of concept prior to pursuing further late-stage development for the global market.
- ***Build a fully integrated platform with drug discovery, development, manufacturing and commercialization capabilities in China and expand globally.*** We will continue to execute our strategy to become a fully integrated biopharmaceutical company in China serving the global market. By focusing on developing and commercializing our late-stage in-licensed drug candidates in parallel with expanding our earlier-stage internal research and discovery capabilities, we believe we can rapidly establish a fully integrated manufacturing and commercialization platform.
- ***Leverage our senior management's experience.*** Our management team has extensive experience in the pharmaceutical industry in the United States and China, and is led by our Chief Executive Officer, Samantha Du, Ph.D., who is widely recognized as a leading figure in the China biotech industry.

Risks associated with our business

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

- 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.
- Even if we consummate this offering, we will likely need substantial additional funding for our drug development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.
- We have a very limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- All of our drug candidates are still in development. If we are unable to obtain regulatory approval and ultimately commercialize our drug candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially adversely harmed.
- If we breach our license or other intellectual property-related agreements for our drug candidates or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our drug candidates.

- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- In addition to in-licensing or acquiring drug candidates, we may engage in future business acquisitions that could disrupt our business, cause dilution to our ADS holders and harm our financial condition and operating results.
- Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our 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.
- The PRC'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.

Corporate information

Zai Lab Limited was incorporated in the Cayman Islands on March 28, 2013 as an exempted company with limited liability under the Companies Law, Cap 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands, which we refer to as the Companies Law. The address of our registered office in the Cayman Islands is P.O. Box 311 19 Grand Pavilion, Hibiscus West Bay Road, Grand Cayman KY1-1205, Cayman Islands. Our principal executive offices are located at 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210. Our telephone number at that address is +86 21 6163 2588.

Investor inquiries should be directed to us at the address and telephone number of our principal executive offices set forth above. Our website address is www.zailaboratory.com. Our website and the information contained on our website do not constitute a part of this prospectus. Our agent for service of process in the United States is , located at .

Implications of being an emerging growth company and a foreign private issuer

As a company with less than US$1.07 billion in revenue during our most recently completed fiscal year as of the initial filing date of the registration statement of which this prospectus forms a part, we qualify as an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, which we refer to as the Securities Act, as modified by the Jumpstart our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies that are not emerging growth companies. These provisions include exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting. The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies.

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. As a foreign private issuer, we may take advantage of certain provisions in the Nasdaq listing rules that allow us to follow Cayman Islands law for

certain corporate governance matters. See “Management—Foreign Private Issuer Status.” Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

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

The offering

ADSs offered by us	ADSs.
Price per ADS	$
ADSs to be outstanding immediately after completion of this offering	ADSs (ADSs if the underwriters exercise their option to purchase additional ADSs in full).
Ordinary shares to be outstanding immediately after completion of this offering	ordinary shares (ADSs if the underwriters exercise their option to purchase additional ADSs in full).
The ADSs	Each ADS represents ordinary shares, par value $0.00001 per share. The ADSs may be evidenced by ADRs. The depositary will hold the ordinary shares underlying your ADSs, and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and owners and holders of ADSs from time to time. If we declare dividends on our ordinary shares, the depositary will pay you the cash dividends and other distributions it receives on our ordinary shares, after deducting its fees and expenses. You may turn in your ADSs to the depositary in exchange of ordinary shares. The depositary will charge you fees for any exchange. We may amend or terminate the deposit agreement without your consent. If an amendment becomes effective and you continue to hold your ADSs, you will be bound by the deposit agreement as amended. To better understand the terms of the ADSs, you should carefully read “Description of American Depositary Receipts” in this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement that includes this prospectus.
Depositary	
Option to purchase additional ADSs	The underwriters have an option for a period of 30 days after the date of this prospectus to purchase up to an additional ADSs.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional ADSs in full, at an assumed initial public offering price of $ per ADS, the midpoint of the price range set forth on the cover of

	this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering to advance the clinical development of our multiple drug candidates and for working capital and other general corporate purposes. See “Use of Proceeds” for additional information.
Dividend Policy	We do not expect to pay any dividends on our ADSs in the foreseeable future.
Risk factors	You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in our ADSs.
Proposed Nasdaq trading symbol	We have applied for listing of the ADSs on the Nasdaq Stock Market under the symbol “ZLAB.”

The number of ordinary shares outstanding after this offering is based on 71,800,000 ordinary shares outstanding as of December 31, 2016, and excludes:

- 43,368,862 shares issuable upon the exercise of options outstanding as of December 31, 2016 pursuant to our 2015 Equity Incentive Plan (the “2015 Plan”) at a weighted-average exercise price of $0.16 per share; and
- shares reserved for future issuance under our 2017 Equity Incentive Plan (the “2017 Plan”), which includes shares reserved for issuance under our 2015 Plan that will become available under our 2017 Plan upon the closing of this offering).

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the effectiveness of our third amended and restated memorandum and articles of association, which will occur immediately prior to the closing of this offering;
- the conversion of our outstanding preferred shares into an aggregate of 158,665,951 ordinary shares upon the closing of this offering;
- 2,770,851 shares issuable upon the exercise of outstanding warrants as of March 31, 2017 at an exercise price of $0.3609 per share;
- no issuance or exercise of options on or after March 31, 2017; and
- no exercise by the underwriters of their option to purchase up to an additional ADSs in this offering.

Our summary consolidated financial data

The following summary consolidated financial data for the years ended December 31, 2015 and December 31, 2016 and the selected balance sheet data as of December 31, 2015 and December 31, 2016 have been derived from our audited consolidated financial statements appearing elsewhere in this prospectus. Our consolidated financial statements appearing in this prospectus have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period. The following information should be read in conjunction with "Risk Factors," "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,	
(in thousands, except share and per share data)	**2015**	**2016**
Research and development expenses	$ (13,587)	$ (32,149)
General and administrative expenses	(2,762)	(6,380)
Loss from operations	(16,349)	(38,529)
Interest income	5	403
Fair value of warrants	(1,980)	(1,920)
Other income	341	2,534
Other expense	(39)	—
Loss before income taxes	(18,022)	(37,512)
Income tax expense	—	—
Net loss	$ (18,022)	$ (37,512)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted(1)	52,161,918	56,634,142
Net loss per share, basic and diluted(1)	(0.35)	(0.66)

	As of December 31,	
(in thousands)	**2015**	**2016**
Balance sheet data:		
Cash and cash equivalents	$ 13,161	$ 83,949
Total assets	13,940	88,907
Total shareholders' deficit	(18,370)	(51,552)
Total current liabilities	3,941	5,173
Total non-current liabilities	62	778

(1) See Note 2 within our notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share.

Risk factors

Investing in our ADSs involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our consolidated financial statements and their related notes appearing at the end of this prospectus, before deciding to invest in our ADSs. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our ADSs could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

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.

We are a clinical stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through private placements. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2014. For the two years ended December 31, 2016 and 2015, we reported a net loss of $37.5 million and $18.0 million, respectively.

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

- continue our development and commence clinical trials of our drug candidates;
- seek regulatory approvals for our drug candidates that successfully complete clinical trials;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- complete construction of and maintain our manufacturing facilities;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- establish a sales, marketing and commercialization infrastructure for any products that obtain regulatory approval;
- 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 develop and eventually commercialize drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing and selling those drug candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of

these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development 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.

Even if we consummate this offering, we will likely need substantial additional funding for our drug development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.

To date, we have financed our activities primarily through private placements. Through April 30, 2017, we have raised $134.5 million in equity financing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $11.5 million for the year ended December 31, 2015 and $32.2 million for the year ended December 31, 2016. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our four clinical-stage drug candidates and continue research and development of our preclinical-stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs that may be required for the manufacture of any drug candidate that receives regulatory approval 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 may also incur expenses as we create additional infrastructure to support our operations as a U.S. public company. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts.

We believe our cash and cash equivalents as of December 31, 2016, combined with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements for the next months at a minimum. 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 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 cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;
- the cash received, if any, received from commercial sales of any drug candidates for which we receive regulatory approval;

- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other drug candidates and technologies;
- our headcount growth and associated costs; and
- the costs of operating as a public company in the United States.

Raising additional capital 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 and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that may take years to complete, and our 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, and even if one or more of our drug candidates is approved, they 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our ADSs. The incurrence of additional indebtedness or the issuance of certain equity securities could 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 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.

Risks related to our business and industry

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 2014. Our operations to date have been limited to organizing and staffing our company, identifying potential partnerships and drug candidates, acquiring product and technology rights, and conducting research and development activities for our drug candidates. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials. We have also not yet obtained regulatory approval for, or demonstrated an ability to manufacture or commercialize, any of our drug candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history and/or approved products on the market.

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

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

All of our drug candidates are still in development. Four 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 their receipt of regulatory approval and successfully commercializing 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 completion of pre-clinical and/or clinical studies;
- successful enrollment in, and completion of, clinical trials;
- 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 maintaining 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 dependent upon our ability to develop and commercialize our clinical-stage drug candidates, particularly niraparib, which received FDA approval as maintenance treatment for recurrent

ovarian cancer patients. During the second half of 2018, we expect to commercialize niraparib for the treatment of ovarian cancer in Hong Kong and Macau. We anticipate initiating Phase III studies of niraparib in patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy in the second half of 2017, and as a first-line maintenance therapy in the first half of 2018. We also anticipate initiating a Phase III study in patients with gBRCA positive breast cancer in the first half of 2018. Additionally, we plan to study niraparib in patients with triple negative breast cancer, squamous-type non-small cell lung cancer and small cell lung cancer in China. For omadacycline, we are in the technology transfer stage and plan to discuss our China development plan with key opinion leaders and the CFDA. We initiated a Phase II trial in advanced HCC patients in China to investigate ZL-2301's optimal treatment schedule and dosage as a second-line treatment in the second quarter of 2017 and, pending successful Phase II results, plan to conduct a Phase III registration trial. As a result, our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize niraparib, omadacycline and ZL-2301 and our other drug candidates in a timely manner.

We cannot commercialize drug candidates in China without first obtaining regulatory approval from the CFDA. Similarly, we cannot commercialize drug candidates in the United States or another jurisdiction outside of China without obtaining regulatory approval from the 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 if our drug candidates were to successfully obtain approval or, in the case of niraparib, have obtained 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 CFDA. 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 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 drug candidate or indication and fail to capitalize on 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 and development programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other 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 drug candidates are subject to extensive regulation, and we cannot give any assurance that any of our drug candidates will receive regulatory approval or be successfully commercialized.

Our 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 CFDA, FDA 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 drug candidates in China, the United States and other jurisdictions unless and until we receive regulatory approval from the CFDA, FDA 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 drug candidate's safety and efficacy. Securing regulatory approval may also require the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our 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. Although niraparib was approved in the United States, we cannot provide any assurance that we will ever obtain regulatory approval for niraparib in China or for any of our other 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 if additional clinical trials are required and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the 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 CFDA, FDA 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 drug candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the CFDA, FDA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the CFDA, FDA or comparable regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- failure of contract research organizations, or CROs, clinical study sites or investigators to comply with the ICH-good clinical practice, or GCP, requirements imposed by the CFDA, FDA or comparable regulatory authorities;
- failure of the clinical trial results to meet the level of statistical significance required by the CFDA, FDA or comparable regulatory authorities for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the CFDA, FDA 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 CFDA, FDA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;

- changes in the approval policies or regulations of the CFDA, FDA or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the CFDA, 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, approve any of our drug candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

If safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with our drug candidates, we may be unable to market such 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 drug candidates for use as a combination therapy. For example, Tesaro, Inc., or Tesaro, is currently developing, and we also plan to develop, niraparib as both a monotherapy and in combination with any potential anti-VEGF or PD-1/PD-L1 treatments. However, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any anti-VEGF or PD-1/PD-L1 treatments or any other therapeutic we use in combination with our drug candidates. We may also seek to develop our drug candidates in combination with other therapeutics in the future.

If the CFDA, FDA or another regulatory agency revokes its approval of any anti-VEGF or PD-1/PD-L1 treatments or another therapeutic we use in combination with our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our 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 anti-VEGF or PD-1/PD-L1 treatments or any other combination therapeutics, we may not be able to complete clinical development of niraparib and/or another of our drug candidates on our current timeline or at all.

Even if one or more of our drug candidates were to receive regulatory approval for use in combination with any anti-VEGF or PD-1/PD-L1 treatments, as applicable, or another therapeutic, we would continue to be subject to the risk that the CFDA, FDA or another regulatory agency could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with one of these combination therapeutics. This could result in niraparib or one of our other products being removed from the market or being less successful commercially.

We face substantial competition, which may result in our competitors discovering, developing or commercializing drugs before or more successfully than we do, or develop 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 drug candidates.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current 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 and biotechnology companies worldwide. For example, there are a number of large pharmaceutical

and biotechnology companies that currently market drugs or are pursuing the development of therapies in the field of 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 drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than drugs that we may develop. Our competitors also may obtain CFDA, FDA or other regulatory approval for their 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 potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our 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, ZL-2301 failed to meet its primary endpoint of overall survival noninferiority for ZL-2301 versus sorafenib in Phase III trials in patients with HCC conducted by Bristol-Myers Squibb Company, or Bristol-Myers Squibb, before we licensed the development rights from them. Although we believe that ZL-2301 has the potential to be an effective treatment for Chinese patients and merits further clinical trials patients, we cannot guarantee that our future clinical trials of ZL-2301 in Chinese patients will be successful.

Commencement of clinical trials is subject to finalizing the trial design based on ongoing discussions with the CFDA, FDA and/or other regulatory authorities. The CFDA, 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 analogous filing) to the CFDA, FDA and/or other regulatory authorities for each drug candidate and, consequently, the ultimate approval and commercial marketing 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.

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 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 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 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 drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our 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 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 CFDA, 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, inspection of the clinical trial operations or trial site by the CFDA, 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 CFDA, 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.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that are currently contemplated, if we are unable to successfully complete clinical trials of our 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 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 certain drugs;
- be subject to restrictions on the distribution and/or commercialization of drugs; and/or
- have the drug removed from the market after obtaining regulatory approval.

Our 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 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 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 CFDA, 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. In addition, for our trials studying niraparib in ovarian cancer patients and certain of our other drug candidates, we plan to focus on enrolling patients who have failed their first or second-line treatments, which limits the total size of the patient population available for such trials. 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 drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' 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 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; and
- the proximity and availability of clinical trial sites for prospective patients.

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which could cause the value of our company to decline and limit our ability to obtain additional financing.

Our 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 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 CFDA, FDA or other regulatory authorities. In particular, as is the case with all oncology drugs, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology drug candidates. For example, the known adverse events for niraparib include thrombocytopenia, anemia and neutropenia and for ZL-2301, the known adverse events include hyponatremia, AST elevation, fatigue, hand-foot skin reaction and hypertension. The results of our 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 drug candidates could be suspended or terminated and the CFDA, FDA or comparable regulatory authorities could order us to cease further development of or deny approval of our 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 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. While we believe that the superior selectivity of niraparib has the potential to significantly improve the unfavorable adverse off-target toxicity issues, if patients were to experience off-target toxicity, we may not be able to achieve an effective dosage level (especially in combination therapies), receive approval to market, or achieve the commercial success we anticipate with respect to, any of our drug candidates, which could prevent us from ever generating revenue or achieving profitability. 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 drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our drug candidates receive regulatory approval and 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 CFDA, FDA or other comparable regulatory authorities may withdraw or limit their approval of such drug candidates;
- the CFDA, 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 drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of our drug candidates;
- the CFDA, 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 drug candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates; and
- our reputation may suffer.

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

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

The CFDA categorizes domestically-manufactured 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. Domestically developed and manufactured innovative drugs will be attributed to Category 1 for their CTA and NDA applications. While some multinational pharmaceutical companies may file CTAs with the CFDA prior to approval of a drug in another country in order to take advantage of Category 1 classification, such drug will most likely be assigned to Category 5 for NDA approval purposes because, based on historical observations, multinational pharmaceutical companies will typically not prioritize applying for local manufacturing rights in China, hence subjecting the drug to the imported drug status. Our CTAs for niraparib and ZL-2302 were accepted as Category 1 drugs by the CFDA, and our CTA for ZL-2301 was approved as a Category 1 drug by the CFDA. Other than fugan, all our other clinical stage drug candidates are eligible for Category 1 designation. These two categories have distinct approval pathways. We believe the local drug registration pathway is a faster and more efficient path to approval in the China market

than the imported drug registration pathway. The imported drug registration pathway is more complex and is evolving. Imported drug registration applications in China may only be submitted after a drug has obtained an NDA approval and received the Certificate of Pharmaceutical Product granted by a major drug regulatory authority, such as the FDA. A Category 1 designation by the CFDA may not be granted for any of our drug candidates or may not lead to faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our drug candidates will receive regulatory approval.

Furthermore, there has been recent regulatory initiatives in China, including (i) the China's State Council's August 2015 statement, *Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices*, which declared the Chinese government's clear determination to encourage transformation and upgrade of the pharmaceutical industry, (ii) the CFDA's November 2015 release, *Circular Concerning Several Policies on Drug Registration Review and Approval*, with aims to accelerate the approval process of clinical trials and (iii) the CFDA's February 2016 release, *Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog*, which further clarified that a fast track clinical trial approval or drug registration pathway will be available to certain designated drugs. As such, the regulatory process in China is evolving and subject to change. Any future policies, or changes to current polices, that the CFDA approves 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 any of our 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 drug candidates, we may be subject to penalties.

If the CFDA, FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and GCPs. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV studies for the surveillance and monitoring the safety and efficacy of the drug.

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

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the CFDA, FDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our 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 drug candidates are based on estimates and third-party sources. If the market opportunities for our 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 drug development strategy, including acquiring or in-licensing 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, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

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, Chairman 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 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 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 a U.S. 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, 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.

We have concluded that there is a material weakness in internal control over financial reporting in the past and cannot assure you that additional material weaknesses will not be identified in the future. This weakness may not be timely eliminated and general reputational harm could result or persist, which could materially and adversely affect our business, operations and financial condition. Our failure to implement and maintain effective internal control over financial reporting could result in material misstatements in our financial statements which could require us to restate financial statements, cause investors to lose confidence in our reported financial information and have a negative effect on our stock price.

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. Our management has not completed an assessment of the effectiveness of our internal control over financial reporting and our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. In the course of auditing our consolidated financial statements for the year ended December 31, 2016, we and our independent registered public accounting firm identified one material weakness in our internal control over financial reporting as of December 31, 2016, in accordance with the standards established by the Public Company Accounting Oversight Board of the United States. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness related to the lack of sufficient accounting personnel with U.S. GAAP knowledge and SEC financial reporting requirements for the purpose of financial reporting, and lack of accounting policies and procedures over financial reporting in accordance with U.S. GAAP. We are seeking to remedy this material weakness by adding staff with extensive U.S. GAAP experience to our accounting team and developing, communicating and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes, although no assurance can be given as to whether these steps will be sufficient. The implementation of these improvements may increase our administrative expenses. To the extent these steps are not successful, we could be forced to incur additional management time and expense.

We cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional

significant deficiencies or material weaknesses, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. Furthermore, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of our fiscal year ending on December 31, 2018. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. The existence of a material weakness could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

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

While we currently have no specific plans to acquire any other businesses, we have, from time to time, evaluated acquisition opportunities 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 our ADS holders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

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

- problems integrating the 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 acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the CFDA, FDA and comparable regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

Reimbursement may not be available for our drug candidates in China, the United States or other countries, which could diminish our sales or affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceuticals vary widely from country to country. In China, the Ministry of Human Resources and Social Security of the PRC or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the PRC's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Drug Reimbursement List, or the NDRL, or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy.

In February 2017, the PRC Ministry of Human Resources and Social Security released a new edition of the NDRL, or the 2017 NDRL. The 2017 NDRL expands its scope by including an additional 339 drugs. The 2017 NDRL reflects an emphasis on innovative drugs and drugs that treat cancer and other serious diseases. For instance, most of the innovative chemical drugs and biological products approved in China between 2008 and the first half of 2016 have been included in the 2017 NDRL or its candidate list. Most of our drug candidates targeted at treating oncology diseases, including niraparib, are unlikely to be included in the NDRL for the National Medical Insurance Program at least in the short-term. As a result, if we were to successfully launch commercial sales of our oncology-based drug candidates, including niraparib, our revenue from such sales is largely expected to be self-paid by patients, which may make our drug candidates less desirable. On the other hand, if the Ministry of Human Resources and Social Security of the PRC or any of its local counterparts accepts our application for the inclusion of our drug candidates in the NDRL or provincial or local medical insurance catalogues, which may increase the demand for our drug candidates, our potential revenue from the sales of our drug candidates may still decrease as a result of lower prices we may be required to charge for our drug candidates that are included in the NDRL or provincial or local medical insurance catalogues.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs which may affect reimbursement rates of our drug candidates if approved. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changed the way health care is financed by both governmental and private insurers. The Affordable Care Act, among other things, subjects biologic products to potential competition by lower-cost biosimilars and establishes annual fees and taxes on manufacturers of certain branded prescription drugs. It also establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated

prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. We expect that additional U.S. state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the Affordable Care Act that are repealed. Thus, the full impact of the Affordable Care Act, or any law replacing elements of it, on our business remains unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Moreover, eligibility for reimbursement in either China or the United States does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution. Interim U.S. reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by U.S. government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

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

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

- obtain a pharmaceutical manufacturing permit and GMP certificate for each production facility from the CFDA and its relevant branches for trading and distribution of drugs not manufactured by the drug registration certificate holder;

- obtain a drug registration certificate, which includes a drug approval number, from the CFDA for each drug manufactured by us;
- obtain a pharmaceutical distribution permit and good supply practice, or GSP, certificate from the CFDA and its relevant branches; and
- renew the pharmaceutical manufacturing permits, the pharmaceutical distribution permits, drug registration certificates, GMP certificates and GSP certificates 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 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. The PRC government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the 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 “Regulation—Government Regulation of Pharmaceutical Product Development and Approval,” “Regulation—Coverage and Reimbursement” and “Regulation—Other Healthcare Laws.”

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

Our business relies, in large part, on our ability to develop and commercialize drug candidates we have licensed and sublicensed from third parties including niraparib from Tesaro, ZL-2301 from Bristol-Myers Squibb, omadacycline from Paratek Bermuda, Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., or Paratek, fugan from GlaxoSmithKline (China) R&D Co., Ltd., an affiliate of GlaxoSmithKline plc, or GSK, ZL-2302 from Sanofi and ZL-1101 from UCB Biopharma Sprl, an affiliate of Union Chimique Belge, or UCB. Because our licenses from Paratek, GSK and UCB are granted to us by a subsidiary or an affiliate of Paratek, GSK or UCB, as applicable, our licenses may not encumber all intellectual property rights owned or controlled by the affiliates of our licensors and relevant to our drug candidates. If we have not obtained a license to all intellectual property rights owned or controlled by such affiliates of our licensors that are relevant to our drug candidates, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors breach such agreements, we may not be able to enforce such agreements against our licensors’ 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 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, under our agreements relating to niraparib and ZL-2301, we are required to use commercially reasonable efforts to conduct the necessary

pre-clinical, clinical, regulatory and other activities necessary to develop and commercialize such drug candidates in the licensed territories. We are also obligated to use commercially reasonable efforts to develop and commercialize omadacycline, fugan, ZL-2302 and ZL-1101 in certain of their respective licensed territories, in each case, under their respective license agreements.

If we fail to meet any of our obligations under our license and 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 drug candidates and other third parties may be able to market drug candidates similar or identical to ours. In such case, we may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. For example, if our agreement with Sanofi for ZL-2302 terminates for any reason, we are required to grant Sanofi an exclusive license with respect to certain of our owned patents and know-how that are necessary to exploit ZL-2302 in the field of oncology in the regions where the license is terminated. In addition, if our agreements with UCB for ZL-1101 and Tesaro for niraparib terminate for any reason, we are required to grant UCB or Tesaro, as applicable, an exclusive license to certain of our intellectual property rights that relate to ZL-1101 or niraparib, 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 license 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 agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party, and have granted us a sub-license. 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 Tesaro and Paratek 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. In addition, our license from Paratek is limited to intellectual property rights under the control of Paratek Bermuda, Ltd. To the extent Paratek Bermuda, Ltd. loses control over any of the licensed intellectual property rights for any reason, we will no longer be licensed to such intellectual property rights to use, develop and otherwise commercialize omadacycline. Also, our license from GSK for fugan includes license agreements between GSK and third parties, which were assigned to us. If we do not comply with our license agreement with GSK or with such other third parties, any such agreements may be terminated or narrowed and we may lose our rights to the licensed intellectual property rights and be required to cease development and commercialization of fugan. 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 intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or sublicensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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 drug candidates in clinical trials or any drug candidates we may decide to commercialize and manufacture in the future. If we cannot successfully defend against claims that the use of such drug candidates in our clinical trials or any products we may choose to manufacture at our production facilities in the future, including any of our 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 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 ADS price.

Existing PRC laws and regulations do not require us to have, nor do we currently, maintain liability insurance to cover product liability claims. We do not have business liability, or in particular, product liability insurance for each of our drug candidates. Any litigation might result in substantial costs and diversion of resources. While

we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), this insurance may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with our collaborators.

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. We currently have no drug candidates beyond pre-clinical trials under our internal discovery programs. Each of our drug candidates will require additional clinical and preclinical development, management of clinical, preclinical 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 CFDA, 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 preclinical 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 CFDA, 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 early 2017 we built a small molecule facility capable of supporting clinical and commercial production and have begun construction of a large molecule facility capable of supporting clinical production of our drug candidates. The construction of the large molecule facility is expected to be completed in the first half of 2018. We intend to rely on these facilities for the manufacture of clinical and commercial supply of some of our product candidates. Prior to being permitted to sell any drugs produced at these facilities the facilities will need to be inspected and approved by regulatory authorities. If 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 manufactured at a new facility in clinical trials or selling any products 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 product candidates, which would adversely affect our business and results of operations.

Risks related to our dependence on third parties

We rely on third parties to conduct our preclinical 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 drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for some of our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical 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 preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Administrative Regulations on Experimental Animals or the Animal Welfare Act requirements. We and our CROs are required to comply with GCP regulations and guidelines enforced by the CFDA, and comparable foreign regulatory authorities for all of our 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 CFDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with ICH-GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

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 preclinical 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 drug candidates. As a result, our results of operations and the commercial prospects for our 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.

If we lose our relationships with CROs, our drug development efforts could be delayed.

We rely on third-party vendors and CROs for some of our preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost and requires

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

We have no experience manufacturing our drug candidates on a large clinical or commercial scale and have built or just started building our manufacturing facilities. We may be dependent on third party manufacturers for the manufacture of our drug candidates as well as on third parties for our supply chain, and if we experience problems with any of these third parties, the manufacture of our drug candidates or products could be delayed, which could harm our results of operations.

In early 2017 we built a small molecule facility capable of supporting clinical and commercial production and have begun construction of a large molecule facility capable of supporting clinical production of our drug candidates. The construction of the large molecule facility is expected to be completed in the first half of 2018. If either of these two facilities is unable to meet our intended production capacity in a timely fashion, we may have to engage a CMO for the production of clinical supplies of our drug candidates.

Additionally, in order to successfully commercialize our drug candidates, we will need to identify qualified CMOs for the scaled production of a commercial supply of certain of our drug candidates. The CMOs should be drug manufacturers holding GMP certificates with a scope that can cover our drug registration candidates, and such CMO arrangement should be approved by the CFDA's provincial level branches. 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, or to obtain the CFDA approval for our CMO arrangement in a timely manner, we may not be able to complete development of our drug candidates, or market or distribute them.

If we were to rely on third-party manufacturers to manufacture our drug candidates, 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 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 CFDA 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 CFDA 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.

Any significant disruption in our potential supplier relationships could harm our business. 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. 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 drug candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our 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 commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.

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. 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 no experience manufacturing pharmaceutical products 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 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 niraparib from Tesaro, omadacycline from Paratek, ZL-2301 from Bristol-Myers Squibb and ZL-2302 from Sanofi. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. We cannot be certain that these patents and patent applications have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our 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 Bristol-Myers Squibb for ZL-2301, Bristol-Myers Squibb has the first right to enforce the licensed patents in China, Hong Kong and Macau, subject to certain exceptions. In addition, with respect to the patent portfolio for omadacycline, which we sub-license from Paratek, Paratek has the first right to enforce such patent portfolio in territories outside of China, Hong Kong, Macau and Taiwan. Similarly, with respect to the patent portfolio for niraparib, which we sub-license from Tesaro, we have the first right to enforce such patent portfolio within China, Hong Kong and Macau. However,

Tesaro 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, Tesaro can control such enforcement actions in those areas as well. In the case where Tesaro controls such enforcement actions, although we have rights to consult with Tesaro on such actions within China, Hong Kong and Macau, rights granted by Tesaro under niraparib to another licensee, such as Janssen Biotech, Inc. to whom Tesaro has granted an exclusive right to develop niraparib for the treatment of prostate cancer, could potentially influence Tesaro'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.

Other risks and risks related to doing business in China

If we fail to comply with environmental, health and safety laws and regulations of the PRC, 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 and third party liability insurance for injuries caused by unexpected seepage, pollution or contamination, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the PRC 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.

The PRC'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. 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 the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC 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 the PRC 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 the PRC, or the MOFCOM, published a discussion draft of the proposed Foreign Investment Law. The MOFCOM has solicited comments on this draft and substantial uncertainties exist with respect to its enactment timetable, interpretation and implementation. If enacted as proposed, the Foreign Investment Law may materially impact our current corporate structure, corporate governance practice and business operations in many aspects and may increase our compliance costs.

Additionally, the CFDA's recent reform of the drug and approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner.

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

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, 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.

Following this offering, we will be 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 expands, the applicability of the FCPA and other anti-bribery laws to our operations will 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, including proceeds from this offering, 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, the amount of these capital contributions must first be approved or filed by the relevant government approval authority.

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 registrations 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 use the proceeds we receive from this offering and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

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, or SAFE Circular 37. SAFE Circular 37 requires PRC residents to register with local branches of SAFE or competent banks designated by 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.

To our knowledge, there are no PRC residents who hold direct or indirect interests in our company, and 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, or the M&A Rules, and other recently adopted 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, or the Prior Notification Rules issued by the State Council in August 2008, 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 MOFCOM 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 Lenders, or the Security Review Rules issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire the 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.

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

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We received approximately $2.41 million and $0.36 million in financial incentives from local governments in China relating to our business operations in 2016 and 2015, respectively. We also received approximately $0.37 million in financial incentives from local governments in Australia as part of its tax incentive program in 2016. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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 PRC Enterprise Income Tax Law, or the EIT Law and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008, 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 is 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, 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 enterprise income tax purposes, that entity would be subject to a 25% enterprise income tax 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 ordinary 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, each of which is a wholly foreign-owned enterprise may pay dividends only out of its respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise 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, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus 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 RMB's depreciation against U.S. dollar in the fourth quarter of 2016, the PBOC and the SAFE have promulgated a series of capital control measure over recent months, 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. 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.

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. For example, the PRC tax authorities may consider that our current offering involves an indirect change of shareholding in our PRC subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Although we believe no SAT Circular 7 reporting is required on the basis that the current offering has commercial purposes and is not conducted for tax avoidance, the PRC tax authorities may pursue us to report under SAT Circular 7 and request that we and our PRC subsidiaries assist in the filing. As a result, we and our subsidiaries may be required to expend significant resources to provide assistance and comply with SAT Circular 7, or establish that we or our non-resident enterprises should not be subject to tax under SAT Circular 7, for the current offering or other transactions, which may have an adverse effect on our and their financial condition and day-to-day operations.

Any failure to comply with 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, 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. 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.

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 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 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 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.

Risks related to intellectual property

If we are unable to obtain and maintain patent protection for our 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 drug candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the 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 drug candidates in all territories in which we plan to commercialize our drug candidates. For example, we do not own or exclusively license any issued patents covering niraparib in Hong Kong and Taiwan. We cannot predict whether any of our other owned or in-licensed pending patent applications will result in the issuance of any patents that effectively protect our drug candidates. If we or our licensors are unable to obtain or maintain patent protection with respect to our 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 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 Tesaro for niraparib, Paratek for omadacycline and Bristol-Myers Squibb for ZL-2301, our exclusive licenses are limited to China, Hong Kong, Macau and, in the case of our agreement for omadacycline, Taiwan. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our 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 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 or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we, or one of our licensors, 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 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, or limit the duration of the patent protection of our technology 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 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 new drug candidates, patents protecting such drug candidates might expire before or shortly after such 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 may become involved in patent litigation against third parties to enforce our owned or in-licensed patent rights, to invalidate patents held by such third parties, or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent we or our licensors have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, third parties may initiate legal proceedings before administrative bodies in the United States or abroad, even outside the context of litigation, against us or our licensors with respect to our owned or in-licensed intellectual property to assert such challenges to such intellectual property rights. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our 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 drug candidates, we would lose at least part, and perhaps all, of the patent protection covering such drug candidates. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations and prospects.

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 to determine the enforceability, scope and validity of our proprietary rights or those of others. 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 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 government authorities 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 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 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 commercialize these drug candidates.

Our commercial success depends significantly on our ability to develop, manufacture, market and sell our 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 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 drug candidates we may develop and any other 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 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 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 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 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 do not obtain patent term extension and data exclusivity for 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 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. In addition, no patent term extension system has been established in the PRC. As a result, the patents we have in-licensed or own in the PRC are not eligible to be extended for patent term lost during 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 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 ADSs and this offering

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

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

After the completion of the global offering, we may be at an increased risk of securities class action litigation.

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

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our business, the price of our ADSs could decline.

The trading market for our ADSs will rely in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We are eligible to be treated as an "emerging growth company," as defined in the Securities Act, and we cannot be certain if the reduced disclosure requirements applicable to us as an "emerging growth company" will make our ADSs less attractive to investors.

We are eligible to be treated as an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, our shareholders may not have access to certain information that they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if our total annual gross revenue exceeds $1.07 billion, if we issue more than $1.0 billion in non-convertible debt securities during any three-year period, or if the market value of our ordinary shares held by non-affiliates exceeds $700.0 million. We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our stock price may be more volatile.

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

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

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

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

As a foreign private issuer we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act and therefore there may be less publicly available information about us than if we were a U.S. domestic issuer. For example, we are not subject to the proxy rules in the United States and disclosure with respect to our annual general meetings will be governed by the Cayman Islands requirements. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules thereunder. Therefore, our shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our ordinary shares or ADSs.

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

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. When our ADSs are listed on the Nasdaq Stock Market, we intend to continue to follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following: (i) the majority independent director requirement under Section 5605(b)(1) of the Nasdaq listing rules, (ii) the requirement under Section 5605(d) of the Nasdaq listing rules that a compensation committee comprised solely of independent directors governed by a compensation committee charter oversee executive compensation and (iii) the requirement under Section 5605(e) of the Nasdaq listing 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. Cayman Islands law does not impose a requirement that our board of directors consist of a majority of independent directors. Nor does Cayman Islands law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

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

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2018. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the U.S. and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on January 1, 2019, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange.

The audit report included in this prospectus was prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, 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 the PRC, 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 announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or CSRC, and the Ministry of Finance, which establishes a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by the PCAOB, the CSRC, or the Ministry of Finance in the United States and the PRC, respectively. The PCAOB continues to be in discussions with the CSRC and the Ministry of Finance to permit joint inspections in the PRC of audit firms that are registered with PCAOB and audit Chinese companies that trade on U.S. exchanges.

This lack of PCAOB inspections in China prevents the PCAOB from regularly 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. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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 the ADSs.

We have never declared or paid any dividends on our ordinary shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ADSs at least in the near term, and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our investors purchased their ADSs.

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

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

The initial public offering price for our ADSs will be determined by negotiations between us and the underwriters and may bear no relationship to the market price for our ADSs after this initial public offering. We cannot assure you that an active trading market for our ADSs will develop or that the market price of our ADSs will not decline below the initial public offering price. If an active trading market for our ADSs does not develop after this offering, the market price and liquidity of our ADSs will be materially and adversely affected.

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

The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to factors, including the following:

- announcements of competitive developments;
- regulatory developments affecting us, our customers or our competitors;
- announcements regarding litigation or administrative proceedings involving us;

- actual or anticipated fluctuations in our period-to-period operating results;
- changes in financial estimates by securities research analysts;
- additions or departures of our executive officers;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; and
- sales or perceived sales of additional ordinary shares or ADSs.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. For example, since August 2008, multiple exchanges in the United States and other countries and regions, including China, experienced sharp declines in response to the growing credit market crisis and the recession in the United States. As recently as August 2015, the exchanges in China experienced a sharp decline. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs, which would also negatively affect the trading prices for our ADSs.

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

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

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

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

If you purchase our ADSs in this offering, you will pay more for your ADSs than the amount paid by our existing shareholders for their ordinary shares on a per ADS basis. As a result, you will experience immediate and substantial dilution of approximately $ per ADS, representing the difference between our net tangible book value per ADS as of December 31, 2016, after giving effect to this offering and an assumed initial public offering price of $ per ADS. In addition, you may experience further dilution to the extent that our ordinary shares are issued upon the exercise of share options. See “Dilution” for a more complete description of how the value of your investment in our ADSs will be diluted upon completion of this offering.

Substantial future sales or perceived sales of our ADSs in the public market could cause the price of our ADSs to decline.

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

The depositary for our ADSs will give us a discretionary proxy to vote our ordinary shares underlying your ADSs if you do not vote at shareholders’ meetings, except in limited circumstances, which could adversely affect your interests.

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

- we do not wish a discretionary proxy to be given;
- we are aware or should reasonably be aware that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would materially and adversely affect the rights of shareholders.

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

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

Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our third amended and restated memorandum and articles of association, which will be effective immediately prior to completion of this offering, an annual general meeting and any extraordinary general meeting at which the passing of a special resolution is to be considered may be called with not less than days' notice, and all other extraordinary general meetings may be called with not less than days' notice. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. If we ask for your instructions, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least days in advance of the meeting date and the depositary will send a notice to you about the upcoming vote and will arrange to deliver our voting materials to you. The depositary and its agents, however, may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the ordinary shares underlying your ADSs. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a holder or beneficial owner of ADSs, you may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if you wish us or the depositary to participate in legal proceedings. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

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

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

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

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration

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

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

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are a PFIC, U.S. holders of our ADSs may suffer adverse tax consequences, including having gains realized on the sale of the ADSs treated as ordinary income rather than capital gain, the loss of the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of the ADSs.

Whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year and which depends on the composition of our income and the composition and value of our assets for the relevant taxable year. Because we hold, and will continue to hold after this offering, a substantial amount of passive assets, including cash, and because the value of our assets for purposes of the PFIC rules (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early stage of our drug candidates, we cannot give any assurance that we will not be a PFIC for the current or any future taxable year.

Whether or not U.S. holders make a timely "qualified electing fund," or QEF election or mark-to-market election may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ADSs. We do not currently intend to provide the information necessary for U.S. holders to make a QEF election if we are treated as a PFIC for any taxable year, and prospective investors should assume that a QEF election will not be available. Prospective investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to the ADSs. See "Material United States federal income tax considerations—Passive foreign investment company considerations."

You may have difficulty enforcing judgments obtained against us.

We are a company incorporated under the laws of the Cayman Islands, and substantially all of our assets are located outside the United States. 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 other than the United States. A substantial portion of the assets of these persons are located outside the United States. As a result, it may be difficult for you to effect service of process within the United States upon these persons. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors, some of whom currently reside in the United States and whose assets are located outside the United States. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts

against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

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

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

Your 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.

Cautionary note regarding forward-looking statements

This prospectus contains forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our operational results and other future conditions. Forward-looking statements can be identified by words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “seek,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” “contemplate” and other similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this prospectus and include statements regarding our intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth, strategies and the industry in which we operate.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We believe that these risks and uncertainties include, but are not limited to, those described in the “Risk Factors” section of this prospectus, which include, but are not limited to, the following:

- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to advance our drug candidates into, and successfully complete, clinical trials;
- the ability of our drug candidates to be granted or maintain Category 1 designation with the CFDA and to receive a faster development, review or approval process;
- our reliance on the success of our clinical-stage drug candidates niraparib, omadacycline and ZL-2301 and certain other drug candidates;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our drug candidates, if approved;
- our ability to develop sales and marketing capabilities;
- 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 the United States, China and other jurisdictions;
- ability to obtain additional funding for our operations;
- the rate and degree of market acceptance of our 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 factors should not be construed as exhaustive and should be read with the other cautionary statements in this prospectus.

Although we base these forward-looking statements on assumptions that we believe are reasonable when made, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this prospectus. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate, are consistent with the forward-looking statements contained in this prospectus, those results or developments may not be indicative of results or developments in subsequent periods.

Given these risks and uncertainties, you are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statement that we make in this prospectus speaks only as of the date of such statement, and we undertake no obligation to update any forward-looking statements or to publicly announce the results of any revisions to any of those statements to reflect future events or developments. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless specifically expressed as such, and should only be viewed as historical data.

Use of proceeds

We estimate that the net proceeds to us from our issuance and sale of ADSs in this offering will be approximately $ million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. This estimate assumes an initial public offering price of $ per ADS, the midpoint of the price range set forth on the cover page of this prospectus.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ADS would increase (decrease) the net proceeds to us from this offering by $ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

We intend to use the net proceeds of this offering, together with the cash generated by our operations and other cash resources, primarily to further advance the clinical development and commercial launch of our multiple drug candidates. In particular, we currently expect to use the net proceeds from this offering as follows:

- approximately $ million to advance niraparib (ZL-2306) through Phase III studies in patients with ovarian, breast cancer and other indications in China;
- approximately $ million to support the commercialization efforts for niraparib (ZL-2306) in China, Hong Kong and Macau;
- approximately $ million to advance omadacycline (ZL-2401) through Phase III studies in China.
- approximately $ million to advance ZL-2301 through Phase II/III studies in patients with HCC in China.
- approximately $ million to fund new business development and licensing opportunities;
- approximately $ million to accelerate and broaden clinical development of our drug candidates for which we have exclusive rights to develop and commercialize globally; and
- approximately $ million for research and clinical development of other drug candidates.

The expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which we could change in our discretion in the future as our plans and business conditions evolve. Due to the many variables inherent to the development of our drug candidates at this time, such as the timing of patient enrollment and evolving regulatory requirements, we cannot currently predict the stage of development we expect to achieve for our pre-clinical and clinical trial and drug candidates with the net proceeds of this offering. We expect to use the remainder of the net proceeds for working capital and other general corporate purposes, such as acquiring the commercial rights to other drug products and expanding our research organization and infrastructure. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the results of the pre-clinical and clinical trial of our drug candidates, our operating costs and expenditures and the amount of cash generated by our operations. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

Pending these uses, we intend to invest the net proceeds in investment-grade, short-term fixed income instruments.

For additional information, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

Dividend policy

We have never declared or paid regular cash dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration 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.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2016:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of our outstanding preferred shares into an aggregate of 158,665,951 ordinary shares upon the closing of this offering, (ii) the exercise of warrants to purchase our preferred shares and further conversion of the preferred shares into ordinary shares upon the closing of this offering, and (iii) the effectiveness of our third amended and restated memorandum and articles of association, which will occur immediately prior to this closing of this offering; and
- on a pro forma and as adjusted basis to reflect the issuance and sale of ordinary shares in the form of ADSs by us in this offering and the application of net proceeds from this offering described under “Use of Proceeds.”

The information below is illustrative only, and assumes an initial public offering price at the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Our capitalization following this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing, including the amount by which actual offering expenses are higher or lower than estimated. The table should be read in conjunction with the information contained in “Use of Proceeds,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as our consolidated financial statements and the related notes included elsewhere in this prospectus.

	As of December 31, 2016		
	Actual	Pro forma	Pro forma as adjusted
Cash and cash equivalents	$ 83,948,770	$ 84,948,770	$
Warrant liabilities	(3,900,000)	—	
Series A1, par value $0.00001 per share; 50,800,001 shares authorized; 50,800,001 shares issued and outstanding (actual); no shares authorized, issued or outstanding (pro forma and pro forma as adjusted)	10,028,572	—	
Series A2, par value $0.00001 per share; 50,653,339 shares authorized; 50,653,339 shares issued and outstanding (actual); no shares authorized, issued or outstanding (pro forma and pro forma as adjusted)	18,278,572	—	
Series B1, par value $0.00001 per share; 33,374,023 shares authorized; 33,374,023 shares issued and outstanding (actual); no shares authorized, issued or outstanding (pro forma and pro forma as adjusted)	53,100,000	—	
Series B2, par value $0.00001 per share; 23,838,588 shares authorized; 23,838,588 shares issued and outstanding (actual); no shares authorized, issued or outstanding (pro forma and pro forma as adjusted)	53,100,000	—	
Shareholders’ deficit:			
Ordinary shares, par value $0.00001 per share; 500,000,000 shares authorized, 70,543,056 (actual); 231,979,858 issued and outstanding (pro forma); shares issued and outstanding (pro forma as adjusted)	579	2,193	
Subscription receivable	(5)	(5)	
Additional paid-in capital	9,313,646	148,719,176	
Accumulated deficit	(60,167,437)	(60,167,437)	
Accumulated other comprehensive loss	(698,532)	(698,532)	
Total shareholders’ deficit	(51,551,749)	(87,855,395)	
Total capitalization	$ (51,551,749)	$ (87,855,395)	$

The information above is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

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

The actual, pro forma and pro forma as adjusted information set forth in the table excludes:

- 43,368,862 shares issuable upon the exercise of options outstanding as of December 31, 2016 pursuant to our 2015 Plan at a weighted-average exercise price of $0.16 per share; and
- shares reserved for future issuance under our 2017 Plan, which includes shares reserved for issuance under our 2015 Plan that will become available under our 2017 Plan upon the closing of this offering).

Dilution

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

As of December 31, 2016, we had a net tangible book value of $ million, or $ per ordinary share and $ per ADS. We calculate net tangible book value per ordinary shares by dividing our total tangible assets less our total liabilities by the number of our ordinary shares outstanding. Pro forma net tangible book value per ordinary share is calculated after giving effect (i) to the conversion of all of our issued and outstanding preferred shares, (ii) the exercise of warrants to purchase our preferred shares and the further conversion of the preferred shares into ordinary shares and (iii) the effectiveness of our third amended and restated memorandum and articles of association. Pro forma as adjusted net tangible book value per ordinary share is calculated after giving effect to the conversion of all our issued and outstanding preferred shares and the issuance of ordinary shares in the form of ADSs by us in this offering. Dilution is determined by subtracting pro forma as adjusted net tangible book value per ordinary share from the public offering price per ordinary share.

Without taking into account any other changes in such net tangible book value after December 31, 2016, after giving effect to the receipt of the estimated net proceeds from our sale of ADSs in this offering, assuming an initial public offering price of $ per ADS (the midpoint of the offering range shown on the cover of this prospectus), and the application of the estimated net proceeds therefrom as described under “Use of Proceeds,” our pro forma as adjusted net tangible book value at December 31, 2016 would have been approximately $, or $ per ordinary share and $ per ADS. This represents an immediate increase in net tangible book value of $ per ordinary share and $ per ADS to existing shareholders and an immediate dilution in net tangible book value of $ per ordinary share and $ per ADS to you, or %. The following table illustrates this dilution per ordinary share.

	Per ordinary share	Per ADS
Assumed initial public offering price	$	$
Historical net tangible book value per ordinary share as of December 31, 2016	$	$
Pro forma increase in net tangible book value per share as of December 31, 2016		
Pro forma net tangible book value per share as of December 31, 2016		
Increase in pro forma net tangible book value per share after this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors in this offering	$	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ADS would decrease (increase) our pro forma net tangible book value after giving effect to the offering by $, assuming no

change to the number of ADSs offered by us as set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

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

The following table sets forth, as of December 31, 2016, the number of ordinary shares purchased from us, the total consideration paid to us and the average price per ordinary share/ADS paid by existing shareholders and to be paid by new investors purchasing ADSs in this offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Ordinary shares purchased		Total consideration		Average price per ordinary share	Average price per ADS
	Number	Percent	Amount	Percent		
Existing shareholders	$	%	$	%	$	$
New investors						
Total	$	100.0%	$	100.0%	$	$

If the underwriters were to fully exercise their option to purchase additional ADSs from us, the percentage of our ordinary shares held by existing shareholders would be %, and the percentage of our ordinary shares held by new investors would be %.

The above discussion and tables are based on 71,800,000 ordinary shares issued and outstanding as of December 31, 2016 and also reflects the conversion of all outstanding preferred shares into an aggregate of 158,665,951 ordinary shares immediately prior to the closing of this offering, and excludes:

- 43,368,862 shares issuable upon the exercise of options outstanding as of December 31, 2016 pursuant to our 2015 Plan at a weighted-average exercise price of $0.16 per share; and
- shares reserved for future issuance under our 2017 Plan, which includes shares reserved for issuance under our 2015 Plan that will become available under our 2017 Plan upon the closing of this offering).

To the extent that any share options or warrants are exercised, there will be further dilution to new investors.

Selected consolidated financial data

The following selected consolidated statement of operations data for the years ended December 31, 2015 and December 31, 2016 and the selected balance sheet data as of December 31, 2015 and December 31, 2016 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our audited consolidated financial statements have been prepared in accordance with U.S. GAAP.

This selected historical consolidated financial data should be read in conjunction with the disclosures set forth under “Capitalization,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and the related notes thereto appearing elsewhere in this prospectus.

	Year ended December 31,	
(in thousands, except share and per share data)	**2015**	**2016**
Research and development expenses	$ (13,587)	$ (32,149)
General and administrative expenses	(2,762)	(6,380)
Loss from operations	(16,349)	(38,529)
Interest income	5	403
Fair value of warrants	(1,980)	(1,920)
Other income	341	2,534
Other expense	(39)	—
Loss before income taxes	(18,022)	(37,512)
Income tax expense	—	—
Net loss	$ (18,022)	$ (37,512)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted(1)	52,161,918	56,634,142
Net loss per share, basic and diluted(1)	(0.35)	(0.66)

	As of December 31,	
(in thousands)	**2015**	**2016**
Balance sheet data:		
Cash and cash equivalents	$ 13,161	$ 83,949
Total assets	13,940	88,907
Total shareholders’ deficit	(18,370)	(51,552)
Total current liabilities	3,941	5,173
Total non-current liabilities	62	778

(1) See Note 2 within our notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share.

Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Consolidated Financial Data," and our financial statements and the related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. The terms "Company", "Zai Lab", "we", "our" or "us" as used herein refer to Zai Lab Limited and its consolidated subsidiaries unless otherwise stated or indicated by context.

Overview

We are an innovative biopharmaceutical company based in Shanghai focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China market, including in the fields of oncology, autoimmune and infectious diseases therapies. Our mission is to transform patients' lives in China and eventually leverage our capabilities to impact human health worldwide.

Since our founding in 2014, we have assembled a pipeline consisting of six drug candidates through partnerships with global biopharmaceutical companies. These include three late-stage assets targeting fast growing segments of China's pharmaceutical market, and three assets addressing global unmet medical needs. We believe that management's decades-long global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, opportunities to partner with global companies aiming to bring innovative products to market in China efficiently and effectively.

Our consolidated net loss attributable to ordinary shareholders for the years ended December 31, 2015 and 2016 was $18.0 million and $37.5 million, respectively.

Basis of presentation

Our consolidated statement of operations data for the years ended December 31, 2015 and December 31, 2016 and our consolidated statement of financial position data as of December 31, 2015 and December 31, 2016 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our audited consolidated financial statements have been prepared in accordance with U.S. GAAP.

Factors affecting our results of operations

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 four clinical-stage drug candidates being investigated. For more information on the nature of the efforts and steps necessary to develop our drug candidates, see "Business" and "Regulation."

To date, we have financed our activities primarily through private placements. Through April 30, 2017, we have raised $134.5 million in equity financing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $11.5 million and $32.2 million for the years ended December 31, 2015 and 2016, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our four clinical-stage drug candidates and continue research and development of our preclinical-stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. These expenses 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; and
- additional costs associated with operating as a public company upon the completion of this offering.

If completed, the net proceeds to us from this offering will be an important source of funds for our research and development. For more information on the nature of the intended uses for the proceeds from this offering, see “Use of Proceeds.”

For more information on the research and development expenses incurred for the development of our drug candidates, see “Key Components of Results of Operations—Research and Development Expenses.”

General and administrative expenses

Our general and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for administrative personnel. Other general and administrative expenses include 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 general and administrative activities. We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as we prepare to manufacture and commercialize our products. These increases will likely include increased headcount, increased share compensation charges, expanded infrastructure and increased costs for insurance. We also anticipate increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Our ability to commercialize our drug candidates

All of our drug candidates are still in development. Four 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 their receipt of regulatory approval for and successful commercialization of such products, which may never occur. Certain of our 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 licensing arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are 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 drug product under these agreements as well as tiered royalties based on the net sales of the licensed products. These expenses are recorded in research and development expense in our consolidated financial statements and totaled $6.2 million and $17.1 million for the years ended December 31, 2015 and 2016, respectively.

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.

Share-based compensation

Awards granted to employees

We grant share options to eligible employees, management and directors and account for these share-based awards in accordance with ASC 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 footnote 10 to the consolidated financial statements included elsewhere in 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, with the assistance of an independent third party valuation firm, determined the fair value of the stock options granted to employees. The binomial option pricing model was applied in determining the estimated fair value of the options granted to employees.

Awards granted to non-employees

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 non-employees.

Fair value measurements

We apply ASC Topic 820, *Fair Value Measurements and Disclosures*, of ASC 820, 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, for example, 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 our company primarily include cash and cash equivalents, prepayments and other current assets, accounts payable, warrant liabilities, payroll payables and other payables. As of December 31, 2015 and 2016, the carrying values of cash and cash equivalents, prepayments and other current assets, accounts payable, payroll payables and other payables approximated their fair values due to the short-term maturity of these instruments. The warrant liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. We determined the fair values of the warrant liabilities with the assistance of an independent third party valuation firm, and we have measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of the years ended December 31, 2015 and 2016.

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, 2015 and 2016, we did not have any significant unrecognized uncertain tax positions.

Key components of results of operations

Taxation

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. For more information, see "Taxation—Cayman Islands taxation."

People's Republic of China

Our subsidiaries incorporated in the PRC are governed by the PRC Enterprise Income Tax Law, or EIT Law, and regulations. Under the EIT Law, the standard Enterprise Income Tax, or 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 up to following five years. For more information, see "Taxation—People's Republic of China taxation."

Results of operations

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

(in thousands, except share and per share data)	Year ended December 31, 2015	2016
Comprehensive Income Data:		
Operating expenses:		
Research and development	$ (13,587)	$ (32,149)
General and administrative	(2,762)	(6,380)
Loss from operations	(16,349)	(38,529)
Interest income	5	403
Fair value of warrants	(1,980)	(1,920)
Other income	341	2,534
Other expense	(39)	—
Loss before income tax	(18,022)	(37,512)
Income tax expense	—	—
Net loss attributable to ordinary shareholders	$ (18,022)	$ (37,512)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	52,161,918	56,634,142
Net loss per share, basic and diluted	(0.35)	(0.66)

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Research and development expenses

The following table sets forth the components of our research and development expenses for the years indicated.

(in thousands)	Year ended December 31, 2015	%	2016	%
Research and development expenses:				
Personnel compensation and related costs	$ 3,172	23.3	$ 6,095	19.0
Licensing fees	6,203	45.7	17,108	53.2
Payment to CROs/CMOs	3,180	23.4	6,759	21.0
Other costs	1,032	7.6	2,187	6.8
Total	$13,587	100.0	$32,149	100.0

Research and development expense increased by $18.6 million to $32.1 million for year ended December 31, 2016 from $13.6 million for year ended December 31, 2015. The increase in research and development expense included the following:

- $2.9 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during year ended December 31, 2016 and the grants of new share options to certain employees;
- $10.9 million for increased licensing fees in connection with the upfront fee paid for licensing agreement with Tesaro for ZL-2306 in fiscal year 2016 (see “Business—Our Clinical Pipeline—Niraparib” for further information); and

- $3.6 million for increased payment to CROs/CMOs in fiscal year 2016 as we advanced our drug candidate pipeline.

The following table summarizes our research and development expense by program for the years ended December 31, 2015 and December 31, 2016, respectively:

	Year ended December 31,			
(in thousands)	**2015**	**%**	**2016**	**%**
Research and development expenses:				
Clinical programs	$ 6,020	44.3	$ 20,129	62.6
Preclinical programs	3,821	28.1	4,839	15.1
Unallocated research and development expenses	3,746	27.6	7,181	22.3
Total	$13,587	100.0	$ 32,149	100.0

During the year ended December 31, 2016, 63% and 15% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. The external research and development expenses of niraparib, our largest clinical program by spending during this period, represented approximately 47% of our total research and development expenses in this period. Though we manage our external research and development expenses by program 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.

General and administrative expenses

The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended December 31,			
(in thousands)	**2015**	**%**	**2016**	**%**
General and Administrative Expenses:				
Personnel compensation and related costs	$1,811	65.6	$3,120	48.9
Professional service fee	340	12.3	2,691	42.2
Other costs	611	22.1	569	8.9
Total	$2,762	100.0	$6,380	100.0

General and administrative expenses increased by $3.6 million to $6.4 million for year ended December 31, 2016 from $2.8 million for year ended December 31, 2015. The increase in general and administrative expenses included the following:

- $1.3 million for increased personnel compensation and related costs which was primarily attributable to increased administrative personnel compensation costs, due to hiring of more personnel during year ended December 31, 2016 and the grants of new share options to certain employees; and
- $2.4 million for increased professional service fee due to the increase of legal due diligence expenses in fiscal year 2016.

Interest income

Interest income increased by $0.4 million for year ended December 31, 2016 due to higher cash on hand in 2016.

Fair value change of warrants

On December 31, 2015, we entered into a warrant agreement with an investor to purchase up to 2,770,551 of our Series A2 preferred shares at $0.3609 per share. The fair value of the warrants of $2.0 million was expensed on the date of issuance and an additional $1.9 million change in fair value was expensed in 2016 on the re-measurement date. The warrants are expected to be exercised in connection with this offering. Upon such conversion of the underlying preferred stock, the preferred stock will be classified as a component of equity and no longer be subject to re-measurement. We will incur a non-cash expense upon such exercise of $ (at an assumed initial public offering price of $ per ADS, the midpoint of the price range set forth on the cover of this prospectus).

Other income

Other income increased by $2.2 million for year ended December 31, 2016 primarily as a result of an 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 $18.0 million the year ended December 31, 2015 compared to net loss attributable to ordinary shareholders of $37.5 million for the year ended December 31, 2016.

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 general and administrative costs associated with our operations. We incurred net losses of $18.0 million and $37.5 million for the years ended December 31, 2015 and 2016, respectively. As of December 31, 2016, we had an accumulated deficit of $60.2 million. Our primary use of cash is to fund research and development costs. Our operating activities used $11.5 million $32.2 million of cash flows during the years ended December 31, 2015 and 2016, respectively. Historically, we have financed our operations principally through proceeds from private placements of preferred shares and warrants of $134.5 million. At December 31, 2016, we had cash and cash equivalents of $83.9 million. We believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations through .

The following table provides information regarding our cash flows for the years ended December 31, 2015 and 2016:

	Year ended December 31,	
(in thousands)	**2015**	**2016**
Net cash (used in) operating activities	(11,465)	(32,158)
Net cash (used in) investing activities	(738)	(2,730)
Net cash provided by financing activities	18,278	106,200
Effect of foreign exchange rate changes	(67)	(524)
Net increases in cash and cash equivalents	6,008	70,788

Net cash used in operating activities

The use of cash resulted primarily from our net losses adjusted for non-cash charges and changes in components of our operating assets and liabilities. The primary use of our cash was to fund the development of

our research and development activities, regulatory and other clinical trial costs, and related supporting administration. Our prepayments and other current assets, accounts payable and other payables balances were affected by the timing of vendor invoicing and payments.

During the year ended December 31, 2016, our operating activities used $32.2 million of cash, which resulted principally from our net loss of $37.5 million, adjusted for non-cash charges of $7.0 million, and by cash used in our operating assets and liabilities of $1.7 million. Our net non-cash charges during the year ended December 31, 2016 primarily consisted of $0.2 million of depreciation expense, $4.9 million of share-based compensation expense and a $1.9 million loss from changes in fair value of warrants.

During the year ended December 31, 2015, our operating activities used $11.5 million of cash, which resulted principally from our net loss of $18.0 million, adjusted for non-cash charges of $4.8 million, and by cash provided by our operating assets and liabilities of $1.7 million. Our net non-cash charges during the year ended December 31, 2015 primarily consisted of $0.1 million of depreciation expense, $2.7 million of share-based compensation expense and a $2.0 million loss from changes in fair value of warrants.

Net cash used in investing activities

Net cash used in investing activities was $2.7 million for the year ended December 31, 2016 compared to $0.7 million for the year ended December 31, 2015. The increase in cash used in investing activities was due to the construction of our small molecule commercial facility and other investments in 2016.

Net cash provided by financing activities

Net cash provided by financing activities was $106.2 million for the year ended December 31, 2016 compared to $18.3 million cash provided by financing activities for the year ended December 31, 2015. The increase was due to the issuance of $106.2 million Series B preferred shares and warrants to certain investors.

Internal control over financial reporting

In connection with the audit of our financial statements as of and for the years ended December 31, 2015 and 2016, we identified a material weakness in our internal control over financial reporting as of December 31, 2016. The material weakness related to the lack of sufficient accounting personnel with U.S. GAAP knowledge and SEC financial reporting requirements for the purpose of financial reporting, and lack of accounting policies and procedures over financial reporting in accordance with U.S. GAAP.

We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- hiring additional financial professionals with U.S. GAAP and SEC reporting experience;
- increasing the number of qualified financial reporting personnel;
- improving the capabilities of existing financial reporting personnel through training and education in the accounting and reporting requirements under U.S. GAAP and SEC rules and regulations;
- developing, communicating and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes; and
- establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our consolidated financial statements and related disclosures.

These additional resources and procedures are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. With the oversight of senior management and our board of directors, we have begun taking steps and plan to take additional measures to remediate the underlying causes of the material weakness.

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2016 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act after the completion of this offering.

Contractual obligations

The following table sets forth our contractual obligations as of December 31, 2016. 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
					(in thousands)
Operating Lease Obligations	$2,119	$ 712	$ 1,209	$ 198	$ —
Purchase Obligations	3,397	3,397	—	—	—
Total	$5,516	$ 4,109	$ 1,209	$ 198	—

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 cancelable if the milestones are not complete and achievement and timing of these obligations are not fixed or determinable.

Off-balance sheet 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.

Qualitative & quantitative 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 (“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 RMB3.5 million and RMB44.2 million, which were denominated in RMB, as of December 31, 2015 and 2016, respectively, representing 4% and 8% of the cash and cash equivalents as of December 31, 2015 and 2016, respectively.

Our business mainly operates in the PRC with most 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.

Translation of the net proceeds that we will receive from this offering into RMB will also expose us to currency risk. 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, the PRC 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 the PRC 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 we receive from this offering 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. The carrying amounts of cash and cash equivalents represent the maximum amount of loss due to credit risk. As of December 31, 2015 and 2016, all of our cash and cash equivalents were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions.

Recently issued accounting standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Updates, or ASU, 2014-09, *Revenue from Contracts with Customers (Topic 606)*, to clarify the principles of recognizing revenue and create common revenue recognition guidance between U.S. GAAP and International Financial Reporting Standards, or IFRS. An entity has the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application. ASU 2014-09 is effective for fiscal years and interim

periods within those years beginning after December 15, 2016, and early adoption is not permitted. In August, 2015, the FASB updated this standard to ASU 2015-14, the amendments in this update defer the effective date of Update 2014-09, that the update should be applied to annual reporting periods beginning after December 15, 2017 and earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.

In May 2016, FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*. The amendments in this update do not change the core principle of the guidance in Topic 606. Rather, the amendments in this update affect only the narrow aspects of Topic 606. The areas improved include: (1) Assessing the Collectability Criterion in Paragraph 606-10-25-1(e) and Accounting for Contracts That Do Not Meet the Criteria for Step 1; (2) Presentation of Sales Taxes and Other Similar Taxes Collected from Customers; (3) Noncash Consideration; (4) Contract Modifications at Transition; (5) Completed Contracts at Transition; and (6) Technical Correction. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements for Topic 606 (and any other topic amended by update 2014-09).

We are in a development stage, with no revenues to date, and will evaluate the application of this ASU, but as a result has not yet determined the potential effects it may have on the Company's financial statements.

In November 2015, FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*, which requires deferred income tax liabilities and assets to be classified as noncurrent on the balance sheet rather than being separated into current and noncurrent. The guidance is effective for public entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption being permitted. We have adopted this guidance during the year ended December 31, 2016, retrospectively. The adoption of this guidance did not have a material effect on the consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"), which requires that equity investments, except for those accounted for under the equity method or those that result in consolidation of the investee, be measured at fair value, with subsequent changes in fair value recognized in net income. However, an entity may choose to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. ASU 2016-01 also impacts the presentation and disclosure requirements for financial instruments. ASU 2016-01 is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted only for certain provisions. We are in the process of evaluating the impact of adoption of this guidance on the consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on the balance sheet. This ASU requires lessees to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Lessees are permitted to make an accounting policy election to not recognize the asset and liability for leases with a term of twelve months or less. The ASU does not significantly change the lessees' recognition, measurement and presentation of expenses and cash flows from the previous accounting standard. Lessors' accounting under the ASC is largely unchanged from the previous accounting standard. In addition, the ASU expands the disclosure requirements of lease arrangements. Lessees and lessors will use a modified retrospective transition approach, which includes a number of practical expedients. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. We are currently evaluating this ASU to determine the full impact on its consolidated financial statements, as well as the impact of adoption on policies, practices

and systems. As of December 31, 2016, we have $2.1 million of future minimum operating lease commitments that are not currently recognized on its consolidated balance sheets. Therefore, we would expect changes to its consolidated balance sheets for the recognition of these and any additional leases entered into in the future upon adoption.

In March 2016, the FASB issued ASU 2016-09, which simplifies several aspects of the accounting for employee share-based payment transactions for both public and non-public entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. For public entities, the ASU is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. Early adoption will be permitted in any interim or annual period for which financial statements have not yet been issued or have not been made available for issuance. We have elected to early adopt this standard on a modified retrospective basis at the beginning of the period presented as we elected to account for forfeitures when they occur to reduce the complexity in the accounting of share based compensation.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230)*. The update is intended to improve financial reporting in regards to how certain transactions are classified in the statement of cash flows. This update requires that debt extinguishment costs be classified as cash outflows for financing activities and provides additional classification guidance for the statement of cash flows. The update also requires that the classification of cash receipts and payments that have aspects of more than one class of cash flows to be determined by applying specific guidance under generally accepted accounting principles. The update also requires that each separately identifiable source or use within the cash receipts and payments be classified on the basis of their nature in financing, investing or operating activities. The update is effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are in the process of evaluating the impact of adoption of this guidance on the consolidated financial statements.

In October 2016, FASB issued ASU 2016-16, *Income Taxes (Topic 740)*. Under the new standard, an entity is to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The new standard does not include new disclosure requirements; however, existing disclosure requirements might be applicable when accounting for the current and deferred income taxes for an intra-entity transfer of an asset other than inventory. The new standard is effective for annual periods beginning after December 15, 2017, including interim reporting periods within those annual periods. The ASU is not expected impact the consolidated balance sheet upon adoption.

In October 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash*. The update applies to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. The update addresses diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows, and requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The update is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The updates should be applied using a retrospective transition method to each period presented. We currently do not have restricted cash balances.

JOBS Act exemptions and foreign private issuer status

We qualify as an “emerging growth company” as defined in the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700.0 million in market value of our ordinary shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

Upon consummation of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

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

Industry

Evolution of China's emerging innovative pharmaceutical market

China's pharmaceutical market is the second largest pharmaceutical market in the world and is projected to grow from $115 billion in 2016 to $160 billion by 2021 and $237 billion by 2026, according to BMI Research. This growth is driven by strong fundamental demand for therapeutic treatments and the Chinese government's focus on providing better quality care to patients including by encouraging greater usage of innovative drugs. We believe that the significant market opportunities for innovative therapies in the China market are due to several trends, including:

1. **Demographics and disease incidence:** China's large and rapidly aging population, increasingly sedentary and westernized lifestyle and environmental pollution are contributing to rising incidence rates of diseases in China, such as cancer. China had a total annual cancer incidence of 4.3 million people, compared to 1.7 million in the United States in 2015. For some specific tumor types, including lung, gastric and liver, China's incidence represents approximately 40% to 50% of worldwide incidences.

2. **Improving access to healthcare:** The Chinese government has been strongly committed to improving healthcare access for patients, including enabling access to healthcare through universal public insurance coverage. Recently, the Chinese government has encouraged commercial private health insurance to further increase healthcare accessibility.

3. **Increasing affordability and demand for healthcare:** According to the Global Wealth Report 2015, China's middle class population, adjusted for local purchasing power, amounted to 109 million people, which is larger than the 92 million middle class population in the United States. Nevertheless, China's middle class accounted for only 11% of the total Chinese adult population in 2015, lower than the 38% in the United States, and this share is expected to grow. The rising middle class in China is expected to lead to increasing self-awareness of health issues and demand for more effective treatments.

4. **Focus on innovation:** Historically, China's pharmaceutical market was dominated by mature and generic products. In 2016, innovative patented prescription drugs accounted for only 22% of total drug sales in China, significantly lower than the approximately 75% share of patented drugs in the United States. In recent years, the Chinese government has focused on promoting innovation especially in areas of high unmet medical need through streamlining regulatory processes, improving drug quality standards and fostering a favorable environment for innovation. For example in 2016, the Chinese government announced the "Healthy China 2030" plan, which included a goal to increase the overall five year survival rate of cancer by 15% by 2030, which we believe underscores the need for innovative therapies. Going forward, innovative patented therapeutics are projected to grow at over 10% annually until 2020, which is expected to surpass the growth rate of generic products.

CFDA regulatory outlook—CFDA reform to accelerate innovation

Historically, time to market of new products has been slow in China due to long regulatory timelines, resulting from large numbers of applications for generic drugs, constrained capability of China's Center for Drug Evaluation, or CDE, and other factors. In 2014, there were approximately 120 staff members in the CDE to review more than 8,000 new drug applications every year. This resulted in a large volume of backlog. Recognizing these issues and determined to promote innovation, in August 2015 China's State Council released its circular *Opinions Concerning the Reform of the Review and Approval System for Drugs and Medical Devices*, or

Circular No. 44, which sets forth the government's clear determination to encourage transformation and upgrade of the pharmaceutical industry. It also officially started the CFDA's reform of the drug review and approval system, with five major goals:

1. Improve the quality of regulatory approval and establish a more scientific and efficient evaluation system for drug and medical device registration;
2. Clear the backlog of registration applications and strictly control the approval of oversupplied drugs;
3. Accelerate the conformance assessment of generic drugs;
4. Encourage clinically oriented drug innovation, improve the review process of innovative drugs, open approval fast lanes for innovative drugs of high clinical demand and introduce the pilot Marketing Authorization Holder, or MAH, scheme to incentivize local biopharmaceutical companies to engage in drug development while utilizing contract manufacturers in China to manufacture their drugs; and
5. Make the approval process more transparent to the public.

Since the launch of this initiative, significant progress has been made by the CFDA. Total CDE staff numbers increased to around 600 by 2016 and the backlog has been almost eliminated, according to the 2016 working report of the CDE. The IND/CTA timeline has been reduced from an average of 33 months to eight months, and the NDA timeline from 35 months to 11 months, according to the Boston Consulting Group. Meanwhile, priority review for innovative drugs with large unmet need has been established. In 2016, approximately 200 drug applications were granted priority review, of which approximately 40% were oncology, autoimmune or infectious disease therapeutics.

More recently, on May 11, 2017, the CFDA issued three new draft policies regarding innovation for public comments. The three draft policies aim to accelerate the review and approval of new drug and medical device applications (Circular No. 52), deregulate the conduct of clinical trials to encourage innovation (Circular No. 53), and enhance post-market supervision throughout a product's entire life cycle (Circular No. 54). Specifically, several new measures were proposed by the draft policies to reduce government controls over clinical studies and marketing authorizations, including, but not limited to:

- ***Streamline of the clinical trial authorization process.*** Like the IND process in the United States, companies would need to submit a CTA to the CDE but will only need to wait 60 working days before initiating the study, unless the CDE rejects the application or issues a deficiency notice during the 60-day period.
- ***Accept foreign clinical study data.*** Foreign clinical data can be submitted to support NDA applications in China as long as (i) the studies comply with Chinese regulations, (ii) the studies pass the CFDA's on-site audits and (iii) applicants can provide clinical data to prove that no ethnicity difference affects the drug's safety and efficacy.
- ***Improve efficiency of ethics reviews.*** Currently, ethics committee review at clinical trial sites occurs after the CDE's approval of the CTA. In the proposed regulatory scheme, companies can apply for ethics committee review and approval in parallel to the CDE's review of the CTA.
- ***Allow conditional approvals for urgently needed therapies.*** Drugs that offer new solutions for treating life-threatening diseases or address critical unmet medical needs could be eligible for conditional approval, as long as early- and mid-stage study data in clinical trials indicate their efficacy and predict their clinical value. Companies receiving conditional approval must develop a risk management plan and initiate confirmatory post-approval studies in accordance with the requirements in the conditional approvals. Innovative drugs sponsored by the National Science and Technology Major Project can be eligible for expedited review and approval.

- ***Market access benefits.*** Hospitals will be encouraged to prioritize their procurement and use of new drugs with definite efficacy and reasonable prices. The government will support inclusion of innovative drugs in the basic medical insurance scheme, and the reimbursable drug list will be updated more frequently.

If the draft polices are adopted, the regulatory process will be further streamlined and speed-to-market of new products is expected to accelerate. Furthermore, these circulars appear to demonstrate the CFDA's direction of gradually conforming to ICH guidelines. Consequently, we believe that not only will this benefit pharmaceutical innovation in China but will also be especially advantageous for China based companies that are experienced with global standards of innovative drug development.

Medical insurance and drug spending outlook—multiple engines for improving affordability

Over the past decade, the Chinese national government has been working on alleviating the burden on individuals by expanding health insurance coverage from approximately 30% of the population in 2003 to over 95% in 2013, with a goal of achieving universal coverage by 2020. At the same time, medical insurance plans at the provincial level have been introduced to complement the basic insurance programs. This increase in health insurance coverage has had a dramatic impact on drug reimbursement and affordability in China.

In China, public drug reimbursement schemes depend on the inclusion on the National Reimbursement Drug List, or NRDL, and/or provincial reimbursement lists, or PRDL. Historically, the NRDL generally included basic or mature drugs, which were subject to significant price cuts with the PRDL having some flexibility to include more expensive and innovative therapies. In early 2017, the Chinese government updated the NRDL for the first time since its last update in 2009. With the strong intention to promote innovation, the Chinese government has added 339 new drugs to the NRDL, some of which are expensive oncology and autoimmune drugs, including Yi Sai Pu, a local recombinant TNFa receptor II product for rheumatoid arthritis, and Conmana®, the first domestically-developed oncology targeted therapy. In addition to these drugs, the Chinese government created a C-list with 44 more innovative drugs for price negotiation in 2017. Once an agreement on price is negotiated with manufacturers, they will be automatically listed in the NRDL. However, to be enrolled in the NRDL or PRDL, developers of innovative therapies typically must agree to a reduced price. We plan to decide on a case-by-case basis whether to seek inclusion of our drug candidates, if approved, on the NRDL or the PRDL.

Aside from the Chinese government's efforts to improve public reimbursement, a large part of China's population has become increasingly affluent and has demonstrated an ability and willingness to pay out-of-pocket for innovative drugs. For example, in June 2011, Betta Pharmaceutical Co., Ltd.'s drug Conmana®, the first domestically-developed oncology targeted therapy in China, was approved by the CFDA for second- or third- line treatment of advanced non-small cell lung cancer. In November 2014, the approved indication expanded to first-line treatment of patients with advanced-stage non-small cell lung cancer with epidermal growth factor receptor, or EGFR, mutations. Conmana®, along with the other EGFR inhibitor Iressa® were not included in the NRDL until 2017. Another EGFR inhibitor Tarceva® was included in the NRDL price negotiation list in April 2017. According to the CFDA Southern Medicine Economic Research Institute, aggregate China sales of these three EGFR inhibitors, mostly driven by patient self-pay, grew from approximately $180 million since Conmana's launch in 2011 to nearly $450 million in 2015. Although rapidly growing in recent years, this represented only 12.3% of the total lung cancer market in 2015. These relatively modest penetration rates highlight the growth potential for targeted therapy drugs as supported by both self-pay and improving public reimbursement environment.

In addition to government health insurance and self-pay, there is also growing government support for the development of commercial private health insurance to provide support for China's growing middle and upper classes. Favorable industry policies such as tax incentives to consumers have been issued. Total private health insurance premiums increased by over two times, from RMB 158.7 billion in 2014 to RMB 404.2 billion in 2016,

according to the China Insurance Regulatory Commission. There are now already more than 100 private insurers in China offering some type of medical coverage.

The advantages of being a China-based, innovation-focused biopharmaceutical platform

Innovation is one of China's strategic priorities in its most recent Five-Year Plan, a high-level master plan guiding China's economic development for a period of five years. The biopharmaceutical industry is one of the six "pillar industry sectors" in the government's pathway to transform China from a manufacturing-focused economy to an innovation-focused economy. Multiple initiatives have been implemented by the government to support this goal. For example, the State Key Healthcare Project designation is granted to promising therapies from China. The grant recipients may benefit from expedited regulatory review and other favorable conditions for the product, including market access benefits. Meanwhile, the Chinese government is also encouraging venture capital and private equity funds to invest in the biopharmaceutical industry and is providing tax incentives to companies that invest in the research and development of innovative drugs. Furthermore, the Chinese government introduced a "Thousand Talents Plan" to recruit leading overseas scientists and business leaders to advance high tech companies and encourage innovation in China. We expect that this multi-pronged approach will support the emergence of innovative, globally competitive China-based biopharmaceutical companies.

However, the China pharmaceutical market remains fragmented and dominated by a large number of generic, small-molecule drug manufacturers. Although the Chinese government is actively promoting consolidation through increasingly stringent regulatory requirements, the historical lack of investment in research and development has created a deficit in the infrastructure needed to keep pace with the government's focus on innovative drugs and its requirement to conduct robust clinical trials in Chinese patients. As a result, while there is a growing demand for innovative drugs to address urgent areas such as oncology, the domestic pharmaceutical companies lack effective clinical development capabilities. We believe there is a significant opportunity for global standard China-based companies that develop, manufacture and commercialize innovative medicines for the China market and beyond.

Some of the key advantages of being a fully integrated, China-based and innovation-focused biopharmaceutical development and commercialization platform include:

Accelerated time to market

The CFDA regulatory framework for new drug development is modeled on the FDA's development pathway. Upon completion of its preclinical research, the developer is required to obtain the CFDA's CTA before initiating clinical trials in China. A three-phase clinical evaluation program is typically required to demonstrate drug safety and efficacy. Developers then submit an NDA.

The CFDA adopted a classification system to guide its registration and approval pathways for chemical drugs, botanical drugs and biological drugs. New drugs and generics (or biosimilars) are assigned to different categories. Under the new classification system adopted by the CFDA in March 2016, chemical drugs are classified into five categories. Category 1 drugs refer to innovative chemical drugs which are not approved anywhere in the world at the time of their initial China CTA submission and are manufactured in China at the time of their NDA submissions. In comparison, imported drugs that are manufactured outside China or have been first approved by a foreign regulatory authority are referred to as Category 5 drugs. When a chemical drug candidate is accepted as Category 1, it is entitled to expedited CTA and NDA review and approval, similar to the FDA Fast Track Designation.

Market exclusivity for up to five years

Innovative drugs which are manufactured in China are monitored for five years by the CFDA following their NDA approval, during which the CFDA will not accept any applications for new drugs with the same active ingredient.

By contrast, an imported drug which receives its NDA approval from the CFDA is not afforded any protection from this monitoring requirement. Therefore, Category 1 new drugs approved by the CFDA and manufactured in China receive a *de facto* exclusivity (assuming no other applications were already on file) for five years plus the time it would take for the CFDA to accept, review and approve a competitor's NDA filing for a drug with the same active ingredient. We believe this regulatory framework provides significant advantages for companies developing and manufacturing new drugs in China.

Customized development programs which are tailored to Chinese patients' specific unmet medical needs, and higher efficiency in executing clinical development programs

Companies with China-based research and development operations are more likely to efficiently execute drug development programs in China. Moreover, we believe that companies with their headquarters and key decision makers in China will be able to develop broad and deep relationships with Chinese key opinion leaders which will have benefits both in the development and commercialization of drugs. By leveraging these strong working relationships, China-based companies can more efficiently collaborate with key opinion leaders to rapidly design clinical trial protocols to focus on the clinical needs and characteristics of Chinese patients that are in line with the standard of care in China, which can be different from the standard of care in either the United States or Europe. This localized approach to clinical development allows China-based companies to generate the clinical data in Chinese patients that satisfies the CFDA's stringent requirements for clinical trials to identify, or confirm the absence of, ethnicity differences a drug may have in Chinese patients. Through these interactions with Chinese key opinion leaders, domestic companies are also able to efficiently enroll and conduct their clinical trials in China. Moreover, by engaging with these key opinion leaders through the clinical trial stage, domestic companies gain prior experience and have superior communication channels to cultivate the endorsement of these key opinion leaders, which is important in commercializing the drug in China.

Global pharmaceutical companies have historically been and, we believe, continue to be focused on accessing familiar, more established markets, such as the United States and Europe, where they have established clinical development infrastructure. Their reluctance to commence early stage clinical trials in China will hinder the speed of executing clinical development programs for the Chinese market.

Commercialization of innovative therapies

China-based, innovation-focused biopharmaceutical companies have several advantages in commercializing their products in China. By engaging key opinion leaders in the design and conduct of local clinical trials, these drugs benefit from the key opinion leaders' practical experience and endorsement of their clinical efficacy in the Chinese population, which we believe may allow more rapid acceptance of the drug by physicians and accelerate market uptake. In addition, locally-developed products have other market access benefits, such as advantages in reimbursement and priority in hospital procurement. These advantages have already been demonstrated in the commercial success of local innovative drugs, which have taken market share from multinationals on several occasions.

For example, in the EGFR inhibitor market, Conmana was launched in 2011, approximately six years after Iressa's entry in China. By 2015, despite being the last EGFR inhibitor to enter the market, Conmana gained significant share from Iressa, reaching approximately 33% market share in the lung cancer EGFR inhibitor market, and becoming the second product in the market, after Iressa's 44% share. The advantage has also

been observed in the case of a local product launched earlier than multinational products. Yi Sai Pu was the first anti-TNF-a product approved for treating rheumatoid arthritis, which was developed by Shanghai CP Guojian Pharmaceutical Co. Ltd. and was launched in China in 2005. Other anti-TNF-a **therapies for rheumatoid arthritis such as Enbrel, Humira and Remicade all received CFDA approval between 2006 and 2010. More than 10 years after its launch, Yi Sai Pu has maintained its leading market position with a market share of over 60% as of 2016, according to 3SBio Inc. the maker of Yi Sai Pu. We believe these examples demonstrate the unique advantage of a local innovator when commercializing a product in China.**

Business

Overview of our business

We are an innovative biopharmaceutical company based in Shanghai focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China market, including in the fields of oncology, autoimmune and infectious diseases. We believe there exists a significant opportunity to build an organization that not only addresses such unmet needs but leverages underutilized resources in China to foster innovation. As part of that effort, we have assembled a management team with global experience and an extensive track record in navigating the regulatory process to develop and commercialize innovative drugs in China. Our mission is to leverage our expertise and insight to address the expanding needs of Chinese patients in order to transform their lives and eventually utilize our China-based competencies to impact human health worldwide.

Furthermore, Zai Lab was built on the vision that, despite having a significant addressable market and sizable growth potential, China has historically lacked access to many innovative therapies available in other parts of the world and its drug development infrastructure has been underutilized. There remains the need to bring new and transformative therapies to China. In recent years, the Chinese government has focused on promoting local innovation through streamlining regulatory processes, improving drug quality standards and fostering a favorable environment, which we believe creates an attractive opportunity for the growth of China-based, innovation-focused companies.

Since our founding in 2014, we have assembled an innovative pipeline consisting of six drug candidates through partnerships with global biopharmaceutical companies. These include three late-stage assets targeting fast growing segments of China's pharmaceutical market, and three assets addressing global unmet medical needs. We believe that our management's extensive global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, opportunities to partner with global companies aiming to bring innovative products to market in China efficiently.

To date, we have in-licensed three late-stage clinical drug candidates for development in China, Hong Kong, Macau and, in certain instances, Taiwan, through partnerships with Tesaro, Bristol-Myers Squibb and Paratek. Our CTAs for two of these drug candidates have been accepted as Category 1 drugs by the CFDA. This classification provides us with a competitive advantage as Category 1 drugs benefit from an expedited review of CTAs and NDAs as well as commercial benefits.

Our lead drug candidate is niraparib (ZL-2306), an oral, once-daily small molecule PARP 1/2 inhibitor being developed and commercialized by our partner Tesaro. In March 2017, Tesaro received FDA marketing approval for niraparib as a maintenance treatment for women with recurrent platinum-sensitive epithelial ovarian cancer and, in April 2017, commercially launched the product in the United States under the commercial name Zejula. Niraparib is the first PARP inhibitor approved by the FDA for ovarian cancer that does not require BRCA mutation or other biomarker testing. We believe niraparib is uniquely suited for the China marketplace where BRCA biomarker diagnostic tests are not widely available. We intend to develop niraparib for Chinese patients across multiple tumor types and anticipate beginning two Phase III studies of niraparib in patients with ovarian cancer, one in the second half of 2017 and the other in the first half of 2018. In addition, we intend to pursue niraparib in other indications.

As part of our licensing strategy, we have also obtained global development and commercialization rights to three drug candidates, including one late-stage clinical and two preclinical drug candidates, through partnerships with GSK, Sanofi and UCB. We intend to leverage our resources and competitive advantages in

China, including our ability to access China's large patient population and conduct efficient clinical trials, to rapidly and cost-effectively establish proof of concept for such candidates prior to pursuing further late-stage development for the global market.

In the longer term, we plan to build a premier, fully integrated drug discovery and development platform that brings both in-licensed and internally-discovered medicines to patients in China and globally. Our strong in-house research and development team had previously been directly involved in the discovery and development of several successful innovative drug candidates at Hutchison Medi-Pharma, including fruquintinib and savolitinib. These assets were out-licensed to Eli Lilly and AstraZeneca, respectively. Our in-house discovery team is currently focused on exploring immuno-oncology approaches to treating cancer. We have collaborations with leading academic institutions in China, including Tsinghua University and Shanghai Institute of Materia Medica, to expand our in-house research projects. We believe this team and our discovery strategy will enable us to achieve our long-term goal of commercializing our internally discovered innovative medicine for patients worldwide.

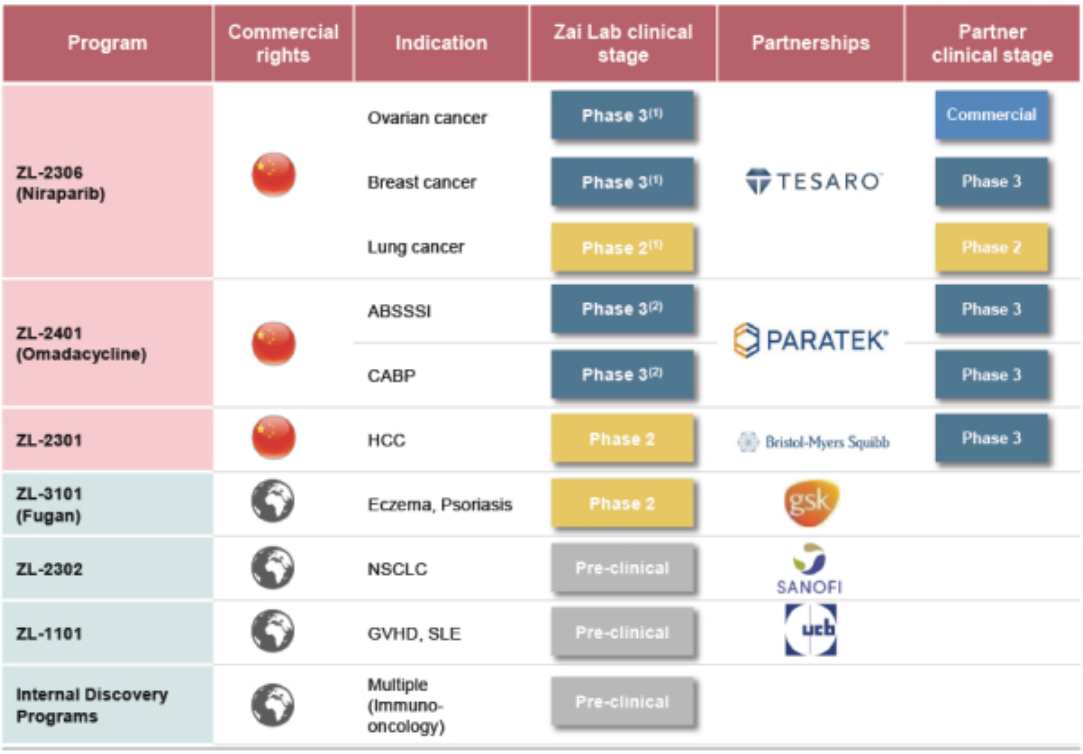
As our business grows, we plan to build our own commercial team to launch our portfolio of drug products. Part of our strategy to become a fully integrated biopharmaceutical company is the ability to produce both large and small molecule therapeutics under global standard cGMP. To this end, in the first half of 2017 we built a small molecule drug product facility capable of supporting clinical and commercial production and have also begun construction of a large molecule facility. Completion of the large molecule facility is expected in the first half of 2018.

Finally, our company is led by a management team with extensive pharmaceutical research, development and commercialization track record in both global and Chinese biopharmaceutical companies. Our team is passionate about bringing transformative medicines to patients in China and worldwide.

Since our founding in 2014, we have raised $134.5 million in equity financing from our dedicated group of investors, including global and China-based healthcare funds.

Our innovative pipeline

We have a broad pipeline of proprietary drug candidates that range from discovery stage to late-stage clinical programs. These include three drug candidates with greater China rights and three drug candidates with global rights. The following table summarizes our drug candidates and programs:



(1) Pending CTA approval from CFDA to initiate the clinical trials.

(2) Pending submission of CTA and approval from CFDA.

Our greater China rights drug candidates

Our three late-stage products with greater China rights focus on oncology and infectious diseases, two therapeutic areas where there is a large unmet need and lack of innovative treatment options in China. These drug candidates include:

- **Niraparib (ZL-2306)**, a highly potent and selective oral, small molecule PARP 1/2 inhibitor with the potential to be a first-in-class drug for treatment across multiple solid tumor types in China including ovarian and certain types of breast and lung cancers. We have licensed niraparib from Tesaro, which in March 2017 received FDA marketing approval for niraparib (Zejula®) as maintenance treatment for women with recurrent platinum-sensitive epithelial ovarian cancer. Niraparib was commercially launched in the United States in April 2017. Niraparib does not require BRCA mutation or other biomarker testing as is necessary for other approved PARP inhibitors which, we believe, significantly expands its availability to ovarian cancer patients in China. During the second half of 2018, we expect to commercialize niraparib for the treatment of ovarian cancer in Hong Kong and Macau where the drug will be eligible for an expedited registration process after being approved by the FDA and EMA. In China, our CTA for niraparib has been accepted as a Category 1 drug by the CFDA. We anticipate

initiating Phase III studies of niraparib in patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy in the second half of 2017, and as a first-line maintenance therapy in the first half of 2018. These studies are expected to be similar in design to Tesaro's clinical studies of niraparib. We also anticipate beginning a Phase III study in patients with gBRCA positive breast cancer in the first half of 2018. In addition, we intend to study niraparib in patients with triple negative breast cancer, squamous-type non-small cell lung cancer and small cell lung cancer in China. Niraparib has the potential to be the first PARP inhibitor marketed in China. In addition to niraparib monotherapy in the potential indications stated, we also intend to explore the combination of niraparib with other potential therapies such as immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

- **Omadacycline (ZL-2401)** is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. We have licensed omadacycline from Paratek which is primarily being developed for ABSSSI, CABP and UTI. Omadacycline is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. If approved, omadacycline is expected to be available in IV and PO once-daily formulations. Paratek has reported the results of two pivotal Phase III studies of omadacycline in ABSSSI and CABP. Both of these studies achieved their primary endpoints. Paratek anticipates reporting top-line data from its oral-only Phase III ABSSSI study in mid-2017. We are in the technology transfer stage and plan to discuss China development plans with key opinion leaders and the CFDA.
- **ZL-2301** is an oral, small molecule dual target TKI which blocks both VEGFR and FGFR. ZL-2301 was studied by our partner Bristol-Myers Squibb mainly for the treatment of HCC, the most common type of liver cancer. In these trials, ZL-2301 demonstrated anti-tumor activity and a generally well-established safety profile in HCC patients. In 2012, Bristol-Myers Squibb terminated its development program of ZL-2301 after it missed the primary endpoints in two Phase III trials with advanced HCC patients. Based on our review of the results from Bristol-Myers Squibb's development program for ZL-2301, our understanding of the etiology and current standard of care of HCC in Chinese patients and our ongoing research, we believe that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical trials. The CFDA has approved our CTA for ZL-2301 as a Category 1 drug, and in the second quarter of 2017 we initiated a Phase II trial of ZL-2301 as a second-line treatment for advanced HCC patients in China. Pending results from this Phase II trial, we plan to initiate a Phase III clinical trial shortly thereafter.

For our late-stage oncology drug candidates with greater China rights, our near-term development plan focuses on specific patient segments. These patient segments have an estimated annual incidence of approximately 816,000 patients in China. We expect that the commercial success of our products will be driven by their differentiated clinical profiles, efficacy in Chinese patients and ability to provide clinical benefit over existing standards of care in a market where targeted therapies are either unavailable or less utilized relative to more developed markets. For additional information, please refer to the "Market Opportunity" section under each our clinical stage product candidates.

In addition to the opportunities available for our oncology products, we believe that, through our development of omadacycline, we have the chance to introduce into China a new broad-spectrum antibiotic with excellent activity not only against common Gram-positive and Gram-negative bacteria, but also against several MDR pathogens. The profile of omadacycline includes MRSA, enterococci, ESBL-E. coli and many Acinetobacter isolates. In addition, availability of an IV and oral formulation allows treatment of hospital- and community-acquired infections. 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. A 2015 study indicated that the total antibiotic usage in China in 2013 accounted for about half of the global antibiotic usage, with a per-capita use of antibiotics in China being more than five times that in Europe and the United States. Based on

our estimates, in 2015 there was an incidence of approximately 2.8 million ABSSSI patients and 16.5 million CABP patients in China.

The China market opportunity for our greater China-rights drug candidates

Program	Clinical Stage	Indication	Annual Incidence (thousands)[a]	Targeted Patient Segment	Targeted Patients (thousands)
ZL-2306 (Niraparib)	Phase 3[b]	Ovarian cancer	52.1[1]	All ovarian patients	52.1
	Phase 3[b]	Breast cancer	272.4[1]	gBRCA positive Triple negative	27.2[2] 40.9[2]
	Phase 2[b]	Lung cancer	733.3[1]	Squamous Non-small cell lung cancer Small cell lung cancer	176.0[3] 146.7[3]
ZL-2401 (Omadacycline)	Phase 3[c]	ABSSSI	2,800.0[4]	All ABSSSI patients	2,800.0[4]
	Phase 3[c]	CABP	16,500.0[4]	All CABP patients	16,500.0[4]
ZL-2301	Phase 2	HCC	372.9[1,5]	HCC	372.9[1,5]

Note:

a) All incidence numbers are based on 2015 data, and include mainland China patients only.

b) Pending CTA approval from CFDA to initiate the stage.

c) Pending submission of CTA and approval by CFDA.

Sources: 1. Cancer Statistics in China, 2015, a study published by Wangqing Chen et. al. in "A Cancer Journal for Clinicians" in 2016, and based on historical data from 72 local, population-based cancer registries, representing 6.5% of China's population. 2. Assumes that 10% and 15% of the total breast cancer patients would be with gBRCA+ mutation and triple negative mutation, respectively. According to the study by Kim and Choi in 2013, the percentage of BRCA 1/2 gene mutation in familial breast cancer and early-onset breast cancer patients ranged from 8.0% to 13.5% and from 8.7% to 11.4%, respectively. 10-20% of breast cancer is Triple-negative, according to the study by Ping-Ping Bao et. al in 2016. 3. American Cancer Society estimated that globally about 80-85% of lung cancers are non-small cell lung cancer, and about 25-30% of lung cancers are squamous cell carcinomas. Calculation is based on 80% for NSCLC, of which 30% is squamous non-small cell lung cancer, and 20% for small cell lung cancer patients. 4. Management estimate. 5. According to the study by Ran Xu Zhu et. al. in 2016, HCC accounts for 80% of liver cancer patients.

In addition to mainland China, we intend to seek registration and commercialization of the above drug candidates, where we have applicable rights, in Hong Kong, Macau and Taiwan. For Hong Kong and Macau, products with existing approvals by the FDA, EMA or a comparable regulatory agency are eligible for an expedited registration process that does not require conducting local clinical trials. In the case of niraparib, we intend to pursue expedited registration and expect to launch and commercialize niraparib in Hong Kong and Macau by the second half of 2018.

While the overall patient population in Hong Kong and Macau is smaller compared to that of China, they are higher income markets with developed medical infrastructure, widely available private insurance and proven capacity to pay for advanced therapeutics. In addition to local patients, there is a significant opportunity to provide treatment for medical tourists from China, who visit these regions in order to access high-end cancer treatment, including prescription drugs which may not be available in mainland China.

Our global rights drug candidates

Our drug candidates for which we retain global rights include:

- **Fugan (ZL-3101)** is a novel steroid-sparing topical product for the treatment of eczema and psoriasis. We are developing fugan as a botanical formulation to offer patients with eczema and psoriasis a natural alternative to topical steroid treatments, which are currently the main forms of treatment and are known to have many side effects associated with long-term use. We licensed the exclusive worldwide rights to fugan from GSK in 2016. We initiated a Phase II study of fugan in patients with eczema in China in the second quarter of 2017. Pending results of this Phase II study, we plan to initiate a Phase III global, multi-center clinical trial.
- **ZL-2302** is a multi-targeted TKI with activity against both ALK mutation and crizotinib-resistant ALK mutations being developed for the treatment of patients with non-small cell lung cancer who have ALK mutations and who have developed crizotinib resistance and/or brain metastasis. We licensed the exclusive worldwide rights to ZL-2302 from Sanofi in 2015. Our preclinical studies demonstrated that ZL-2302 has ability to penetrate the blood-brain barrier, which could make ZL-2302 an effective therapy for a subset of patients who have non-small cell lung cancer with ALK mutations and brain metastasis. Such patients typically have limited treatment options, poor prognosis and low quality of life. Our CTA for ZL-2302 has been accepted as a Category 1 drug by the CFDA, and we expect to initiate a Phase I study of ZL-2302 in China in the first half of 2018.
- **ZL-1101** is an anti-OX40 antagonistic antibody with first-in-class potential for the treatment of a range of autoimmune diseases such as graft-versus-host disease or systemic lupus erythematosus. We licensed the exclusive worldwide rights to ZL-1101 from UCB in 2015. Its anti-inflammatory activities have been validated by a variety of inflammatory and autoimmune disease models. ZL-1101's bioactivities and functional potency have been investigated in both *in vitro* and *in vivo* studies. In such studies, cellular proliferation and production of inflammatory cytokines was markedly suppressed, demonstrating that ZL-1101 effectively inhibits lymphocyte activation. ZL-1101 was also found to be highly potent. We intend to file an IND in 2018.

Our vision and strategy

Our vision is to become a leading global innovative biopharmaceutical company based in China and deliver transformative medicines to patients in China and around the world. We intend to utilize our strengths to pursue the following strategies:

Rapidly advance and commercialize our in-licensed late stage clinical drug candidates.

Two of our late stage assets, niraparib and ZL-2301, have the potential to address large unmet medical needs in China's oncology drug market, where there is a higher total incidence in our targeted indications compared to the United States market. In addition to our oncology products, we believe that through our development of ZL-2401 we have the chance to introduce into China a new and effective broad-spectrum antibiotic, while ZL-3101 could offer eczema and psoriasis patients with a natural alternative to topical steroid treatments, which are known to have many side effects associated with long-term use.

We intend to advance our lead asset, niraparib, into two Phase III trials in China as a second-line and first-line maintenance treatment in platinum sensitive ovarian cancer patients, regardless of their gBRCA mutation status, in the second half of 2017 and first half of 2018, respectively. We also anticipate beginning a Phase III study in patients with gBRCA mutation positive breast cancer in the first half of 2018. Niraparib has the potential to be the first PARP inhibitor marketed in China. During the second half of 2018, we plan to begin commercializing niraparib for the treatment of ovarian cancer in Hong Kong and Macau, where the drug will be eligible for an expedited registration process after being approved by the FDA and EMA.

In April 2017, we received an exclusive sub-license from Paratek to develop, manufacture and commercialize omadacycline in China, Hong Kong, Macau and Taiwan. Based on the clinical data, we believe omadacycline has the potential to be an effective treatment of patients with serious bacterial infections. We are in the technology transfer stage and plan to discuss China development plans with key opinion leaders and the CFDA.

In the second quarter of 2017, we initiated a Phase II trial for our dual target TKI, ZL-2301, in advanced HCC patients in China to investigate its optimal treatment schedule and dosage as a second-line treatment. Pending Phase II results, we intend to initiate to a Phase III registration trial. We also initiated a Phase II study of fugan, our global rights product, in patients with eczema in China in the second quarter of 2017. Pending results from this Phase II study, we plan to initiate a Phase III global, multi-center trial.

Capitalize on our location in China, our management team's domestic and international drug development experience and our track record of licensing to further solidify our position as a strategic gateway partner into China for biopharmaceutical companies outside of China.

Our drug development team has extensive domestic and international development expertise, combining unique insight in screening drug candidates in global development and an in-depth understanding of the Chinese development pathway. We believe that our management team's experience navigating the Chinese regulatory framework, combined with potential enrollment efficiencies, including many treatment-naïve patients, concentrated treatment centers, and relatively lower clinical costs, gives us the ability to bring products to market in China expediently. Moreover, we benefit from China's recent regulatory reforms, which aim to elevate drug quality standards and achieve a faster drug application review process. Given our plans to develop and manufacture our current clinical-stage drug candidates in China, we believe our current clinical drug candidates, other than fugan, will remain Category 1 drugs throughout the development and approval process, making them eligible for expedited regulatory pathways in China.

Conversely, global pharmaceutical companies have historically been and, we believe, continue to be, focused on mature western markets, with which they are more familiar and where they have established clinical development infrastructure. Their reluctance to commence early stage clinical trials in China and to prioritize obtaining China manufacturing rights for innovative products restricts such drug candidates potential to be classified as Category 1, which typically results in a longer regulatory review process than a domestically-manufactured drug candidate classified as Category 1. This has resulted in significant medical demand for innovative treatment options in China. In order to address this unmet medical need and to capture the rapid growth in the Chinese pharmaceutical market, we believe that an increasing number of pharmaceutical companies outside of China will seek to commercialize their drugs in China through a local partner that can do so in a timely and cost-effective manner.

As a result, we believe the combination of our management's experience and knowledge, the changing regulatory landscape in China, the manufacturing and commercial capabilities we are developing and the global pharmaceutical industry's current approach to the China market makes us an ideal gateway partner for biopharmaceutical companies outside of China seeking access to the China market. The recognition of our team as a local partner of choice in China is evidenced by our partnerships with global biopharmaceutical companies, including Tesaro, Paratek and Bristol-Myers Squibb, that out-licensed their clinical products to Zai Lab. We will continue to actively seek high quality drug candidates and to evaluate inbound interest we receive. We are currently in active negotiations for multiple promising assets to further our ambitions to bring new medicines to the China market.

Continue to license promising programs for global rights.

We have a track record of in-licensing the global rights of drug candidates from leading global biopharmaceutical companies such as GSK, Sanofi and UCB. We will continue to seek new in-licensing

opportunities which grant us the global rights for differentiated drug candidates. In particular, we focus on candidates that are complementary to our drug pipeline, have demonstrated promising data in early clinical studies and have large global market potential. 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.

Build a fully integrated platform with drug discovery, development, manufacturing and commercialization capabilities in China and expand globally.

We will continue to execute our strategy to become a fully integrated biopharmaceutical company in China. We have assembled an internal research and development team with extensive capabilities, whom we will leverage to discover and develop innovative drug candidates in China and globally. By focusing on developing, manufacturing and commercializing our late-stage in-licensed drug candidates in parallel with expanding our earlier-stage internal research and discovery capabilities, we believe we can rapidly establish a fully integrated biopharmaceutical platform. We believe that building our own China manufacturing and commercialization capabilities presents tangible benefits, which include maintaining better control over the quality and compliance of our operations with increasingly stringent industry regulations and receiving government manufacturing incentives. In addition, where appropriate, we will use China-based high-quality contract manufacturers as back-up and to supplement our internal manufacturing capabilities. By using our own internal manufacturing facilities or China-based contract manufacturers, we believe that we will be able to seek and maintain a Category 1 classification for our current clinical stage drug candidates (other than fugan) throughout the IND and NDA review process, where utilizing China-based manufacturing is a necessary condition for such classification. We believe these capabilities make us a more attractive China licensing partner for global pharmaceutical companies.

We have already built a cGMP-compliant small molecule facility capable of supporting clinical and commercial production and have begun construction of a cGMP-compliant large molecule facility capable of supporting clinical production of our drug candidates in China. The construction of the large molecule facility is expected to be completed in the first half of 2018.

Furthermore, to support our planned commercial launch of niraparib in Hong Kong and Macau in the second half of 2018, we have developed a targeted sales and marketing strategy and plan to build a specialized sales force to cover major medical centers in greater China, where the administration of innovative treatments for cancers and other diseases tend to be concentrated.

Leverage our senior management's experience.

Our management team has extensive experience in the global pharmaceutical industry and is led by our Chief Executive Officer, Samantha Du, Ph.D., who is widely recognized as a leading figure in the China biotech industry. Before the founding of our business, Samantha Du managed the healthcare investment team for Sequoia Capital China, or Sequoia, where she led the fund's investments, including Betta Pharma, BGI Genomics, and JHL Biotech. Prior to Sequoia, Samantha Du founded Hutchison Medi-Pharma as its Chief Executive Officer for over 10 years and co-founded and served as the Chief Scientific Officer of Hutchison China MediTech Limited, or Hutchison, a Nasdaq-listed biopharmaceutical company, where she pioneered China-based global biopharmaceutical innovation by bringing five innovative drug candidates into clinical development and for forging drug collaborations with AstraZeneca, Johnson & Johnson, Eli Lilly and Merck Serono. While at Hutchison, Samantha Du spearheaded the regulatory strategy for securing the very first green channel treatment, a CFDA policy that allows for an expedited registration process for innovative medical assets, for a Category 1 new drug asset, and also produced two programs that successfully completed multiple

global Phase III trials. Prior to Hutchison, she was responsible for its global metabolic licensing programs on the scientific side for Pfizer in the United States and was also involved in the development of two clinical stage assets which were launched globally.

In addition to Samantha Du, our senior management team includes our Chief Medical Officer, Oncology, Qi Liu, M.D., Ph.D., a board-certified medical oncologist and hematologist, and our Chief Medical Officer, Autoimmune and Infectious Diseases, Harald Reinhart, M.D., board-certified in internal medicine and infectious diseases.

Prior to joining our company, Dr. Liu was the clinical lead of the BioVenture group at AstraZeneca and executive medical director of AstraZeneca Oncology Global Medicine Development, where she played an essential role in establishing AstraZeneca's biologics joint ventures and was responsible for its joint venture global development programs, regulatory strategy and submissions. She also played an important role in AstraZeneca's TKI development program. Dr. Liu completed her post-doctoral fellowship at Memorial Sloan-Kettering Cancer Center and medical oncology and hematology fellowship at the MD Anderson Cancer Center where she was an assistant professor prior to joining AstraZeneca.

Prior to joining our company, Dr. Reinhart was the head of clinical development and medical affairs at Shionogi US, where he managed a broad portfolio of antibiotics, diabetes, allergy and pain medications, as well as guided a pharmaceutical compound through an NDA submission and approval. He also held senior roles at Novartis, where he oversaw successful filings of SNDAs and NDAs for Coartem, Famvir, Sebivo and Cubicin Dr. Reinhart received a medical degree from the University of Würzburg in Germany and completed his specialty training in the United States.

Our clinical pipeline

Niraparib

Niraparib (ZL-2306) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) polymerase 1/2, or PARP 1/2, inhibitor with the potential to be a first-in-class drug for treatment across multiple solid tumor types in China. In March 2017, niraparib was approved by the FDA 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-chemo therapy for more than six months.

Niraparib is the first PARP inhibitor to be approved by the FDA for ovarian cancer that does not require BRCA mutation or other biomarker testing as is required for other approved PARP inhibitors. This makes niraparib suitable for a wide patient population and significantly more accessible to patients in China where BRCA biomarker diagnostic tests are not widely available. If approved by the CFDA, niraparib may potentially be the first PARP inhibitor on the China market approved for second-line maintenance treatment in all recurrent platinum-sensitive ovarian cancer patients.

We obtained an exclusive license for the development and commercialization of niraparib in China, Hong Kong and Macau in 2016. During the second half of 2018, we expect to commercialize niraparib in Hong Kong and Macau where the drug will be eligible for an expedited registration process after it has been approved by the FDA and the EMA. In addition, our CTA for niraparib has been accepted as a Category 1 drug, and we plan to initiate a Phase I pharmacokinetics, or PK, trial and two Phase III trials for niraparib as a first-line and second-line maintenance treatment in patients with platinum-sensitive ovarian cancer in China. We also intend to study niraparib in patients with gBRCA positive breast cancer and lung cancer in China, either as a monotherapy or combination.

Market opportunity

We believe that niraparib 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 niraparib as a potential first-in-class treatment in ovarian and certain types of breast and lung cancers. Across our targeted patient segments in the ovarian, breast cancer and lung indications, we estimate a total annual incidence of 443,000 patients based on 2015 data.

In addition to the drug's broad applicability, we believe niraparib is likely to be the first PARP inhibitor on the market in China. Based on our understanding, local PARP inhibitor product candidates are currently in early stage China clinical trials. Global PARP inhibitor products have either not yet made an application in China (Clovis Oncology, Pfizer, AbbVie), or have included a limited number of Chinese patients as part of its global Phase III studies in BRCA+ patient population, which would likely require additional local clinical trials prior to obtaining CFDA approval (AstraZeneca).

Our currently targeted indications for niraparib include the following:

Ovarian cancer

Ovarian cancer had an estimated annual incidence of 52,000 patients in China in 2015, which is more than double that of the 21,300 patients in the United States and has seen increasing mortality rates. Since early symptoms of ovarian cancer are non-specific and difficult to detect, a majority 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. Given the broad applicability of niraparib 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 available.

The current 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 women. Many women 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. Therefore, we believe effective maintenance therapies that address a broad patient population are needed to prolong the duration of response following platinum-based treatment.

Breast cancer

Breast cancer is one of the leading causes of cancer death among women in China, with a total estimated annual incidence of 268,600 female patients in 2015, which is nearly 16% larger than the incidence of 231,840 female patients in the United States. Breast cancer has also seen an increasing mortality rate. We initially intend to seek approval for niraparib for treatment of gBRCA positive breast cancer. We also contemplate seeking indication expansion in other patient sub-groups, such as triple negative breast cancer patients. If

approved for usage in gBRCA mutation positive and triple negative breast cancer patients, we estimate a target patient pool of approximately 68,000 people, representing about a quarter of total breast cancer incidence in China.

There is no single standard treatment in patients with metastatic breast cancer who have previously failed anthracycline and taxane treatments. Furthermore, there are no approved treatments for patients with BRCA mutations, and patients are only treated according to the status of their hormone receptor and human epidermal growth factor receptor 2, or HER2, status, where Herceptin is the recommended targeted therapy. Therefore, more effective therapies that specifically address the gBRCA+ patient population are needed.

We believe niraparib could bring significant benefits to gBRCA+ metastatic breast cancer patients in China based on available clinical results from niraparib and further clinical validation from other PARP inhibitors. In a Phase I dose-escalation and confirmation study in participants with advanced solid tumors, two of the four breast cancer patients carrying gBRCA mutations had partial response as best response (response rate in patients with gBRCA mutations: 50%; 95% CI: 7%, 93%). The clinical potential of PARP inhibitors in this patient population has also been established by the results of a positive Phase III study of AstraZeneca's olaparib. In February 2017, AstraZeneca announced that olaparib improved progression-free survival versus standard chemotherapy in patients with gBRCA+ metastatic breast cancer, according to findings from its Phase III trial.

Epidemiologic studies of BRCA 1/2 mutations in Chinese breast cancer patients performed in China, Hong Kong, Taiwan, and Singapore have shown a prevalence of BRCA 1/2 gene mutation in familial breast cancer and early-onset breast cancer patients that ranged from 8.0% to 13.5% and from 8.7% to 11.4%, respectively. In addition, triple-negative breast cancer accounts for 10%—20% of all invasive breast cancer subtypes.

In the case of triple negative breast cancer patients, since tumor cells lack the necessary receptors, common treatments like hormone therapy and drugs that target HER-2 are ineffective. While chemotherapy is used as standard treatment, there is unmet need for other treatment options that can improve patient survival and overcome the long-term issue of chemoresistance. Global clinical data has suggested that the combination of a PARP inhibibitor and chemotherapy might be more effective than chemotherapy alone, and we intend to explore usage of niraparib in this patient segment.

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 733,300 patients in China in 2015, which is more than triple the 221,200 patients in the United States. We intend to explore niraparib's efficacy in patients with squamous-type non-small cell lung cancer and small cell lung cancer based on the large unmet need for effective treatment for such patients in China. According to the American Cancer Society, approximately 80% to 85% of lung cancers are non-small cell lung cancer and squamous cell carcinoma is about 25% to 30% of lung cancers. Based on an assumption of 80% share of non-small cell lung cancer and 30% of cancers being squamous, we estimate a potential target patient population of 176,000 patients with squamous-type non-small cell lung cancer and 147,000 in small cell lung cancer in China.

The standard of care for advanced small cell lung cancer and non-small cell lung cancer in China is platinum-based chemotherapy. For EGFR mutation positive patients, geftinib (Iressa®) and erlotibib (Tarceva®) are recommended as first-line therapies for patients in the advanced/metastatic stage of non-small cell lung cancer who are EGFR mutation positive. For non-small cell lung cancer patients with unclear EGFR mutation status, as well as for small cell lung cancer, chemotherapy is the standard of care in China.

We believe niraparib has first-in-class potential in both indications in China, by representing an attractive addition to the current standard of care in small cell lung cancer and squamous type non-small cell lung cancer.

While globally monoclonal antibodies, which block the interaction between checkpoint molecules PD-1 on immune cells and PD-L1 on cancer cells, have been used to successfully treat non-small cell lung cancer, these drugs have yet been launched in China and remain in clinical trials. Given the relatively limited therapy options for Chinese physicians and patients we believe that a small molecule PARP inhibitor will offer an attractive addition to the standard of care with an attractive price level relative to large molecule drugs.

In addition to niraparib monotherapy in the potential indications stated above, we also intend to explore the combination of niraparib with other potential therapies such as immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

Our clinical trial designs and strategy for niraparib in the China market

Ovarian cancer

We plan to initiate three clinical studies of niraparib in ovarian cancer patients in China. One is a Phase I PK study for niraparib in patients with platinum-sensitive ovarian cancer. The other two studies will be Phase III studies of niraparib as a maintenance therapy in patients with platinum-sensitive ovarian cancer either as a first-line or second-line maintenance therapy. If approved, niraparib may potentially be the first PARP inhibitor on the China market approved as a second-line maintenance therapy in all recurrent platinum-sensitive ovarian cancer patients, and we would look to rapidly expand niraparib to be available as a first-line maintenance therapy.

Our Phase I PK study is intended to establish the PK profile of niraparib in Chinese patients. We expect to initiate this study in the second half of 2017.

Our first Phase III study is expected to evaluate niraparib as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. Patients with recurrent platinum sensitive ovarian cancer who have responded to a second line platinum-containing treatment will be enrolled in the study. Patients will be randomly assigned in a 2:1 ratio to receive niraparib or placebo once daily. Patients will be stratified by gBRCA status. The primary endpoint is progression-free survival. The primary analysis will be conducted in the entire study population, regardless of gBRCA mutation status. If the primary analysis meets the statistical significance, the study will be ended. If it does not, the study will continue for gBRCA mutation positive patients with the second-step primary analysis conducted in this population. We expect to initiate this study in the second half of 2017.

Our second Phase III study is expected to evaluate niraparib as a first-line maintenance therapy in patients with platinum-sensitive ovarian cancer. The details of the clinical trial designs are being discussed with the CFDA, and, pending authorization, we plan to initiate this trial in the first half of 2018. Tesaro is also evaluating niraparib in the PRIMA trial, a Phase III clinical trial in the first-line maintenance setting in platinum sensitive ovarian cancer patients.

Breast cancer

We plan to initiate a Phase III clinical trial of niraparib in patients with recurrent gBRCA positive breast cancer in China. The details of the clinical trial designs are being discussed with the CFDA and key opinion leaders and, pending authorization, we plan to initiate this trial in the first half of 2018.

Other indications

We also intend to initiate Phase II clinical trials to evaluate the efficacy of niraparib in squamous-type non-small cell lung cancer and small cell lung cancer patients in China. Details of the clinical trial designs are being discussed with the CFDA and key opinion leaders.

Background on PARP inhibitors

One well-studied area of PARP activity relates to DNA repair. 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. Since PARP inhibitors block DNA repair, PARP inhibition is thought to be an important part of cancer therapy.

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 temozolomide, cisplatin, carboplatin, gemcitabine and topotecan.

Niraparib 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.

Niraparib 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, niraparib 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.

Niraparib clinical results

NOVA, a Phase III maintenance study of niraparib versus placebo in patients with recurrent platinum-sensitive ovarian cancer.

In March 2017, the FDA approved niraparib 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). Niraparib's FDA approval followed the release of successful results from Tesaro's NOVA trial in which niraparib demonstrated a clinically meaningful increase in progression-free survival in women with recurrent ovarian cancer, regardless of gBRCA mutation or biomarker status. Treatment with niraparib 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. This means that FDA's approval for niraparib is broader than the approval for AstraZeneca's PARP inhibitor, olaparib, which is only approved for BRCA mutation positive patients.

The NOVA trial was a phase III randomized double-blind trial that assessed the effectiveness of niraparib 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 niraparib or placebo, and were continuously treated with placebo or niraparib until progression. The primary endpoint of this study was progression free survival. Secondary endpoints included patient-reported outcomes, chemotherapy free interval length, and overall survival. This trial successfully achieved its primary endpoint in both cohorts, showing that niraparib 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, niraparib 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 four prior lines of chemotherapy. The most common treatment-emergent grade 3/4 adverse events in the niraparib 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.

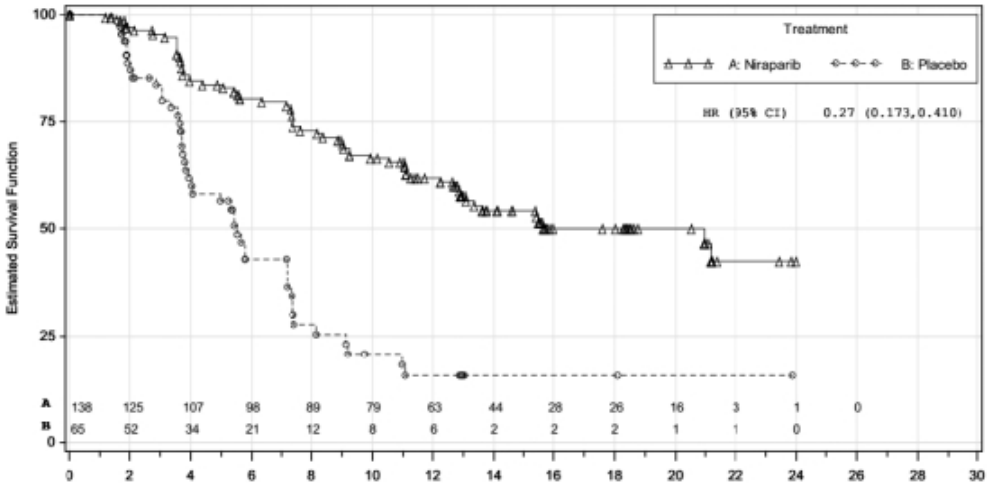
Figure 1: Progression free survival was significantly longer for patients who received niraparib compared to those who received placebo for all primary efficacy populations.

Treatment	Median PFS (95% CI) (Months)	Hazard Ratio (95% CI) p Value	Disease Progression Free (%)		
			6 Months	12 Months	18 Months
gBRCAmut Cohort					
Niraparib (N = 138)	21.0 (12.9, NE)	0.27 (0.173, 0.410) p <0.0001	80%	62%	50%
Placebo (N = 65)	5.5 (3.8, 7.2)		43%	16%	16%
HRDpos Subgroup					
Niraparib (N = 106)	12.9 (8.1, 15.9)	0.38 (0.243, 0.586) p <0.0001	69%	51%	37%
Placebo (N = 56)	3.8 (3.5, 5.7)		35%	13%	9%
Non-gBRCAmut Cohort					
Niraparib (N = 234)	9.3 (7.2, 11.2)	0.45 (0.338, 0.607) p <0.0001	61%	41%	30%
Placebo (N = 116)	3.9 (3.7, 5.5)		36%	14%	12%

Source: Tesaro.

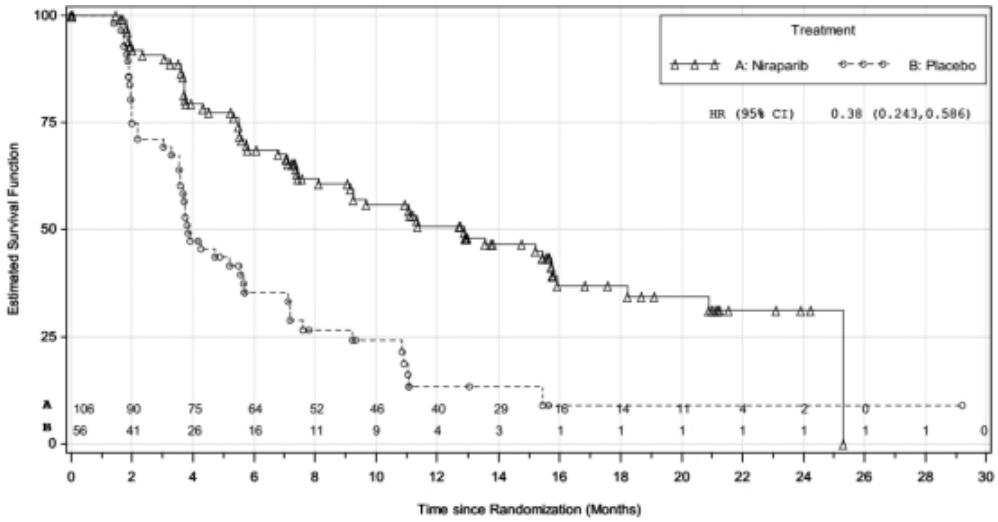
Notes: gBRCAmut = gBRCA mutation positive; non-gBRCA mut = gBRCA mutation negative

Figure 2: Progression free survival in the gBRCA mutation positive cohort of patients treated with niraparib versus placebo



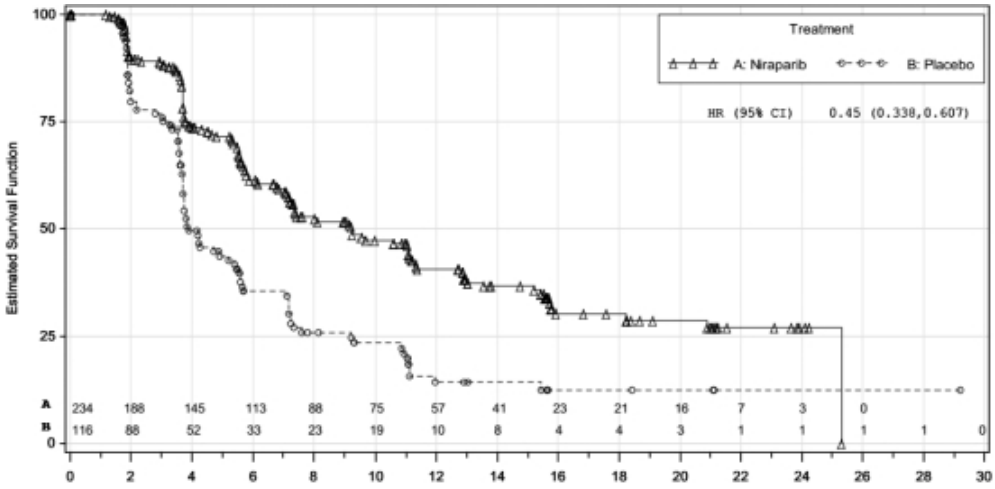
Source: Tesaro.

Figure 3: Progression free survival in the HRDpos group of the gBRCA mutation negative cohort of patients treated with niraparib versus placebo



Source: Tesaro.

Figure 4: Progression free survival in the overall gBRCA mutation negative cohort of patients treated with niraparib versus placebo



Source: Tesaro.

Within the gBRCA mutation positive cohort, the median progression free survival was 21.0 months on niraparib versus 5.5 months on placebo (hazard ratio=0.27; p<0.0001). As shown in the chart above, niraparib'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 niraparib 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 niraparib (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 niraparib-treated patients reported no significant difference from placebo in measures associated with symptom specific and general quality of life.

Furthermore, niraparib 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. Overall survival data, while immature, showed no negative impact of niraparib 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 (69% vs 5%), treatment-emergent adverse events leading to dose reduction (67% vs 15%), and treatment-emergent adverse events leading to treatment discontinuation (15% vs 2%) were higher for niraparib versus placebo. There were no on-treatment deaths reported.

The most commonly observed hematologic treatment-emergent adverse events (all CTC grades) related to niraparib were thrombocytopenia (61%), anemia (50%) and neutropenia (30%). Although CTC grade 3/4 hematologic 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.

Niraparib preclinical development

As discussed below, Merck and our partner Tesaro have completed various preclinical trials to evaluate the pharmacodynamics, pharmacokinetics and toxicology profile of niraparib.

Pharmacodynamics. In preclinical trials studying niraparib's pharmacodynamics, niraparib was found to be a potent and selective PARP-1 and PARP-2 inhibitor that displayed at least a 100-fold selectivity over other PARP-family members PARP-3, v-PARP, and Tankyrase-1. A commonly used quantitative measure of potency is IC_{90}, which represents the concentration of a drug that is required to suppress 90% of the target enzyme. The IC_{90} of niraparib for PARylation in BRCA-deficient tumor cells correlates with functional suppression of single strand breakage repair and anti-tumor effects on BRCA mutation positive tumor cells.

Normal primary cells were resistant to niraparib with the most sensitive cells (megakaryocytes) exhibiting a 13-fold selectivity margin as compared to BRCA mutation positive tumor cells *in vitro*. Maximal *in-vivo* efficacy was achieved in BRCA 1 mutation positive ovarian tumor models with once-daily oral administration of niraparib at a dose sufficient to suppress 90% of the PARP enzymatic activity in the tumor at eight hours after the dose, which translated to greater than 50% inhibition of PARP activity in peripheral blood mononuclear cells at eight hours post dose.

The therapeutic potential of niraparib was evaluated in a study designed to examine the benefit of niraparib in maintenance setting, *i.e.,* daily niraparib treatment following a regression induced with a platinum-based

regimen. In this study, tumors in mice receiving maintenance niraparib therapy became undetectable whereas regrowth was observed in those receiving only the chemotherapy regimen. These data support the concept that maintenance niraparib therapy after tumor response to chemotherapeutic agents may prolong recurrence-free survival.

Niraparib showed no significant observable effects in nonclinical safety pharmacology studies at clinically relevant doses across the species evaluated.

Pharmacokinetics. Niraparib elicited desirable and consistent pharmacokinetic profiles in nonclinical species *in vivo.* The oral absorption in rats and dogs was rapid, with moderate to high bioavailability. The compound is readily distributed to the brains of rats and monkeys to a modest extent, suggesting additional therapeutic potential.

Elimination of niraparib and its metabolites was fecal and renal in rats, while mainly renal in dogs. The potential risk for drug—drug interactions was determined to be minimal for niraparib, due to the lack of the interactions between niraparib and the hepatic drug-metabolizing CYP enzymes, the major hepatic and renal uptake transporters (OATP1B1, OATP1B3, OAT1, OAT3, and OCT2), and BESP, an efflux transporter known to be associated with hepatotoxicity. The *in vitro* metabolic results, combined with the *in vivo* pharmacokinetic findings, demonstrated that niraparib had a desirable disposition profile with a minimal potential for drug—drug interactions, consistent with the development of niraparib as an anticancer agent.

Toxicology. A comprehensive preclinical toxicology program was conducted to support the administration of niraparib in patients with cancer. This program included oral repeat-dose toxicity studies (up to three-months duration) in dogs and rats, genotoxicity and phototoxicity studies. The results obtained from the general toxicity studies in rats and dogs indicated that niraparib causes bone marrow suppression which leads to decreases in circulating white and red blood cells. Infections and septicemia were a consequence of bone marrow suppression and lymphoid depletion. These findings are linked to pharmacology of niraparib and showed reversibility.

Niraparib—Pharmacokinetics

The pharmacokinetic profile of niraparib has been evaluated in multiple clinical studies, with an overall niraparib-dosed population of 526 patients.

Absorption. Niraparib exhibited linear pharmacokinetic, dose proportional exposure, and dose-independent absorption and clearance. Following repeat administrations of the daily recommended dose of 300 mg, niraparib accumulation on day 21 was consistent for both the area under the plasma concentration-time curve and maximum concentration (approximately two- to three-fold). Niraparib was shown to be highly orally bioavailable (F ~73%). Bioavailability is a measure of the absorption of drug and is expressed as a percentage of the administrated case of the drug which reaches the patient’s system. Niraparib can be administered with or without food.

Distribution. Niraparib was moderately protein bound to human plasma (83.0%). The apparent volume of distribution was 1220 L, indicating an extensive tissue distribution of niraparib.

Metabolism. The carboxylesterases-catalyzed amide hydrolysis was delineated to be the major primary pathway, followed by the uridine-5’-diphospho-glucuronosyltransferases (UGT)-mediated glucuronidation and the other minor secondary pathway (*i.e*., methylation). The major circulating metabolites in humans are the carboxylic acid and the glucuronides of carboxylic acid. The metabolic profile seen in humans is consistent with what was detected in the experimental species (rats and dogs).

Elimination. In an absorption, metabolism and elimination study in cancer patients using 14C-radioactive niraparib, a mean measured total of 86.2% of the radioactive dose was recovered in urine and fecal samples collected daily from 0 to 504 hours (21 days) post dose after single oral administration of 14C-niraparib. It suggests minimal long-term retention of niraparib or its metabolites in body. Moreover, hepatobiliary clearance and renal excretion are the major routes of elimination in humans.

Intrinsic Effects. Population pharmacokinetic analysis identified no intrinsic factors such as age, gender, race, hepatic impairment, renal impairment would have significant impact on the pharmacokinetic of niraparib.

Omadacycline

Omadacycline is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. Omadacycline is primarily being developed for ABSSSI, CABP and UTIs 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 status in the U.S. and has been granted Fast Track status by the FDA. The drug has been administered to over 1,500 patients and has an established safety profile. If approved, omadacycline is expected to be available in 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. Paratek had previously reached agreement with the FDA under a Special Protocol Assessment, or SPA, whereby if both the Phase III ABSSSI and CABP studies are positive, the Company could seek approval for both indications.

A Phase III registration study in ABSSSI comparing once-daily oral-only dosing of omadacycline to twice-daily oral-only dosing of linezolid was initiated in August 2016, and top-line data is expected as early as mid-2017.

Paratek plans to submit its NDA in the U.S. as early as the first quarter of 2018 and its EMA submission in late 2018. In addition to its Phase III program for omadacycline, a Phase Ib study in UTIs was initiated in May 2016 and positive top-line PK proof-of-principle data was reported in November 2016. Paratek plans to begin enrolling patients in a proof-of-concept Phase II study of omadacycline in complicated UTI, or cUTI, as early as the fourth quarter of 2017.

We obtained the exclusive license 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.

Market opportunity

We believe omadacycline addresses an unmet need in China for a broad-spectrum antibiotic that provides a new treatment option for physicians in China challenged by growing antibiotic resistance. A 2015 study by the State Key Laboratory of Organic Geochemistry under the Chinese Academy of Sciences indicated that the total antibiotic usage in China in 2013 accounted for about half of the antibiotic usage globally, with the per-capita use of antibiotics in China being more than five times that in Europe and the United States. As a result, China has one of the world’s most serious problems with antibiotic misuse and antibiotic resistance. According to a May 2016 study from the Wellcome Trust in London, antimicrobial resistance in China could cause 1 million premature deaths annually by 2050 and cost the country $20 trillion.

In 2015, there were approximately 2.8 million ABSSSI patients and 16.5 million CABP patients in China. We believe that omadacycline will provide a new treatment option for patients with such infections, including those caused by drug-resistant pathogens whose numbers are expected to increase as the result of the abuse of antibiotics. The product has been designed to provide potential advantages over existing antibiotics, including broad-spectrum, antibacterial activity and activity against resistant bacteria, no known drug interactions and a favorable safety and tolerability profile. In addition, once daily dosing of the oral and IV formulations will offer a unique advantage by reducing hospital days through a step-down from IV to the oral formulation, which not only has important cost-saving implications but increases patient comfort and reduces exposure to nosocomial pathogens.

The competitive field in China and worldwide is characterized by the wide use of various generic formulations of older tetracyclines, such as oral formulations of doxycycline. Minocycline is rarely used except for long-term treatment of acne. Tigecycline, a member of a new generation of tetracyclines known as glycylcyclines, dominates the market and has experienced a considerable growth rate despite a limited list of labeled indications, the absence of an oral formulation, and significant tolerability and safety issues.

In two well-controlled Phase III trials, designed with full FDA input, omadacycline was shown to be as efficacious as best-in-class comparators. Omadacycline met all regulatory efficacy standards as stipulated by the FDA and EMA. The safety and tolerability profile at tested doses was comparable to that of comparators, linezolid and moxifloxacin, drugs commonly used for ABSSSI and CABP infections, respectively.

Omadacycline's product profile is superior to tigecycline (Tygacil®), the most advanced tetracycline derivative available today and marketed in China and worldwide. One of omadacycline's differentiating features is the availability of a bioequivalent oral formulation while tigecycline is an IV-only drug. Therefore, unlike tigecycline, omadacycline can be used in the outpatient setting. In the hospital, the ability to switch from IV to oral administration enables greater flexibility in patient management and potential cost savings. Furthermore, tigecycline's FDA label includes a black box warning regarding an increase in all-cause mortality with this drug. Based on a cross comparison of reported studies for both tigecycline and omadacycline, tigecycline is associated with significantly greater rates of nausea and vomiting.

Omadacycline has a broad microbiologic profile with effective microbiological activity against a broad spectrum of pathogens, including problem pathogens like MRSA, PRSP, *N. gonorrhoeae* and various Gram-negative bacteria. It has strong activity against most of the pathogens encountered in the indications pursued, ABSSSI, CABP and UTI. It has useful activity against *Acinetobacter,* a multi-drug resistant pathogen in the health care setting which is frequently encountered in Chinese hospitals.

In addition, omadacycline has a favorable and differentiated PK profile with significantly lower protein binding than competitor tetracyclines. Omadacycline has effective tissue penetration, including lung, skin and kidney, thereby achieving high concentrations at the sites of infection under study. In the clinical setting, both the IV and oral formulations had few gastro-intestinal tolerability issues.

The only competitor in development is eravacycline, a drug developed by Tetraphase. Although this fluorocycline compound has a spectrum similar to omadacycline, it lacks an effective oral formulation. Eravacycline is being developed for cIAI and cUTI; it failed to demonstrate non-inferiority in a recent pivotal cUTI trial and, thus, its development program is delayed and its clinical use appears more limited.

Our clinical trials designs and strategy for omadacycline in the China market

We are in the technology transfer stage and plan to discuss China development plan with key opinion leaders and the CFDA.

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

Omadacycline is absorbed incompletely. 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 16-18 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.

Omadacycline clinical results

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 5: Omadacycline vs Linezolid—ABSSSI Trial—Primary Efficacy Outcomes

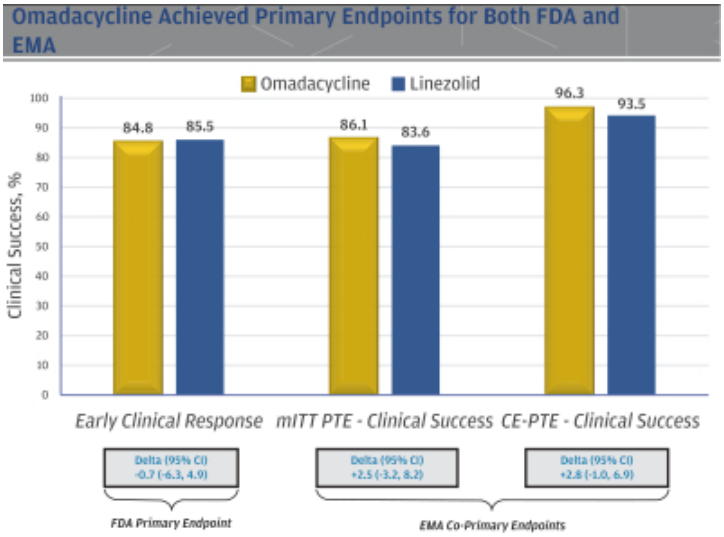
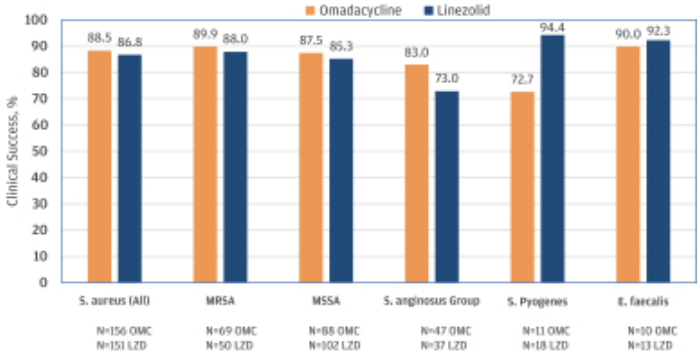


Figure 6: Early Clinical Success by Pathogen—micro-mITT Population



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.

Figure 7: 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

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.

S. 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 8: CABP Study—OPTIC: Primary Efficacy Results—FDA Analysis

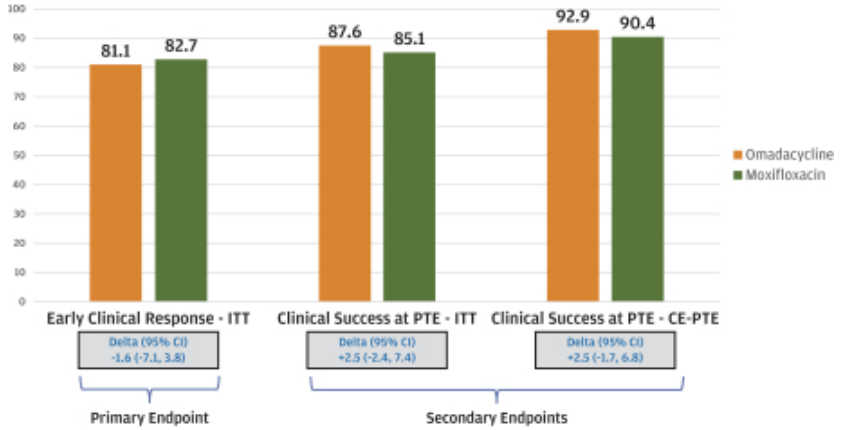


Figure 9: CABP Study—OPTIC: Primary Efficacy Results—EMA Analysis

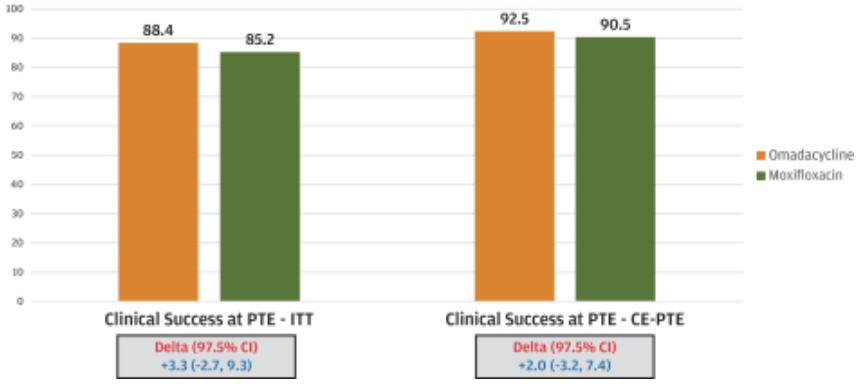


Figure 10: CABP Study—OPTIC: Clinical Success at PTE by Baseline Pathogen

	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)
Streptococcus 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)
Staphylococcus Aureus	11	8 (72.7)	11	9 (81.8)
*10 or More Isolates for Omadacycline				

Omadacycline demonstrated a benign safety/tolerability profile. 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.

Figure 11: 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)

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 considered exploratory 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.

Phase I studies

Omadacycline has been evaluated in 16 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 within the 80-125% range.

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 (syst and diast) 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 to obtain PK information for different oral dosing regimens of omadacycline.

ZL-2301

ZL-2301 is an oral, small molecule dual TKI which blocks both VEGFR and FGFR. ZL-2301 was studied by our partner Bristol-Myers Squibb mainly for the treatment of HCC, the most common type of liver cancer. To date, ZL-2301 has been tested in 26 trials, including 19 Phase I trials, two Phase II trials and five Phase III trials, with 2,651 oncology patients around the world. In these trials, ZL-2301 has demonstrated anti-tumor activity and a generally well-established safety profile, particularly in HCC patients. In 2012, Bristol-Myers Squibb terminated its development program for ZL-2301 after it missed the primary endpoints in two Phase III trials with advanced HCC patients.

Based on our review of the results from Bristol-Myers Squibb’s development program for ZL-2301, our understanding of the etiology of HCC in Chinese patients, standard of care of HCC patients in China and our

ongoing research, a number of factors lead us to believe that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical trials. These factors include:

- in prior clinical trials, ZL-2301 was observed to have comparable anti-tumor activity in HCC patients to sorafenib, particularly in patients with HCC induced by hepatitis B infection rather than hepatitis C infection. In Chinese patients HCC is typically induced by hepatitis B infection, rather than hepatitis C infection;
- in China, chemotherapy, rather than TKIs, such as sorafenib, remains the primary first-line treatment for HCC and, as a result, a much greater percentage of Chinese patients are TKI-naive going into second-line treatment, hence more sensitive to TKI treatment;
- limited target therapy treatment options for HCC patients, especially in China; and
- our PD analysis and PK modeling data suggest that there may be a more effective dosing schedule of ZL-2301 compared to the dosing schedule studied in prior clinical trials.

In Bristol-Myers Squibb's BRISK-FL study, which was a Phase III non-inferiority study of ZL-2301 compared to sorafenib in patients without prior systemic treatment, 223 Chinese HCC patients out of 1,155 patients in total participated. Although the study missed the primary end point of overall survival noninferiority for ZL-2301 versus sorafenib based on the prespecified margin, ZL-2301 demonstrated evidence of anti-tumor activity. Median OS was 9.9 months for sorafenib and 9.5 months for ZL-2301. TTP, ORR, and DCR were similar between sorafenib and ZL-2301. Most frequent grade 3/4 adverse events for sorafenib and ZL-2301 were hand-foot skin reaction (15% and 2%, respectively), hyponatremia (9% and 23%, respectively), AST elevation (17% and 14%, respectively), fatigue (7% and 15%, respectively), and hypertension (5% and 13%, respectively). Discontinuation as a result of adverse events was 33% for sorafenib and 43% for ZL-2301; rates for dose reduction were 50% and 49%, respectively.

Our analysis of Chinese patients in the BRISK-FL study showed that ZL-2301 demonstrated a trend of efficacy and a safety profile comparable to those of sorafenib. In particular, more Chinese HCC patients experienced no dose reduction compared to non-Chinese patients. Our analysis also showed that less Chinese HCC patients experienced one dose or two dose reductions compared to non-Chinese patients. This data suggests that ZL-2301 treatment may be better tolerated by Chinese HCC patients than non-Chinese patients. While the BRISK-FL study was not designed specifically to determine efficacy and safety in a Chinese patient population, we concluded that our analysis of such clinical data was promising and warranted further clinical trials.

It has been debated within the HCC expert community that the biology of Chinese HCC may be different from that of non-Chinese HCC. In China, hepatitis B infections are much more prevalent than that of hepatitis C, and as a result HCC among Chinese patients are usually induced by the hepatitis B virus rather than the hepatitis C virus, which more commonly induces HCC in patients from western countries. We believe that this difference between Chinese HCC patients and non-Chinese HCC patients could potentially explain the difference in outcomes in patients treated with ZL-2301. For example, the subgroup analysis of 512 patients enrolled in the BRISK-FL study whose HCC was induced by hepatitis B infection showed overall survival of 8.4 months for ZL-2301 treated patients compared to 8.1 months for sorafenib treated patients; the subgroup analysis of 235 patients enrolled in the BRISK-FL study whose HCC was induced by hepatitis C infection showed overall survival of 10.9 months for ZL-2301 treated patients compared to 12.9 months for sorafenib treated patients. The treatment available to most advanced HCC patients in China is generally limited to traditional chemotherapy, and only a very small portion of Chinese HCC patients have access to sorafenib (Nexavar®), a kinase inhibitor co-developed and co-marketed by Bayer Healthcare and Onyx Pharmaceuticals Inc., a subsidiary of Amgen Inc., and used to treat 1st line HCC in the United States and other jurisdictions. Due to the difference in the standard-of-care in first-line treatment, most Chinese patients are TKI naïve, and they are therefore likely more

sensitive and responsive to TKI therapy as compared to western second-line HCC patients who have already been exposed to TKI treatment and in most cases have become TKI resistant.

In addition, our pharmacodynamics analysis and pharmacology modeling data suggest that a 400 mg twice-a-day treatment regime seems to have better coverage for target inhibition as compared to a regime of 800 mg once daily. Therefore, we will explore and optimize the dose and dosing schedule in our further trials.

In 2015, we obtained an exclusive license for the development and commercialization of ZL-2301 in China, Hong Kong and Macau. The CFDA has approved our CTA for ZL-2301 as a Category 1 drug, and in the second quarter of 2017 we initiated a Phase II trial of ZL-2301 as a second-line treatment comparing 800mg once daily to 400mg twice daily for advanced HCC patients in China. Pending results from such Phase II trial, we plan to initiate a Phase III clinical trial shortly thereafter.

Market opportunity

The annual incidence for liver cancer was estimated at 466,100 patients in China in 2015, as compared with 35,660 patients in the United States. Among liver cancer patients in China, HCC is largely caused by the hepatitis B virus, or HBV, while hepatitis C is the main cause for non-Chinese HCC patients. HBV is found in more than two thirds of cases in China as compared to only 8% in the United States, according to the *Hepatology Journal*. This corresponds to over 10 times more HCC patients in China compared to the US. The number of hepatitis B cases in China is expected to continue to grow as the result of poor control of hepatitis B infection.

When identified in its early stages, liver cancer can often be treated with surgical resection or liver transplantation. At a more advanced stage, trans-catheter arterial chemoembolization, or TACE, and systemic drug therapy are considered. TACE is a combination of regional chemotherapy and some form of hepatic artery occlusion. Consistently higher response rates have been reported for TACE when compared with systemic chemotherapy. Sorafenib, a TKI, and chemotherapy are approved as the standard-of-care, first-line targeted therapies in China. In addition, sorafenib is also recommended for use with TACE as an adjuvant in the China guidelines.

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, largely due to the low level of engagement of the leading physicians in the HCC area in China. It has been observed in HCC community that many Chinese patients with HCC who take sorafenib either do not respond well or show poor tolerance to such treatment. We believe this could be the result of a difference in biology of Chinese patients from non-Chinese patients and the fact that HCC is typically secondary to a hepatitis B infection in China. There is, therefore, a large unmet medical need to develop a widely accessible drug for advanced HCC treatment in China which presents better tolerability for Chinese patients. This is especially relevant since chemotherapy drugs are generally less effective in HCC, compared to other cancers.

Our clinical trial designs and strategy for the China market

In the second quarter of 2017 we initiated a Phase II trial in advanced HCC patients in China to further investigate ZL-2301's optimal treatment schedule and dosage as a second-line treatment. The study is an open label study of ZL-2301 with two treatment arms of 30 patients each. One arm is receiving 800 mg of ZL-2301 once daily and the other arm is receiving 400 mg of ZL-2301 twice daily. The primary endpoints of this Phase II trial are disease control rate at three months post treatment and time to tumor progression. The PK profile of each treatment schedule and dosage level is also being investigated.

Pending results from the Phase II trial, including the optimal dosage level and schedule, we plan to initiate a Phase III double-blind, randomized, parallel trial to compare ZL-2301 at the selected treatment schedule/

dosage with best supportive care versus placebo with best supportive care as a second-line treatment of advanced HCC patients. We plan to enroll 348 patients at a 2:1 ratio for the Phase III trial. The primary endpoints will be overall survival and the secondary endpoints will be time to tumor progression, disease control rate, objective response rate and overall safety. If this Phase III trial yields positive results, we plan to use the results to support an NDA submission of ZL-2301 in China.

Background on tyrosine kinase inhibitors

Tyrosine kinases are enzymes responsible for the activation of many proteins by signaling transduction cascades, the process by which a foreign DNA is introduced into a cell by a virus or viral vector. The tyrosine kinase inhibitors comprise a relatively new group of anticancer drugs that have been developed as oral formulations. The mechanism of action of tyrosine kinase inhibitors includes modulation of key pathways and mechanisms of angiogenesis, the formation of new blood vessels in human body, and tumorigenesis, the formation of cancers, such as VEGFR. However, tyrosine kinase involvement and activity may vary from tumor to tumor, resulting in differing responses to different TKIs.

VEGF plays a key role in tumor angiogenesis during the development of cancer, tumors at an advanced stage can secrete large amounts of VEGF to stimulate excessive angiogenesis around the tumor in order to provide greater blood flow, oxygen, and nutrients to fuel the rapid growth of the tumor. VEGF and other ligands can bind to three VEGF receptors, VEGFR1, 2 and 3, each of which has been shown to play a role in angiogenesis. Therefore, inhibition of the VEGF/VEGFR signaling pathway can act to stop the growth of the vasculature around the tumor and thereby starve the tumor of the nutrients and oxygen it needs to grow rapidly.

In addition, a growing body of evidence has demonstrated the oncogenic potential of FGFR aberrations in driving tumor growth, promoting angiogenesis, and conferring resistance mechanisms to anti-cancer therapies. There is also evidence that anti-VEGF therapy treatment could increase FGFR pathway activation, leading to drug resistance to anti-VEGF therapies. As a result, simultaneously targeting VEGFR and FGFR is an attractive approach to improve clinical efficacy.

ZL-2301 mechanism of action

By inhibiting VEGFR and FGFR, ZL-2301 affects the human vein endothelium cells, which are responsible for angiogenesis. Since essentially all solid tumors require angiogenesis to progress beyond a few millimeters in diameter, anti-angiogenesis drugs have demonstrated benefits in a wide variety of tumor types.

The exact mechanisms by which ZL-2301 inhibits tumor growth are not entirely understood, but clinical trial results to date suggest that ZL-2301 effectively inhibits tumor growth and such inhibition is associated with the inactivation of VEGFR-2, increased apoptosis, a process of programmed cell death, a reduction in microvessel density, inhibition of cell proliferation and down-regulation of cell cycle regulators.

ZL-2301 preclinical and clinical background

As discussed below, Bristol-Myers Squibb completed various preclinical studies to evaluate the pharmacodynamics, pharmacokinetics and toxicology profile of ZL-2301.

Pharmacodynamics. In preclinical studies, ZL-2301 demonstrated strong in vitro inhibitory effects on human umbilical vein endothelial cells when stimulated with VEGF and basic fibroblast growth factor for VEGFR-2 and basic fibroblast growth factor receptor-1, respectively. Each of ZL-2301 and ZL-2301 alaninate, which becomes the pharmacologically active ZL-2301 after being metabolized, demonstrated, in vivo, a broad spectrum of antitumor activities, with cytostasis, the inhibition of cell growth and multiplication, observed in all human tumor models tested.

In addition, when ZL-2301 was administered in combination with cetuximab, enhanced antitumor activities were observed against mouse xenograft lung tumor tissue samples. Enhanced antitumor activities were also observed when ZL-2301 was administered in combination with ixabepilone and paclitaxel. When tested on a model of human lung carcinoma tissues, ZL-2301 demonstrated more prolonged tumor growth delay than sorafenib. Furthermore, complete tumor stasis was also observed in a staged tumor xenograft derived from HCC patients after ZL-2301 was administered.

Further studies demonstrated that ZL-2301 effected mainly the gastrointestinal, vascular, skeletal and female reproductive systems. The effects of ZL-2301 on these target systems were consistent with the expected pharmacology of ZL-2301. In addition, in repeat-dose studies, reversible increases in serum transaminases were observed in studies conducted on mice, rats and monkeys, total bilirubin and liver weight gains were observed in studies conducted on rats, and microscopic alterations of hepatocellular vacuolation were observed in studies conducted on rats and monkeys, which indicated that ZL-2301 has a significant effect on livers.

Pharmacokinetics. ZL-2301 elicited desirable and consistent pharmacokinetic profiles in nonclinical species in vivo. The oral absorption of ZL-2301 alaninate in mice, rats, dogs and monkeys was rapid, with bioavailability ranging from 52% to 97%.

Elimination of ZL-2301 and its metabolites was minimum and mainly renal. ZL-2301 was also found to be highly bound to serum proteins and exhibit a moderate level of extravascular distribution.

Toxicology. Comprehensive preclinical toxicology studies were conducted to support the administration of ZL-2301 in patients with cancer. These studies indicated that ZL-2301 alaninate and ZL-2301 inhibited hERG/IKr channels resulting in a high, in the case of ZL-2301 alaninate or moderate, in the case of ZL-2301, risk for QT prolongation. However, neither ZL-2301 alaninate nor ZL-2301 produced substantive effects on rabbit Purkinje fiber action potential duration and no biologically relevant inhibitory effect on any of 53 different receptors, transporters, and ion channels investigated in vitro. ZL-2301 produced no central nervous system-related effects on rats and monkeys, and apart from a slight decrease in heart rates on monkeys, dose-dependent increases in blood pressure, and mild decreases in heart rate in a telemetered rat model, it produced no changes in respiratory function and heart rates or sounds in exploratory or pivotal toxicity studies conducted in dogs or monkeys.

The effects of ZL-2301 alaninate on male and female fertility have not been studied. However, repeat-dose toxicity studies in rats and monkeys indicated that ZL-2301 could potentially impair reproductive function and fertility in females. ZL-2301 alaninate also produced embryo-fetal developmental toxicity in rats and rabbits at doses that did not produce maternal toxicity. As a result, ZL-2301 is considered a selective developmental toxicant in these two species. The effects of ZL-2301 from these studies were consistent with the expected pharmacology of ZL-2301.

With respect to clinical stage studies, Bristol-Myers Squibb conducted three Phase III studies of ZL-2301. The Phase III study called the BRISK-FL study tested the efficacy of ZL-2301 against sorafenib in patients with advanced HCC without prior systemic treatment. The second study, BRISK-PS, tested ZL-2301 against best supportive care in patients that failed or were intolerant to sorafenib. In both studies, ZL-2301 failed to meet its primary endpoint but nonetheless it did demonstrate some anti-tumor activity. Due to these results, a third Phase III trial in which ZL-2301 was used as an adjuvant to TACE was terminated by Bristol-Myers Squibb, prior to its completion in 2012.

Fugan

Overview

Fugan (ZL-3101) is a novel steroid-sparing topical product for the treatment of eczema and psoriasis. We licensed the exclusive worldwide rights to fugan in 2016 from GSK. The active botanical ingredients in fugan were originally used in a hospital setting within China to treat patients with eczema and psoriasis. Our management team, who has extensive experience developing botanical products in the clinical setting, acquired fugan from GSK because it identified fugan as a potential steroid-sparing treatment for eczema and psoriasis sufferers who have limited natural treatment options. The potential anti-inflammatory benefit of fugan results from its active botanical formula which incorporates the herbs Glycyrrhizae Radix et Rhizoma and Sophorae Flavescentis.

We started our Phase II study in patients with mild to moderate subacute eczema in China in the second quarter of 2017.

Market opportunity

Eczema. Atopic dermatitis, also known as eczema, is a chronic disease of the skin that is believed to be caused by a combination of hereditary and environmental factors. The main symptoms of atopic dermatitis include dry, itchy skin leading to rashes on the face, hands, feet, along with inside the elbows and behind the knees. Scratching results in redness, swelling, cracking, “weeping” clear fluid, and crusting or scaling. Globally, the disease has a prevalence rate of 15-20% in children and 1-3% in adults and 90% of eczema cases represent mild to moderate forms, according to studies by S. Nutten and Zhang JZ, respectively.

Most patients with mild to moderate eczema are currently treated with topical agents such as corticosteroids and moisturizers. Corticosteroids were the first immunomodulators available in topical formulations and exert anti-inflammatory and immunosuppressive effects. However, treatment-related side effects associated with corticosteroid use, such as local application-site reactions, including skin atrophy with prolonged use, and profound effects on neuroendocrine system, which can lead to growth retardation in adolescents and an increased risk for diabetes, underscore the need for novel therapies to treat this disease.

Non-steroidal medications such as topical calcineurin inhibitors are also sometimes applied to the parts of the skin affected by eczema for purposes of controlling symptoms for short periods of time, but there are safety risks to application of calcineurin inhibitors to large areas of skin due to systemic absorption of these immunosuppressive agents.

In recent years, drug makers have responded to the significant unmet need in the market for eczema and have actively been developing safe and efficacious prescription drug alternatives. In December 2016, the FDA granted approval for Eucrisa™ (Pfizer), a topical treatment for mild to moderate eczema, while in March 2017, the FDA granted approval for Dupixent® (Sanofi/Regeneron), a monoclonal antibody for adults with moderate to severe eczema. According to GMR data, sales of Eucrisa™ and Dupixent® are estimated to be $2.0 billion and $3.8 billion, respectively, by 2026. These products are expected to contribute to a broader and fast growing market opportunity. The global eczema drug market is expected to grow from $0.8 billion in 2016, to $10.5 billion by 2026, representing a CAGR of 29.4%.

Fugan is a novel botanical topical product, with the key target indication of mild to moderate eczema. We believe fugan could offer a natural, topical, steroid-sparing product with strong efficacy and limited long-term safety concerns, at a more attractive price point, compared to global competitors. In addition, fugan has shown efficacy and safety in published prototype clinical studies conducted in China. We believe that fugan will allow us to access a large and fast-growing global market opportunity.

Psoriasis. Psoriasis is a common chronic disorder of the skin characterized by dry scaling patches, called “plaques,” for which current treatments are few, and those that are available have potentially serious side effects. According to a study (L. Cai) in 2016, the prevalence of psoriasis in China is approximately 0.12-0.47%. Globally, prevalence of psoriasis is even higher, with the disease being more prevalent in colder climates. According to WHO, the worldwide prevalence of psoriasis is around 2%.

The majority of psoriasis sufferers have mild cases and are treated with topical steroids that can have undesirable side effects. Biologics treatments treat moderate to severe psoriasis and are not advisable for people with compromised immune systems. We believe fugan could offer a natural, steroid-sparing product with strong efficacy and limited long-term safety effects for psoriasis patients.

Our clinical trial designs and strategy

We have initiated a Phase II proof-of-concept study in patients with mild to moderate subacute eczema in China. This Phase II study is a multi-center, randomized, double-blind, parallel, placebo controlled study to evaluate the efficacy and safety of different fugan ointment treatment schedule/dose in patients. This study will enroll an estimated 310 patients to ensure at least 250 clinically evaluable patients are available. Enrollment is expected to be completed in early 2018 and top-line results are expected to be reported in mid-2018.

Patients will be recruited and randomized in a ratio of 2:2:1 into groups that receive fugan twice daily, once daily and placebo. Randomization will be stratified by disease severity. The primary objective is to evaluate efficacy of fugan using the Eczema Area and Severity Index. The Eczema Area and Severity Index is a tool for the measurement of severity of eczema. It ranges from zero (no eczema) to 72. The primary endpoint is Eczema Area and Severity Index score changes from baseline to day 21 of treatment. The secondary objective is to assess the safety and tolerability of fugan ointment in subjects with mild to moderate subacute eczema. The safety endpoints include incidence, severity and relationship of adverse events, the proportion of subjects with adverse events leading to discontinuation and local tolerability at various points during the trial.

Pending results of the Phase II study, we plan to initiate a Phase III global, multi-center clinical trial.

Fugan mechanism of action

Pharmacologic disease management of eczema and psoriasis is typically aimed at targeting the immune system dysfunction responsible for the inflammatory reaction at the site of the flares, that is, proinflammatory cytokines and other products of T-cell activation. Topical therapies are the mainstay of treatment for most patients with these conditions.

Our preclinical studies demonstrated that the active components of the formulation is not absorbed systematically, we believe fugan may offer an improved safety profile over currently approved topical therapies and could significantly improve outcomes for patients globally. Furthermore, GSK-sponsored preclinical studies have demonstrated that fugan may inhibit cell infiltration and suppress inflammatory cytokines that would otherwise go unchecked and continue to propagate chronic inflammation. Preclinical studies also suggest that fugan can inhibit overexpression of proinflammatory cytokines such as such as tumor necrosis factor, or TNF-a, and interferon gamma, IFN-g, and ICAM-1, a gene that may be associated with pro-inflammatory pathways.

Fugan preclinical development

In preclinical development, fugan demonstrated inhibitory effects in mouse and rat acute inflammation models, with significant inhibition seen in xylene-induced ear swelling, skin capillary permeability and carrageenan-induced paw swelling models. The preclinical studies used 4-dinitrofluorobenzene-, or DNFB-, induced mice

which more closely reflect the characteristics of chronic T-cell-dependent inflammation. The degree of swelling in mouse auricles and the inflammatory cell counts were decreased in DNFB-induced delayed type hypersensitivity models of dermatitis and eczema. Significant decreases in IFN-g TNF-a and ICAM-1 levels in auricular tissues were seen following topical application of fugan. Furthermore, histamine-induced itching reactions were reduced in guinea pigs, with significant increases in the itching thresholds following fugan application. These results suggest that fugan inhibits the overexpression of inflammation-related cytokines (IFN-g) and intercellular cell adhesion molecule-1 (ICAM-1), subsequently alleviating the inflammatory, anaphylactic and pruritic characteristics of eczema.

In addition to the anti-inflammatory effects, fugan demonstrated potent bacteriostatic or bactericidal effects in vitro against Staphylococcus aureus, beta-streptococcus and candida albicans at a low concentration. Staphylococcus aureus is the most common bacteria to infect and colonize the skin in eczema, the bactericidal effects of fugan could be helpful in treating eczema. Fugan showed no significant observable effects in preclinical safety pharmacology studies across the species evaluated.

Pharmacokinetics. The systemic exposure of four representative marker compounds from the two herbs used in fugan's formula was assessed following single and repeat dose dermal administration of fugan (doses up to 5.6 g herb/kg/day) to miniature pigs for up to 28 days. No consistent kinetic profile was observed for any of the marker compounds prohibiting any conclusion to be made on the relationship between dose, dose duration and exposure for these four markers.

Toxicology. The results obtained from preclinical toxicology studies of fugan in in miniature pig and rabbit species indicated there were dermal changes at the application site, including erythema, rash, sores and skin scaling, which primarily occurred in the fourth week of the dosing period. When averaged over the entire study per CFDA guidelines, the response was classified as "no irritation" at all doses. However, possible adverse events at the application site will be monitored in our clinical trials.

Our preclinical pipeline

ZL-2302

ZL-2302 is a multi-targeted TKI with activity on both ALK and crizotinib-resistant ALK mutations developed for the treatment of patients with non-small cell lung cancer who have ALK mutations and have developed crizotinib-resistant mutations and/or brain metastasis. We licensed the exclusive worldwide rights to ZL-2302 from Sanofi in 2015. Our preclinical studies demonstrated that ZL-2302 has a great ability to penetrate the blood-brain barrier, which could make ZL-2302 an effective therapy for the significant portion of the patients who have non-small cell lung cancer with ALK mutations and brain metastasis. Such patients typically have poor prognosis, a low quality of life and limited treatment options.

Our clinical trial designs and strategy

Our CTA for ZL-2302 has been accepted as a Category 1 drug by the CFDA, and we expect to initiate a Phase I study of ZL-2302 in China in the first half of 2018.

Mechanism of action

ZL-2302 was designed with broad-spectrum activity against resistant ALK mutations and brain penetration as the next-generation ALK inhibitor.

ZL-2302 preclinical development

Comprehensive preclinical studies have been done to analyze ZL-2302. The key results are summarized as indicated below. Based on the study data, an IND package has been prepared and filed with the CFDA.

In vitro pharmacology studies demonstrated that ZL-2302 can inhibit the ALK kinase in both wild-type and active against activated mutant forms (R1275Q, F1174L and F1245V) as well as the resistance gatekeeper mutant (ALK L1196M) and EML4-ALK oncogenic fusion. Such studies have also shown that it inhibits the proliferation of the Ba/F3 expressing wild-type and mutant forms of EML4-ALK and ALK dependent cell lines NCI-H3122, KARPAS-299 and SU-DHL-1. However, it was shown not to inhibit the proliferation of PC3, an ALK independent cell line, at concentrations up to 3 mM.

In vivo patient-derived xenograft models showed ZL-2302 had antitumor activity in mice bearing the ALK-dependent and Crizotinib-resistant tumors. It also has great brain penetration abilities in mice and can inhibit the intracranial tumor growth in the ALK-dependent xenograft model. The brain-to-plasma ratio of drug exposure is 1.26, which indicated it has good brain penetration.

Preclinical studies have shown that it can be easily absorbed after oral administration with the 15-75% bioavailability in different species. The drug can be widely distributed in the body, but high drug concentration was found in tumor tissues and lung. No drug accumulation was fond after repeated dose administration. Safety pharmacology, general toxicology and gene toxicity studies in different species showed ZL-2302 has a good safety profile. No significant toxicity was found. All adverse effects found in the studies are reversible and can be managed and monitored.

ZL-1101

ZL-1101 is an anti-OX40 antagonistic antibody with first-in-class potential for the treatment of a range of autoimmune diseases such as graft-versus-host disease or systemic lupus erythematosus. We licensed the exclusive worldwide rights to ZL-1101 from UCB, a multinational biopharmaceutical company based in Belgium, in 2015. Its anti-inflammatory activities have been validated by a variety of inflammatory and autoimmune pharmacology models.

Our clinical trial designs and strategy

We intend to file an IND in 2018.

Mechanism of action

OX40, also known as CD134, TNFRSF4, ACT35 or TXGP1L, is a member of the TNF receptor superfamily, which is a group of ligands and receptors involved in diverse biological processes ranging from the selective induction of cell death in potentially dangerous and superfluous cells to providing costimulatory signals that help mount an effective immune response. OX40 is predominantly expressed on activated T-cells, and its cognate ligand, OX40L, is expressed on activated antigen presenting cells. OX40 functions as a major costimulatory receptor on T cells, and ligation by OX40L delivers activation signals to increase the proliferation and longevity of effector T cells, increase production of effector cytokines, suppress regulatory function, preserve cellular memory and facilitate migration. When immune activation is excessive or uncontrolled, pathological allergy, asthma, inflammation, autoimmune and other related diseases may occur. In such instances, activation and differentiation of T-cells play an important role. Because OX40 functions to enhance immune responses, it may exacerbate autoimmune and inflammatory diseases, including graft-versus-host disease, systemic lupus erythematosus, asthma and viral-induced lung inflammation, and therefore drugs which block or suppress OX40 have the potential to treat a range of such disorders.

ZL-1101 is an isolated antagonist antibody that specifically binds to a human OX40. It exhibits complete blockade of OX40-OX40L interaction with high potency as such it is expected to inhibit pathogenic effector T cells while simultaneously restore regulatory T cell generation and/or function, thus re-balancing the immune system.

ZL-1101 preclinical development

ZL-1101's bioactivities and functional potency have been investigated both *in vitro* and *in vivo* studies. In such studies, cellular proliferation and production of inflammatory cytokines was markedly suppressed, demonstrating that ZL-1101 effectively inhibits lymphocyte activation. ZL-1101 was also found to be highly potent. The efficacy of a single dose of ZL-1101 has been shown to be potent enough to effectively inhibit human T cell proliferation *in vivo*, supporting ZL-1101 as a viable therapeutic candidate. *In vitro* activity and cell-based assays demonstrated that ZL-1101 has a good affinity and ligand-blocking capacity. In a functional assay, it has been demonstrated that ZL-1101 is capable of blocking OX40L binding to cynomolgus cell-surface expressed OX40.

In addition, pharmacokinetic and pharmacodynamic studies confirmed it has a profile that is sufficient for development into a drug candidate. Preliminary modeling to predict the human half-life and the pharmacologically active dose have shown that the expected half-life in humans is 14 days and 17 days when the 0.3 mg/kg data were excluded from the analysis. The target turnover model indicates that approximately1 mg/kg dose would result in almost complete target engagement.

Internal discovery programs

Our in-house research and development team focuses on the development of immuno-oncology large molecules for the treatment of oncology. Our team members have been directly involved in the discovery, development and commercialization of several successful global drug launches, including fruguintinib and savolitinib while they were at Hutchison Medi-Pharma. We have collaborations with leading academic institutions in China, Tsinghua University and Shanghai Institute of Materia Medica, to support our in-house research projects.

Overview of our license agreements

Tesaro

In September 2016, we entered into a collaboration, development and license agreement with Tesaro Inc., or Tesaro, under which we obtained an exclusive license under 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, niraparib, in mainland 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). We also obtained the right of first negotiation to obtain a license from Tesaro to develop and commercialize certain follow-on compounds of niraparib being developed by Tesaro 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 Tesaro 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. Tesaro has the option to elect to co-promote the licensed products in our licensed territory. This co-marketing right must be exercised by Tesaro twelve months prior to the first commercial sale of niraparib in the China Territories.

Under the terms of the agreement, we made an upfront payment of $15.0 million to Tesaro. If we successfully develop and commercialize the licensed products, we will make a milestone payment to Tesaro for the achievement of a certain development milestone event. In addition, if Tesaro does not exercise its co-promotion option, we will pay Tesaro milestone payments for the achievement of certain sales milestone events, and also 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.

The agreement with Tesaro 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 Tesaro.

Paratek

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda, Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., under which we obtained an exclusive license under certain patents and know-how of Paratek Bermuda Ltd. 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. 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. 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.

Under the terms of the agreement, we are required to make an upfront payment to Paratek Bermuda Ltd. of $7.5 million. If we successfully develop and commercialize the licensed product, we will make milestone payments 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.

Bristol-Myers Squibb

In March 2015, we entered into a collaboration and license agreement with Bristol-Myers Squibb Company, or 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 mainland China, Hong Kong and Macau, or licensed territory, in the field of diagnosis, prevention, treatment or control of oncology indications, or licensed field, with the 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 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 will pay BMS milestone payments for the achievement of certain development and sales milestone events, 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.

GSK

In October 2016, we entered into a license and transfer agreement with GlaxoSmithKline (China) R&D Co., Ltd, or GSK China, an affiliate of GSK, under which GSK China transferred to us its rights under certain patents, know-how, inventory and regulatory materials to develop, manufacture, use and commercialize FUGAN and GRAPE, two formulations comprising extracts from traditional Chinese herbs, for the treatment, diagnosis and prevention of any human diseases. In connection with such transfer, GSK China also assigned to us its agreements with Chengdu Bater Pharmaceutical Co., Ltd, or Bater, and Traditional Chinese Medical Hospital, Xinjiang Medical University, or Xinjiang, relating to FUGAN and GRAPE.

We are obligated to use commercially reasonable efforts to develop at least one licensed product. Under the terms of the agreement, we made an upfront payment to GSK China of RMB4.5 million. We will make milestone payments to GSK China for the achievement of certain development milestone events. In addition, we will pay to GSK China tiered royalties at percentage rates in the low- to mid-single digits on the net sales of FUGAN and GRAPE. We also assumed the obligation to make milestone payments under the assigned agreements with Bater and Xinjiang for milestones achieved after the assignment of the agreements to us. If we sublicense, sell or otherwise divest the patents and know-how acquired from GSK China to third parties before the completion of certain development phase, we are also required to pay to GSK China a share of our income attributed to such sublicense, sale, or divesture.

The agreement with GSK China 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. In addition, we have the right to terminate the agreement for convenience upon advance notice to GSK China at any time after completion of certain stage of development work. GSK China has the right to terminate the agreement if we fail to reach certain development milestones, fail to make payments owed to GSK China, or fail to use commercially reasonable efforts in the development and commercialization of the licensed products and cannot correct such failure in the agreed period. Upon termination of the agreement with GSK China for our uncured breaches, we must, among other actions, assign back to GSK China and/or Bater and Xinjiang the transferred know-how and the license agreements between GSK China and Bater and Xinjiang.

Sanofi

In July 2015, we entered into a license agreement with Sanofi, under which we obtained an exclusive and worldwide license under certain patents and know-how of Sanofi to develop, manufacture, use, sell, import and commercialize Sanofi's ALK inhibitor SAR 348830, or the licensed compound, or ZL-2302 for any oncology indications in humans. Sanofi retains the non-exclusive right to use SAR348830 to conduct internal research.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed product in each of the major market countries. Sanofi has the option to exclusively negotiate with us to obtain the exclusive rights to commercialize the licensed product in the oncology field in such major market countries or throughout the world under certain circumstances.

Under the terms of the agreement, we made upfront payments to Sanofi totaling $0.5 million. If we successfully develop and commercialize the licensed product, we will make milestone payments to Sanofi for the achievement of certain development milestone events. In addition, we will pay Sanofi tiered royalties at percentage rates in the range of high single digits to low double digits 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 country-by-country basis. If we sublicense, transfer or assign (other than through a change of control transaction) the right to the licensed product to third parties, we are also required to pay to Sanofi a share of our sublicensing income.

The agreement with Sanofi 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. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to Sanofi. Sanofi has the right to terminate the agreement if we challenge any of the licensed patents. Sanofi may also terminate the agreement for our bankruptcy or insolvency.

UCB

In September 2015, we entered into a license agreement with UCB Biopharma Sprl, under which we obtained an exclusive and worldwide license under certain patents and know-how of UCB Biopharma Sprl to develop, manufacture, use, sell, import and commercialize UCB Biopharma Sprl's proprietary antibody UCB3000, or the licensed compound, or ZL-1101 for the treatment, prevention and diagnosis of any human diseases. UCB Biopharma Sprl retains the non-exclusive right to use the licensed compound for its own research purposes.

We are obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in the U.S. and EU and to file an IND within a certain specified time period. UCB Biopharma Sprl has the right of first negotiation to acquire the rights to the licensed products back from us upon our successful completion of certain clinical development work.

Under the terms of the agreement, we made upfront payments to UCB Biopharma Sprl totaling $0.8 million. If we successfully develop and commercialize the licensed products, we will make milestone payments to UCB Biopharma Sprl for the achievement of certain development and sales milestone events. In addition, we will pay to UCB Biopharma Sprl royalties at percentage rates in the range of mid-single digits to low-double digits 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 country-by-country basis. If we sublicense the right to the licensed product to third parties, we are also required to pay to UCB Biopharma Sprl a share of our sublicensing income.

The agreement with UCB Biopharma Sprl 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 UCB Biopharma Sprl. Each party also has the right to terminate the agreement if the other party challenges its patents.

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 drug companies, biologics drug companies, academic institutions, government agencies and research institutions.

For our global product 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. For additional information, please refer to the "Market Opportunity" description under each our drug candidates.

Patents and other intellectual property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates and 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.

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.

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 filing covered by pending third-party patent applications. If third parties prepare and file patent applications in China, the United States or other markets that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings, which could result in substantial costs to us, even if the eventual outcome is favorable to us, which is highly unpredictable. 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.”

Niraparib

As of April 30, 2017, we exclusively licensed two issued patents in the PRC directed to niraparib’s free base compound and analogues. These issued patents are projected to expire between 2027 and 2028. We also exclusively licensed one pending patent application in the PRC directed to a salt that covers 4-methylbenzenesulfonate monohydrate, the active pharmaceutical ingredient, or API, of niraparib. If this patent application issues as a patent, such patent will be projected to expire in 2029. There are no patent term adjustments or patent term extensions available for issued patents in the PRC. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC.

Omadacycline

As of April 30, 2017, we exclusively licensed three issued patents in the PRC directed to omadacycline’s compound, formulations and crystal form and two pending patent applications in the PRC directed to other crystalline forms of omadacycline. The issued composition of matter patent covering omadacycline is projected to expire in 2021 and the other two issued patents are projected to expire in 2029. If the two patent applications are issued, they are expected to expire in 2029. There are no patent term adjustments or patent term extensions available for issued patents in the PRC.

ZL-2301

As of April 30, 2017, we exclusively licensed five issued patents in the PRC, two issued patents in Korea and one issued patent in Taiwan, which are directed to the compound and composition of ZL-2301, the manufacturing process of intermediaries of ZL-2301 and the crystal form of brivanib alaninate, an ester of ZL-2301. Of the issued patents we exclusively licensed, two patents in the PRC, one patent in Korea and one patent in Taiwan are composition-of-matter patents that cover the ZL-2301 compound and its analogues. One patent in the PRC covers the medical use of ZL-2301. These patents are projected to expire between 2020 and 2023, excluding any additional term for patent term adjustments or patent term extensions in jurisdictions where such adjustments

and extensions are available. Our exclusively licensed patents also include one patent in the PRC and one patent in Korea that are process patents, which cover the manufacturing process for ZL-2301's API. These patents are projected to expire between 2023 and 2027, excluding any additional term for patent term adjustments or patent term extensions in jurisdictions where such adjustments and extensions are available. In addition, one patent we exclusively licensed in the PRC covers the crystal form of brivanib alaninate and is projected to expire in 2026. There are no patent term adjustments or patent term extensions available for this issued patent in the PRC. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than the PRC, Korea and Taiwan.

Fugan

As of April 30, 2017, we own one issued patent in the PRC directed to the pharmaceutical composition and therapeutic uses of fugan. Our issued patent in the PRC is projected to expire in 2029. There are no patent term adjustments or patent term extensions available for this issued patent in the PRC. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC.

ZL-2302

As of April 30, 2017, we exclusively licensed one pending patent application in the PRC. We also exclusively licensed one issued U.S. patent, one pending U.S. patent application, and two issued patents and 21 pending patent applications in other jurisdictions, including Australia, Canada, Europe, Japan, South Korea and Taiwan. The issued patents in this portfolio are directed to the pharmaceutical composition and therapeutic uses of ZL-2302, and are projected to expire in 2033, excluding any additional term for patent term adjustments or patent term extensions in jurisdictions where such adjustments and extensions are available.

ZL-1101

As of April 30, 2017, we exclusively licensed one issued patent in the PRC. We also exclusively licensed three issued U.S. patents, two pending U.S. patent applications and approximately 22 issued patents and 49 pending patent applications in other jurisdictions, including Australia, Canada, Europe, Hong Kong, Japan, South Korea, South Africa and Taiwan. The issued patents and pending patent applications in this portfolio cover antibody sequences and therapeutic uses of ZL-1101. The issued patents in this portfolio are projected to expire between 2030 and 2032, excluding any additional term for patent term adjustments or patent term extensions in jurisdictions where such adjustments and extensions are available.

Patent Term

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, a patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when our drug candidates receive approval by the FDA or other regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors. There can be no assurance that any of our pending patent applications will be issued or that we will benefit from any patent term extension.

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.

Employees

As of December 31, 2016, we employed a total of 50 full-time employees and two part-time employees, including a total of 20 employees with M.D. or Ph.D. degrees. Of our workforce, 40 employees are engaged in research and development. Due to the initiation of discovery efforts and increase in number of development-stage products, we increased our headcount between fiscal years 2015 and 2016, mainly in respect of our research and development personnel. None of our employees is represented by labor unions or covered by collective bargaining agreements.

Facilities

We are headquartered in Shanghai where we have two main administrative and laboratory offices, which are 3,632 and 938 square meters in size. The leases for these two facilities expire in 2020 and 2018, respectively. We also have a 98 square meter office in Beijing, the lease for which expires in 2018. In early 2017, we built a small molecule drug product facility in Suzhou, China capable of supporting clinical and commercial production and have begun construction of a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. The construction of the large molecule facility is expected to be completed in the first half of 2018. We believe our current facilities are sufficient to meet our near-term needs.

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 CFDA 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

We are, from time to time, subject to claims and suits arising in the ordinary course of business. Although the outcome of these and other claims cannot be predicted with certainty, management does not believe that the ultimate resolution of these matters will have a material adverse effect on our financial position or on our results of operations. We are not currently a party to, nor is our property the subject of, any material legal proceedings.

Regulation

Government regulation of pharmaceutical product development and approval

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.

Regulatory authorities

In the PRC, the CFDA is the authority under the State Council that monitors and supervises the administration of pharmaceutical products and medical appliances and equipment as well as food (including food additives and health food) and cosmetics. The CFDA's predecessor, the State Drug Administration, or the SDA, was established on August 19, 1998 as an organization to assume the responsibilities previously handled by the Ministry of Health of the PRC, or the MOH, the State Pharmaceutical Administration Bureau of the PRC and the State Administration of Traditional Chinese Medicine of the PRC. The SDA was replaced by the State Food and Drug Administration in March 2003 and was later reorganized into the CFDA following the institutional reform of the State Council in March 2013.

The primary responsibilities of the CFDA include:

- monitoring and supervising the administration of pharmaceutical products, medical appliances and equipment as well as food, health food and cosmetics in the PRC;
- formulating administrative rules and policies concerning the supervision and administration of food, health food, cosmetics and the pharmaceutical industry;
- evaluating, registering and approving of new drugs, generic drugs, imported drugs and traditional Chinese medicine, or TCM;
- approving and issuing permits for the manufacture and export/import of pharmaceutical products and medical appliances and equipment and approving the establishment of enterprises to be engaged in the manufacture and distribution of pharmaceutical products; and
- examining and evaluating the safety of food, health food, pharmaceutical products and cosmetics and handling significant accidents involving these products.

The National Health and Family Planning Commission, or NHFPC, is an authority at the ministerial level under the State Council and is primarily responsible for national public health. The predecessor of NHFPC is the Ministry of Health, or MOH. Following the establishment of the CFDA in 2003, the MOH was put in charge of the overall administration of the national health in the PRC excluding the pharmaceutical industry. The MOH performs a variety of tasks in relation to the health industry such as establishing social medical institutes and producing professional codes of ethics for public medical personnel. The MOH is also responsible for overseas affairs, such as dealings with overseas companies and governments. The MOH was reorganized into the NHFPC following the institutional reform of the State Council in March 2013.

Healthcare system reform

The PRC government recently promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the Central Committee of the PRC Communist Party and the State

Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System. The State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System on December 27, 2016. On April 21, 2016, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2016.

Highlights of these healthcare reform policies and regulations include the following:

- One of the main objectives of the reform was to establish a basic healthcare system to cover both urban and rural residents and provide the Chinese people with safe, effective, convenient and affordable healthcare services. As of 2017, basic medical insurance coverage has reached more than 95% of the country's population. By 2020, a basic healthcare system covering both urban and rural residents should be established.
- Another main objective of reform was to improve the healthcare system, through the reform and development of a graded diagnosis and treatment system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision.
- The reforms aimed to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education were to be provided to urban and rural residents. In the meantime, the reforms also encouraged innovations by pharmaceutical companies to eliminate pharmaceutical products that fail to prove definite efficacy and positive risk-benefit ratio.
- The key tasks of the reform in 2016 were as follows: (1) to deepen the reform of public hospitals, (2) to accelerate the development of a graded diagnosis and treatment system, (3) to consolidate and improve the universal medical insurance system, (4) to guarantee drug supply, (5) to establish and improve a comprehensive supervision system, (6) to cultivate talented health-care practitioners, (7) to stabilize and perfect the basic public health service equalization system, (8) to advance the construction of health information technology, (9) to accelerate the development of the health services industry generally, and (10) to strengthen organization and implementation.

Drug administration laws and regulations

The PRC Drug Administration Law as promulgated by the Standing Committee of the National People's Congress in 1984 and the Implementing Measures of the PRC Drug Administration Law as promulgated by the MOH in 1989 have laid down the legal framework for the establishment of pharmaceutical manufacturing enterprises and pharmaceutical trading enterprises and for the administration of pharmaceutical products including the development and manufacturing of new drugs and medicinal preparations by medical institutions. The PRC Drug Administration Law also regulates the packaging, trademarks and advertisements of pharmaceutical products in the PRC.

Certain amendments to the PRC Drug Administration Law took effect on December 1, 2001. Subsequent amendments were also made on December 28, 2013 and April 24, 2015. They were formulated to strengthen the supervision and administration of pharmaceutical products, and to ensure the quality of pharmaceutical products and the safety of pharmaceutical products for human use. The current PRC Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products. It regulates and prescribes 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.

According to the current PRC Drug Administration Law, no pharmaceutical products may be produced in China without a pharmaceutical production license. A local manufacturer of pharmaceutical products must obtain a pharmaceutical production license from one of CFDA's provincial level branches in order to commence production of pharmaceuticals. Prior to granting such license, the relevant government authority will inspect the manufacturer's production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards.

The PRC Implementing Regulations of the Drug Administration Law promulgated by the State Council took effect on September 15, 2002, were amended on February 6, 2016 and serve to provide detailed implementation regulations for the revised PRC Drug Administration Law.

Good laboratories practice certification for nonclinical research

To improve the quality of animal research, the CFDA promulgated the Good Laboratories Practice of Preclinical Laboratory in 2003 and began to conduct the certification program of the GLP. In April 2007, the CFDA promulgated the Administrative Measures for Certification of Good Laboratory Practice of Preclinical Laboratory, providing that the CFDA is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Preclinical Laboratory, the CFDA 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 CFDA and published on the CFDA's website.

Animal testing permits

According to Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission in November 1988, as amended in January 2011, July 2013 and March 2017, and Administrative Measures on the Certificate for Animal Experimentation promulgated by the State Science and Technology Commission and other regulatory authorities in December 2001, performing experimentation on animals requires a Certificate for Use of Laboratory Animals. Applicants must satisfy the following conditions:

- Laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;
- The environment and facilities for the animals' living and propagating must meet state requirements;
- The animals' feed and water must meet state requirements;
- The animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- The management systems must be effective and efficient; and
- The applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

Administrative measures for drug registration

In July 2007, the CFDA released the Administrative Measures for Drug Registration which took effect on October 1, 2007. The Administrative Measures for Drug Registration cover (1) definitions of drug registration applications and regulatory responsibilities of the CFDA; (2) general requirements for drug registration; (3) drug

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) re-examination; and (10) liabilities and other supplementary provisions.

In July 2016, the CFDA released the revised Administrative Measures for Drug Registration (Draft for Comments) to seek comments from the public, which as compared to the current Administrative Measures for Drug Registration, includes the following key highlights:

- encourage clinically oriented drug innovation, under which innovative drugs should have definite clinical value and modified drugs should present obvious clinical advantages over the drugs being modified;
- broaden the definition of applicants for marketing authorization from “domestic institutions” to “domestic entities” to cover both the drug research and development institutions and the scientific researchers;
- on-site inspections and sample taking are not compulsory prerequisites for CFDA approval, and the CFDA may determine whether to take such steps based on the results of regulatory review of drug registration applications;
- clinical trials can be conducted in the sequence of Phase I, II and III, or different stages can cross-over or overlap;
- recommend that decisions of regulatory review in each stage should be made within the prescribed time frame and the CFDA should establish a priority review system based on clinical needs and the characteristics of drugs;
- remove the section of “application and approval of generic drugs” and set out all relevant provisions in the section of “drug marketing authorization”;
- change the regulatory review process of bioequivalence study from approval to a more simplified recordal process;
- adjust and stipulate the functions of the CFDA and its branches.

Although there is no definitive timeline for the official enactment of the revised Administrative Measures for Drug Registration (Draft for Comments), it embodies a regulatory trend of promoting drug innovation, accelerating the drug registration process and setting forth higher quality and technical requirements.

Regulations on the clinical trials and registration of drugs

Four phases of clinical trials

According to the Administrative Measures for Drug Registration, a clinical development program consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate’s therapeutic effectiveness and safety for particular indication(s) in patients, which provides evidence and support for the design of Phase III clinical trials and settles the administrative dose regimen. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase III is used to further verify the drug’s therapeutic effectiveness and safety on patients with target indication(s), to evaluate overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug’s post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups, and to adjust the administration dose, etc.

Approval authority for clinical trial application

According to the Administrative Measures for Drug Registration, upon completion of its pre-clinical research, a research institution must apply for approval of a CTA before conducting clinical trials. As of May 1, 2017, the clinical trial approval can be directly issued by the CDE on behalf of the CFDA. This delegation of authority can shorten the approval timeline for the approval of a CTA.

Special examination and approval for domestic Category 1 drugs

According to the Administrative Measures for Drug Registration, drug registration applications are divided into three different types, namely Domestic New Drug Application, Domestic Generic Drug Application, and Imported Drug Application. Drugs fall into one of three general types divided by working mechanism, namely chemical medicine, biological product or traditional Chinese or natural medicine. Under the Administrative Measures for Drug Registration, a Category 1 drug refers to a new drug that has never been marketed in any country, and is eligible for special review or fast track approval by the CFDA.

In March 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Medicine, or the Reform Plan, which outlined the reclassifications of drug applications under the Administrative Measures for Drug Registration. Under the Reform Plan, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the Domestic New Drug Application and the Imported Drug Application procedures under the Administrative Measures for Drug Registration, respectively.

According to the Special Examination and Approval Provisions, the CFDA conducts special examination and approval for new drug registration applications when:

(1). the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered;

(2). the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing home and abroad;

(3). the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinic treatment; or

(4). the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval Provisions provide that the applicant may file for special examination and approval at the CTA stage if the drug candidate falls within items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

We believe that our current drug candidates fall within items (2) and (3) above. Therefore, we may file an application for special examination and approval at the CTA stage, which may enable us to pursue a more expedited path to approval in China and bring therapies to patients more quickly.

Fast track approval for clinical trial and registration of domestic Category 1 drugs

In November 2015, the CFDA released the *Circular Concerning Several Policies on Drug Registration Review and Approval*, which further clarified the following policies, potentially simplifying and accelerating the approval process of clinical trials:

- a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug's clinical trials, replacing the current phase-by-phase application and approval procedure, will be adopted for new drugs' CTAs; and
- a fast track drug registration or clinical trial approval pathway for the following applications: (1) registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases; (2) registration of pediatric drugs; (3) registration of geriatric drugs and drugs treating China-prevalent diseases in elders; (4) registration of drugs listed in national major science and technology projects or national key research and development plan ; (5) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the United States or European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (8) CTAs for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

In addition, in February 2016, the CFDA released the Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog, or the Priority Review Opinions, which further clarified that a fast track clinical trial approval or drug registration pathway will be available to the following drugs:

- the following drugs with distinctive clinical benefits: (1) registration of innovative drugs not sold within or outside China; (2) registration of innovative drug transferred to be manufactured locally in China; (3) registration of drugs using advanced technology, innovative treatment methods, or having distinctive treatment advantages; (4) CTAs for drugs with patent expiry within three years, and manufacturing authorization applications for drugs with patent expiry within one year; (5) concurrent applications for new drug clinical trials which are already approved in the United States or European Union, or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; (6) traditional Chinese medicines (including ethnic medicines) with clear position in prevention and treatment of serious diseases; and (7) registration of new drugs listed in national major science and technology projects or national key research and development plans; and
- drugs with distinctive clinical benefits for the prevention and treatment of the following diseases: HIV, phthisis, viral hepatitis, orphan diseases, cancer, children's diseases, and generic and prevalent diseases in elders.

Other than fugan, we believe that all of our current clinical stage drug candidates will be classified as Category 1 drugs. Therefore, we will be entitled to the fast track clinical trial approval or drug registration pathway under the Priority Review Opinions.

According to the Administrative Measures for Drug Registration, Category 5 drug applications may only be submitted after a company obtains an NDA approval and receives the Certificate of Pharmaceutical Product

granted by a major regulatory authority, such as the FDA or the EMEA. Multinational companies may need to apply for conducting multi-regional clinical trials, which means that companies do not have the flexibility to design the clinical trials to fit Chinese patients and standard-of-care. Category 5 drug candidates may not always qualify to benefit from fast track review with priority at the CTA stage. Moreover, a requirement to further conduct local clinical trials when the multi-regional clinical trials do not present sufficient Chinese patient data can potentially delay market access by several years from its international NDA approval. Further, according to the Reform Plan, the drugs which have already been marketed abroad may no longer be categorized as new drugs under Chinese law in the future, and therefore may not be able to enjoy any preferential treatment for new drugs.

Drug clinical practice certification and compliance with GCP

To improve the quality of clinical trials, the CFDA promulgated the Administration of Quality of Drug Clinical Practice in August 2003. In February 2004, the CFDA issued the Circular on Measures for Certification of Drug Clinical Practice (Trial), providing that the CFDA is responsible for certification of clinical trial institutions, and that the National Health and Family Planning Commission of the PRC, formerly known as the Ministry of Health, is responsible for certification of clinical trial institutions within its duties. Under the Circular on Measures for Certification of Drug Clinical Practice (trial), the CFDA and the National Health and Family Planning Commission of the PRC decide whether an institution is qualified for undertaking pharmaceutical clinical trials upon the evaluation of the institution's organizational administration, its research personnel, its equipment and facilities, its management system and its standard operational rules. If all requirements are met, a GCP Certification will be issued by the CFDA and the result will be published on the CFDA's website.

The conduct of clinical trials must adhere to the GCP and the protocols approved by the ethics committees of each study site. Since 2015, the CFDA has strengthened the enforcement against widespread data integrity issues associated with clinical trials in China. To ensure authenticity and reliability of the clinical data, the CFDA mandates applicants of the pending drug registration submissions to conduct self-inspection and verification of their clinical trial data. Based on the submitted self-inspection results, the CFDA also regularly launches onsite clinical trial audits over selected applications and reject those found with data forgery.

Pilot plan for the marketing authorization holder system

Under the authorization of the Standing Committee of the National People's Congress, the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism on May 26, 2016, which provides a detailed pilot plan for the marketing authorization holder system, or the MAH System, for drugs in 10 provinces in China. Under the MAH System, domestic drug research and development institutions and individuals in the piloted regions are eligible to be holders of drug registrations without having to become drug manufacturers. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and GMP-certified, and are also located within the piloted regions. Drugs qualified for the MAH System are: (1) new drugs (including Category 1 and 2 drugs under the Reform Plan) approved after the implementation of the MAH System; (2) generic drugs approved as Category 3 or 4 drugs under the Reform Plan; (3) previously approved generics that have passed the equivalence assessments against originator drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the piloted regions, but have been moved out of the piloted regions due to corporate mergers or other reasons.

Administrative protection and monitoring periods for new drugs

According to the Administrative Measures for Drug Registration, the Implementing Regulations of the Drug Administration Law and the Reform Plan, the CFDA may, for the purpose of protecting public health, provide for

an administrative monitoring period of five years for Category 1 new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs.

During the monitoring period of a new drug, the CFDA will not accept other applications for new drugs containing the same active ingredient. This renders an actual five-year exclusivity protection for Category 1 new drugs. The only exception is that the CFDA will continue to handle any application if, prior to the commencement of the monitoring period, the CFDA has already approved the applicant's clinical trial for a similar new drug. If such application conforms to the relevant provisions, the CFDA may approve such applicant to manufacture or import the similar new drug during the remainder of the monitoring period.

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.

New drug application

When Phases I, II and III of the clinical trials have been completed, the applicant may apply to the CFDA for approval of an NDA. The CFDA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the CFDA. We must obtain approval of an NDA before our drugs can be manufactured and sold in the China market.

International multi-center clinical trials regulations

On January 30, 2015, the CFDA promulgated Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), or the Multi-Center Clinical Trial Guidelines, which took effect as of March 1, 2015, aiming to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to CFDA for approval of an NDA, such international multi-center clinical trials shall satisfy, in addition to the requirements set forth in Drug Administration Law and its implementation regulations, Provisions for Drug Registration 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 international multi-center clinical trial research centers shall be subject to on-site inspections by competent PRC governmental agencies.

International multi-center clinical trials shall follow international prevailing 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 international multi-center clinical trial, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researchers and clinical trial organizations on the CFDA drug clinical trial information platform.

Data derived from international multi-center clinical trials can be used for the NDAs with the CFDA. When using international multi-center clinical trial data to support NDAs 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 NDA process in China.

On March 17, 2017, the CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration (Draft for Comments) for public comment, which includes the following key points:

- If the International Multicenter Clinical Trial, or 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 vaccines.
- If the IMCCT is conducted in China, the application for drug marketing authorization can be submitted directly after the completion of the IMCCT.
- With respect to 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.
- With respect to drug applications that have been accepted before the release of this Draft, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from IMCCT.

Uncertainties exist as to when this Draft will be officially enacted and take effect, and significant amendments may be made before then.

Drug technology transfer regulations

On August 19, 2009, the CFDA promulgated the Administrative Regulations for Technology Transfer Registration of Drugs to standardize the registration process of drug technology transfer, which includes application for, and evaluation, examination, approval and monitoring of, drug technology transfer. Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer and the application for drug registration by the transferee according to the provisions in the new regulations. Drug technology transfer includes new drug technology transfer and drug production technology transfer.

Conditions for the application for new drug technology transfer

Applications for new drug technology transfer may be submitted prior to the expiration date of the monitoring period of the new drugs with respect to:

- drugs with new drug certificates only; or
- drugs with new drug certificates and drug approval numbers.

For drugs with new drug certificates only and not yet in the monitoring period, or drug substances with new drug certificates, applications for new drug technology transfer should be submitted prior to the respective expiration date of the monitoring periods for each drug registration category set forth in the new regulations and after the issue date of the new drug certificates.

Conditions for the application of drug production technology transfer

Applications for drug production technology transfer may be submitted if:

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

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

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

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

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

Permits and licenses for manufacturing of drugs

Pharmaceutical manufacturing permit

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 permit number, the name, legal representative and registered address of the enterprise, the site and scope of production, issuing institution, date of issuance and effective period.

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.

Business licenses

In addition to a Pharmaceutical Manufacturing permit, the manufacturing enterprise must also obtain a business license from the administrative bureau of industry and commerce at the local level after it has obtained the requisite Pharmaceutical Manufacturing Permit. The name, legal representative and registered address of the enterprise specified in the business license must be identical to that set forth in the Pharmaceutical Manufacturing Permit.

GMP certificates

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.

A GMP certification certifies that a manufacturer's factory and quality management system have met certain criteria for engaging in the planning and manufacturing of drug products, which address institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, maintenance of sales records and manner of handling customer complaints and adverse reaction reports. In January 2011, the MOH issued an updated set of GMP standards, also known as the new GMP, to replace the previous version issued in 1998. There are also five annexes to the new GMP issued by the CFDA in February 2011, with detailed requirements for the manufacture of sterile drugs, drug/substances/APIs, biologics, blood products and traditional Chinese medicines.

The GMP certificate is valid for a term of five years and an application for renewal must be submitted six months prior to its expiration date. The CFDA and its provincial branches are authorized to monitor the continued compliance of pharmaceutical manufacturers, for example, by a follow-up inspection of implementation of the GMP requirements. Failure to continuously comply with the statutory requirements may lead to rectification orders imposed on the manufacturers. Penalties for breach of GMP compliance can vary depending on the degree of seriousness. Administrative sanctions range from a rectification notice to monetary fines, suspension of production and business operation, and revocation of the pharmaceutical manufacturing permit and the Pharmaceutical GMP Certificate.

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 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 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;
- 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; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by FDA.

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. 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 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.
- 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 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and

the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time 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

Following trial completion, trial results and data are analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling for the drug, information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application may include negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product to the satisfaction of the FDA. Under federal law, the submission of most NDAs is subject to the payment of an application user fees; a waiver of such fees may be obtained under certain limited circumstances. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

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, 2015, the user fee for an application requiring clinical data, such as an NDA, is $2,335,200. PDUFA also imposes an annual product fee for human drugs ($110,370) and an annual establishment fee ($569,200) on facilities used to manufacture prescription drugs. 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 limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a 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.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Special FDA expedited review and approval programs

The FDA has various programs, including Fast Track Designation, accelerated approval, priority review and Breakthrough Therapy Designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Fast track designation

To be eligible for a Fast Track Designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast track designation determination within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with FDA, FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a priority review.

Breakthrough therapy designation

Under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted by Congress in 2012, a sponsor can request designation of a drug candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA may take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Accelerated approval

FDASIA also codified and expanded on FDA's accelerated approval regulations, under which FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. This determination takes into account the severity, rarity or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform Phase 4 or post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track Designation, priority review, accelerated approval and Breakthrough Therapy Designation, do not change the standards for approval and may not ultimately expedite the development or approval process.

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 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.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that drugs be manufactured in specific approved facilities and in accordance with cGMP. Applicants may also rely on third parties for the production of clinical and commercial quantities of drugs, and these third parties must operate in accordance with cGMP regulations. cGMP regulations 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. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using third party 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 firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and 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 drugs manufactured, processed or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. 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.

U.S. patent term restoration and marketing exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent that covers the approved drug (and to only those patent claims covering the approved drug, a method for using it, or a method for manufacturing it) is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a NCE. A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent

invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Specifically, the applicant must certify with respect to each relevant patent that: the required patent information has not been filed; the listed patent has expired; the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

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

Historically, most Chinese healthcare costs have been borne by patients out-of-pocket, which has limited the growth of more expensive pharmaceutical products. However, in recent years the number of people covered by government and private insurance has increased. According to the PRC National Bureau of Statistics, as of

December 31, 2015, 666 million urban employees and residents in China were enrolled in the national medical insurance program, representing an increase of 11.44% from December 31, 2014. The PRC government has announced a plan to give every person in China access to basic healthcare by year 2020.

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 issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance 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 on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. The State Council expects the pilot Urban Resident Basic Medical Insurance to cover the whole nation by 2010.

Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the Medical Insurance Catalogue. The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee, jointly issued by several authorities including the Ministry of Labor and Social Security and the MOF, among others, on May 12, 1999, provides that a pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements:

- it is set forth in the Pharmacopoeia of the PRC;
- it meets the standards promulgated by the CFDA; and
- if imported, it is approved by the CFDA for import.

Factors that affect the inclusion of a pharmaceutical product in the Medical Insurance Catalogue include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public.

The PRC Ministry of Human Resources and Social Security, together with other government authorities, has the power to determine the medicines included in the NDRL. In February 2017, the PRC Ministry of Human Resources and Social Security released the 2017 NDRL. The 2017 NDRL expands its scope and covers 2,535 drugs in total, including 339 drugs that are newly added. The 2017 NDRL reflects an emphasis on innovative drugs and drugs that treat cancer and other serious diseases. For instance, most of the innovative chemical drugs and biological products approved in China between 2008 and the first half of 2016 have been included in the 2017 NDRL or its candidate list.

Medicines included in the NDRL are divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the NDRL in their provincial Medical Insurance Catalogue,, but have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the NDRL. As a result, the contents of Part B of the provincial Medical Insurance Catalogues may differ from region to region in the PRC.

Patients purchasing medicines included in Part A of the NDRL are entitled to reimbursement of the entire amount of the purchase price. Patients purchasing medicines included in Part B of the NDRL 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.

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.

National list of essential drugs

On August 18, 2009, MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Drugs and the Guidelines on the Implementation of the National List of Essential Drugs System, which aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National List of Essential Drugs. MOH promulgated the National List of Essential Drugs (Catalog for the Basic Healthcare Institutions) on August 18, 2009, and promulgated the revised National List of Essential Drugs on March 13, 2013. 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. Remedial drugs in the National List of Essential Drugs are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Commercial insurance

On October 25, 2016, the State Council and the Communist Party of China jointly issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

Price controls

Instead of direct price controls which were historically used in China but abolished in June 2016, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices as discussed below.

Centralized procurement and tenders

The Guiding Opinions concerning the Urban Medical and Health System Reform, promulgated on February 21, 2000, aims to regulate the purchasing process of pharmaceutical products by medical institution. The MOH and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions promulgated on July 7, 2000 and the Notice on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions promulgated on August 8, 2001, medical institutions established by county or higher level government or state-owned enterprises (including state-controlled enterprises) 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), or there Centralised Procurement Regulations, on March 13, 2002, and promulgated Sample Document for Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation), or the Centralised Tender Sample Document in November 2001, to implement the tender process requirements and ensure the requirements are followed uniformly throughout the country. The Centralised Tender Regulations and the Centralised Tender Sample Document provide rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On January 17, 2009, the MOH, the CFDA and other four national departments jointly promulgated the Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions. According to the notice, public 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 public medical institutions shall be covered by the catalogue of drugs subject to centralised procurement. On July 7, 2010, the MOH and six other ministries and commissions jointly promulgated the Notice on Printing and Distributing the Working Regulations of Medical Institutions for Centralised Procurement of Drugs to further regulate the centralised procurement of drugs and clarify the code of conduct of the parties in centralised drug 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.

Insurance reform

The Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents issued by the State Council on January 3, 2016, call for the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, 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.

According to the Main Tasks of Healthcare System Reform in 2016 issued by the General Office of the State Council on April 21, 2016, the key tasks of the medical insurance reform are: (1) to advance the establishment of the mechanisms of stable and sustainable financing and security level adjustment, (2) to advance the integration of the basic medical insurance systems for urban and rural residents, (3) to consolidate and improve the system for serious illness insurance for urban and rural residents, (4) to reform medical insurance payment methods, and (5) to advance the development of commercial health insurance.

The Human Resources and Social Security Departments issued the Guiding Opinions on Actively Promoting the Coordinated Healthcare, Medical Insurance and Pharmaceutical Reforms on June 29, 2016, which state that

reform will focus on exploring and leveraging the fundamental role of medical insurance through further integration of medical insurance systems in all aspects, deepening the reform of the payment methods for medical insurance and promoting innovation in the medical insurance management system.

According to the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System issued by the State Council on December 27, 2016, one of the guiding principles is to insist on the reform of the coordinated development among healthcare, medical insurance and pharmaceutical systems. The reform intends to establish a complete policy structure in healthcare by 2017, including by perfecting the graded diagnosis and treatment system, establishing and improving the comprehensive supervision and modern hospital management systems, improving the universal medical insurance system, perfecting drug production and distribution policies and strengthening public health service, medical service, medical insurance, drug supply, supervision and management systems throughout the healthcare industry.

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. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Medicare payment for some of the costs of prescription drugs may increase demand for drugs for which we receive marketing approval. However, any negotiated prices for our drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality and the

National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, if third-party payors do not consider a drug to be cost-effective compared to other available therapies, they may not cover such drugs as a benefit under their plans or, if they do, the level of payment may not be sufficient.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, enacted in March 2010, has had a significant impact on the health care industry. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013, and, due to subsequent legislative amendments, will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Rest of the world coverage and reimbursement

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal drugs for which their national health insurance systems provide reimbursement and to control the prices of medicinal drugs for human use. A member state may approve a specific price for the medicinal drug or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the medicinal drug on the market. Historically, drugs launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other healthcare laws

Other PRC healthcare laws

Advertising of pharmaceutical products

Pursuant to the Provisions for Drug Advertisement Examination, which were promulgated on March 13, 2007 and came into effect on 1 May 2007, an enterprise seeking to advertise its drugs must apply for an advertising approval code. The validity term of an advertisement approval number for pharmaceutical drugs is one year.

The content of an approved advertisement may not be altered without prior approval. Where any alteration to the advertisement is needed, a new advertisement approval number shall be obtained by submitting a reapplication.

Insert sheet and labels of pharmaceutical products

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the CFDA. 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 effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards. If no national or professional standards are available, the enterprise can formulate its own standards and put into implementation after obtaining the approval of the food and drug administration 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.

Anti-kickback statute

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

False claims

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Analogous state law equivalents may apply and may be broader in scope than the federal requirements. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Payments to physicians

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports to the government by March 31, 2014 and June 30, 2014, and the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Data privacy and security

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered

entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Other significant PRC regulation affecting our business activities in china

PRC regulation of foreign investment

Investment activities in China by foreign investors are principally governed by the Guidance Catalogue of Industries for Foreign Investment, or the Catalogue, which was promulgated and is amended from time to time by the MOFCOM and the National Development and Reform Commission. Industries listed in the Catalogue are divided into three categories: encouraged, restricted and prohibited. Establishment of wholly foreign-owned enterprises is generally allowed in encouraged and permitted industries. Some restricted industries are limited to equity or contractual joint ventures, while in some cases Chinese partners are required to hold the majority interests in such joint ventures. In addition, restricted category projects are subject to higher-level government approvals. Foreign investors are not allowed to invest in industries in the prohibited category. Industries not listed in the Catalogue are generally open to foreign investment unless specifically restricted by other PRC regulations. Pursuant to the latest Catalogue amended in March 2015, the manufacture of pharmaceutical products falls in the encouraged category.

Under PRC law, the establishment of a wholly foreign-owned enterprise is subject to the approval of, or the requirement for record filing with, the MOFCOM or its local counterparts and the wholly foreign owned enterprise must register with the competent administrative bureau of industry and commerce. We have duly obtained the approvals from the MOFCOM or its local counterparts for our interest in our wholly-owned PRC subsidiaries and completed the registration of these PRC subsidiaries with the competent administrative bureau of industry and commerce.

In October 2016, the MOFCOM issued the Interim Measures for Record-filing Administration of the Establishment and Change of Foreign-invested Enterprises, or FIE Record-filing Interim Measures. Pursuant to FIE Record-filing Interim Measures, the establishment and change of foreign-invested enterprises are subject to record-filing procedures, instead of prior approval requirements, provided that the establishment or change does not involve special entry administrative measures. If the establishment or change of FIE matters involve the special entry administrative measures, the approval of the MOFCOM or its local counterparts is still required. Pursuant to the Announcement 2016 No. 22 of the National Development and Reform Commission and the MOFCOM dated October 8, 2016, the special entry administrative measures for foreign investment apply to restricted and prohibited categories specified in the Catalogue, and the encouraged categories are subject to certain requirements relating to equity ownership and senior management under the special entry administrative measures.

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 which became effective on March 1, 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, or the PRC Civil Law, promulgated on April 12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

On February 22, 1993, the Product Quality Law of the PRC, or the Product Quality Law, was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised by the Ninth National People's Congress on July 8, 2000 and by the Eleventh National People's Congress on August 27, 2009. 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 was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep 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 which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as 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.

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, most recently amended in December 2008, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten 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.

Medical patent compulsory license

According to the PRC Patent Law, for the purpose of public health, the SIPO may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded.

Exemptions for Unlicensed Manufacture, Use, Sale or Import of Patented Products

The PRC Patent Law provides five exceptions for unauthorized manufacture, use, sale or import of patented products. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope;
- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;
- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or
- Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, uses or imports patented drugs or patented medical equipment for the abovementioned person.

However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in PRC Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

Trade secrets

According to the PRC Anti-Unfair Competition Law, 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, solicitation or coercion; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; or (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. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB10,000 to RMB200,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a Chinese court for loss and damages incurred due to the misappropriation.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

Trademarks and domain names

Trademark. The PRC Trademark Law and its implementation rules protect registered trademarks. The PRC Trademark Office of State Administration of Industry and Commerce 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. As of April 30, 2017, we had two registered trademarks in China and four trademark applications pending outside China.

Domain Name. Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names. We have registered zaibio.com, zaibiotech.com, zailaboratory.com, zailab.com.cn, zaimedicine.com and zaipharma.com.

PRC regulation of labor protection

Under the Labor Law of the PRC, effective on January 1, 1995 and subsequently amended on August 27, 2009, the PRC Employment Contract Law, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the PRC.

Pursuant to the Law of Manufacturing Safety of the PRC effective on November 1, 2002 and amended on August 27, 2009 and August 31, 2014, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable PRC laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011, the Interim Regulations on the Collection and Payment of Social Security Funds which became effective on January 22, 1999, Interim Measures concerning the Maternity Insurance of Employees which become effective on December 14, 1994, and the Regulations on Work-related Injury Insurance which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Regulations relating to foreign exchange registration of offshore investment by PRC residents

In July 2014, SAFE issued the SAFE Circular 37, and its implementation guidelines, which abolished and superseded the SAFE Circular 75. 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, 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, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE on March 28, 2007. 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

The principal regulations governing distribution of dividends paid by wholly foreign-owned enterprises include:

- Company Law of the PRC (1993), as amended in 1999, 2004, 2005 and 2013; and
- Foreign Investment Enterprise Law of the PRC (1986), as amended in 2000 and 2016; and
- Administrative Rules under the Foreign Investment Enterprise Law (1990), as amended in 2001 and 2014.

Under these laws and regulations, foreign-invested enterprises in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise in China is required to set aside at least 10.0% of its after-tax profit based on PRC accounting standards each year to its general reserves until the accumulative amount of such reserves reach 50.0% of its registered capital. These reserves are not distributable as cash dividends. The foreign-invested enterprise has the discretion to allocate a portion of its after-tax profits to staff welfare and bonus funds. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Regulations relating to foreign exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where 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, or SAFE Circular No. 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 No. 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 SAFE Circular No. 19, which took effective and replaced SAFE Circular No. 142 on June 1, 2015. Although SAFE Circular No. 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, or Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to nonassociated enterprises. Violations of SAFE Circular 19 or Circular 16 could result in administrative penalties.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e.g. profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in 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, or SAFE Circular No. 13, which took effect on June 1, 2015. SAFE Circular No. 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. We believe that we are currently in compliance with these laws and regulations; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

Management

Our executive officers and directors

Below is a list of our directors and executive officers as of the date of this prospectus, as well as a brief account of the business experience of each of them:

Name	Age	Position(s)
Executive Officers		
Ying (Samantha) Du	52	Director, Chairman and Chief executive officer
Qi Liu	52	Chief medical officer, oncology
Harald Reinhart	65	Chief medical officer, autoimmune and infectious diseases
Ning Xu	53	Executive vice president, clinical operations and regulatory affairs
James Yan	52	Executive vice president, head of early development and drug safety
Non-Management Directors		
Nisa Leung	46	Director
Marietta Wu	49	Director
Jianming Yu	45	Director
Other Key Employees and Advisors		
Minghui Chen	49	Vice president, government and regulatory affairs
Xiaopeng (Tom) Feng	44	Vice president, finance
Jonathan Wang	35	Vice president, head of business development
Bo Zhang	44	Senior vice president, chemistry, manufacturing and controls
Richard A. Flavell	71	Scientific Advisor
Gwen Fyfe	65	Scientific Advisor
Neal Rosen	67	Scientific Advisor
Peter Wirth	66	Senior Advisor

Executive officers

Ying (Samantha) Du, Ph.D., co-founded our company and has been our director, chairman and chief executive officer since our inception. Prior to founding our company, Dr. Du spent two years as managing director of healthcare investments at Sequoia Capital China. From 2001 to 2011, Dr. Du was founder and chief executive officer of Hutchison Medi-Pharma and the co-founder and chief scientific officer of Hutchison China MediTech Limited, a Nasdaq-listed biopharmaceutical company, 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. Dr. Du began her career with Pfizer in the United States in 1994, where she was involved in the development and launch of two global drugs. While at Pfizer, she was responsible for Pfizer's global metabolic licensing program on the scientific side. She received a Ph.D. in biochemistry from the University of Cincinnati.

Qi Liu, M.D., Ph.D. has been our chief medical officer, oncology since 2015. Prior to joining our company, Dr. Liu was the clinical lead of the BioVenture group at AstraZeneca and the executive medical director of AstraZeneca Oncology, where she played an important role in establishing AstraZeneca's biologics joint ventures and was responsible for its joint venture global clinical development programs and regulatory strategy and submissions. Prior to joining AstraZeneca, Dr. Liu was an assistant professor at the MD Anderson Cancer Center. Dr. Liu received a medical degree from Shanghai Medical University (currently known as Shanghai Medical College of Fudan University) and a Ph.D. in molecular genetics from the University of Georgia. She completed a post-doctoral fellowship at Memorial Sloan Kettering Cancer Center and a medical oncology and hematology fellowship at the MD Anderson Cancer Center.

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, in 2012, Dr. Reinhart joined Shionogi US as head of Clinical Development and Medical Affairs, where he directed a broad portfolio of antibiotics, diabetes, allergy and pain medications, as well as guided a pharmaceutical product through NDA submission and approval. Between 2003 and 2011, Dr. Reinhart held senior roles at Novartis, where he oversaw successful filings of SNDAs and NDAs for Coartem, Famvir, Sebivo, and Cubicin, managed clinical development groups for transplantation, renal disease and immunity, and supervised the transitioning of projects from research into clinics. Dr. Reinhart received a medical degree from the University of Würzburg in Germany. He completed his medical specialty training in the United States with board-certifications in internal medicine and infectious diseases.

Ning Xu, M.D., has been our executive vice president, clinical operations and regulatory affairs 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 GlaxoSmithKline. Dr. Xu received a medical degree from Peking Union Medical College and a master of business administration from the University of Illinois at Chicago. 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 executive vice president and head of pre-clinical development and drug safety since 2015. 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 been 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, a council member of the China Society of Toxicology and a member of the Drug Toxicity and Drug Safety Evaluation Committee.

Non-management directors

Nisa Leung has been our independent director since 2014. Ms. Leung is a Managing Partner at Qiming Venture Partners, where she leads its health care investments. In addition to serving on our board of directors,

Ms. Leung is also a member of the board of directors of Berry Genomics, a biotechnology company that provides prenatal genetic testing; CanSino Biotechnology, 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.

Marietta Wu, M.D., Ph.D., co-founded our company, has been our director since 2014 and served as our chief operating officer from 2014 to 2017. Prior to founding our company, Dr. Wu served as general manager of greater China and later managing director of Burrill & Company, or Burrill, where she led Burrill's operation in greater China and focused on venture capital investing in China and Taiwan related to life science opportunities. Prior to joining Burrill, Dr. Wu was director of strategy at Edwards Lifesciences. From 2009 to 2010, Dr. Wu also served as acting chief operating officer of Waterstone Pharmaceuticals, a specialty pharmaceutical company with key operations in China. She also held various financial and business development positions at Eli Lilly & Company. Dr. Wu received her medical degree from Shanghai Jiaotong University School of Medicine, a Ph.D. in Medical Sciences from Medical College of Ohio and a master of business administration from the University of Michigan Ross School of Business. Dr. Wu is a founding member of the China Healthcare Investment Conference.

Jianming Yu, Ph.D., has been our director since 2016. Dr. Yu is a co-founder of New Horizon Capital and has been its managing partner and chief executive officer since its inception in 2005. Dr. Yu also founded Advantech Capital, a growth fund specializing in innovative technologies and healthcare, and has served as its managing partner since 2015. In addition, Dr. Yu is founder and managing partner of Redview Capital, a private equity fund with focus on consumer products and services, advanced manufacturing, and new energy sectors. Dr. Yu received a master of business administration from Kellogg School of Management, Northwestern University, and a Ph.D. in biology from Harvard University.

Other key employees and advisors

Minghui Chen has been our vice president, government and regulatory affairs since 2017. Prior to joining our company, he was senior director at a subsidiary of Wuxi Apptec. From 2012 to 2013, he was vice president at Cenova Ventures. From 2008 to 2011, he was head of regulatory affairs at Hutchison Medi-Pharma, where he maintained a highly successful track record of leading new drug submissions and obtaining fast approvals through the green channel. Mr. Chen also had significant experience working in the regulatory affairs department at AstraZeneca in China prior to joining Hutchison Medi-Pharma. Mr. Chen received a bachelor of science in pharmacology from Fudan University Medical School.

Xiaopeng (Tom) Feng has been our vice president, finance since 2017. Prior to joining our company, Mr. Feng was the financial director of Ascletis Bioscience Limited, where he was responsible for financial reporting and management. From 2012 to 2015, Mr. Feng served as financial controller of GMT Shipping Nigeria. From 2002 to 2011, Mr. Feng served as financial director in various subsidiaries of Hutchison China MediTech Limited. Mr. Feng received a bachelor of economics from Fudan University. He is a member of CICPA and a fellow member of the FCCA.

Jonathan Wang has been our 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.

Bo Zhang has been our senior vice president, chemistry, manufacturing and controls since 2014. Prior to joining our company, Dr. Zhang was a director of the nature product business unit at GlaxoSmithKline, where he was responsible for chemistry, manufacturing and controls development. From 2010 to 2013, Dr. Zhang served as senior director of Hutchison Medi-Pharma, where he was responsible for chemistry, manufacturing and controls development. Before returning to China, Dr. Zhang had significant experience at Pfizer in the United States. Dr. Zhang received a Ph.D. in analytical chemistry from Iowa State University and a masters degree in chemical fibers from Sichuan University.

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. Prior to joining the Yale faculty in 1988, Dr. Flavell was the President and Chief Scientific Officer of Biogen Research Corporation. Dr. Flavell received a Ph.D. in biochemistry from the University of Hull, England, and performed postdoctoral work in Amsterdam and Zurich. He is an Investigator of the Howard Hughes Medical Institute, a fellow of the Royal Society, a member of the National Academy of Sciences, and a member of the Institute of Medicine of the National Academies. He has published over 800 papers and has received many awards, including the Invitrogen Meritorious Career Award from the American Association of Immunologists.

Gwen Fyfe, M.D., has served on our scientific advisory board since 2016. Since 2009, Dr. Fyfe has been a consultant for venture capital firms and for a variety of biotechnology companies. From 1997 to 2009, Dr. Fyfe held various positions with Genentech Inc. (now a member of the Roche Group), including Vice President, Oncology Development and Vice President, Avastin Franchise Team, as well as the honorary title of Senior Staff Scientist. Dr. Fyfe played an important role in the development of Genentech's approved oncology agents including Rituxan®, Herceptin®, Avastin® and Tarceva®. From 1990 to 1997, Dr. Fyfe was Medical Director at Chiron Therapeutics. Dr. Fyfe currently serves as a director of Array Biopharma, Inc., Cascadian Therapeutics and Molecular Partners AG and previously served as a director of Infinity Pharmaceuticals, Inc. Dr. Fyfe received a medical degree from Washington University and is a board-certified pediatric oncologist. She has been an invited member of Institute of Medicine panels, National Cancer Institute working groups and grant committees and American Society of Clinical Oncologists oversight committees.

Neal Rosen, M.D., Ph.D. has served on our scientific advisory board since 2016. 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. He is also a Professor of Pharmacology, Cell Biology and Medicine at Cornell University Medical School. He has played an important role in the development of tyrosine kinase-mediated signaling inhibitors and has pioneered the concept that cancer cells are dependent on cellular machinery for protein folding. Dr. Rosen received a medical degree and a Ph.D. in Molecular Biology from the Albert Einstein College of Medicine. He completed a residency in Internal Medicine at the Brigham and Women's Hospital and post-doctoral training and a fellowship in Medical Oncology at the National Cancer Institute, where he served on the senior staff prior to joining the faculty of Memorial Sloan Kettering Cancer Center. He was the recipient of the NIH/NCI Outstanding Investigator Award in 2016.

Peter Wirth has been our senior advisor since 2015. He is chairman of FORMA Therapeutics Holdings LLC, a small molecule drug discovery company; executive chairman of ZappRx, a digital health care company; chair of the board of directors at Syros Pharmaceuticals, a Nasdaq-listed biopharmaceutical company; and director of Aura Biosciences, Inc., a biopharmaceutical company. From 2011 to 2014, Mr. Wirth served as president and director of Lysosomal Therapeutics, Inc., a biopharmaceutical company focused on small molecule research. 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. During the last five years, Mr. Wirth also served as a director of Synageva BioPharma Corp., a biopharmaceutical company which is now owned by Nasdaq-listed Alexion Pharmaceuticals. Mr. Wirth received a law degree from Harvard Law School.

Foreign private issuer status

The Nasdaq listing rules include certain accommodations in the corporate governance requirements that allow foreign private issuers, such as us, to follow “home country” corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. The application of such exceptions requires that we disclose each noncompliance with the Nasdaq listing rules that we do not follow and describe the Cayman Islands corporate governance practices we do follow in lieu of the relevant Nasdaq corporate governance standard. When our ADSs are listed on the Nasdaq Stock Market, we intend to continue to follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following:

- the majority independent director requirement under Section 5605(b)(1) of the Nasdaq listing rules;
- the requirement under Section 5605(d) of the Nasdaq listing rules that a remuneration committee comprised solely of independent directors governed by a remuneration committee charter oversee executive compensation;
- the requirement under Section 5605(e) of the Nasdaq listing 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
- the requirement under Section 560-5(b)(2) of the Nasdaq listing rules that the independent directors have regularly scheduled meetings with only the independent directors present.

Cayman Islands law does not impose a requirement that the board consist of a majority of independent directors or that such independent directors meet regularly without other members present. Nor does Cayman Islands law impose specific requirements on the establishment of a remuneration committee or nominating committee or nominating process.

Code of ethics and corporate governance guidelines

Prior to the completion of this offering, we will adopt a code of ethics, which will be applicable to all of our directors, executive officers and employees. Following the completion of this offering we will make our code of ethics publicly available on our website.

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

Board of directors

Composition of our board

Upon consummation of this offering, our articles of association will provide that the size of our board of directors will be determined from time to time by resolution of our board of directors. Following the completion of this offering, we anticipate that our board of directors will consist of directors, of whom we expect to qualify as independent directors under the rules and regulations of the SEC and Nasdaq Stock Market. Prior to the completion of this offering, we will complete our review of the composition of our board of directors and its committees and the independence of each director.

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

Prior to the completion of this offering, our board of directors will establish an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit committee

At the time of the completion of this offering, we will establish an audit committee with at least one member qualifying as a financial expert as set forth under the applicable rules of the SEC. At the time of the completion of this offering, we believe that each audit committee member satisfies 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

Prior to the completion of this offering, we will establish a compensation committee.

Our compensation committee will be 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 and corporate governance committee

Prior to the completion of this offering, we will establish a nominating and corporate governance committee.

Our nominating and corporate governance committee will be responsible for, among other things:

- selecting 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.

Employment arrangements with our executive officers

We have entered into employment agreements with each of our executive officers and our directors (other than our non-executive directors) (together, the "executive officers"). All of our executive officers are employed by both of our Hong Kong subsidiary, Zai Lab (Hong Kong) Limited, and our Shanghai subsidiary, Zai Lab (Shanghai) Co., Ltd., except Dr. Reinhart, who is employed only by Zai Lab (Hong Kong) Limited.

Employment agreements with executive officers at Zai Lab (Hong Kong) Limited

Under the terms of the Zai Lab (Hong Kong) Limited employment agreements, except with respect to the main founder Dr. Du, we may terminate an executive officer's employment with Zai Lab (Hong Kong) Limited 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 termination by the company for cause, the executive officer except for Dr. Du will receive the unpaid portion of the 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 will receive the accrued compensation, plus, except for Dr. Du, a separation benefit consisting of either one or three months' base pay and fringe benefits depending on service (the "severance period") plus any additional compensation that may be required by applicable law.

For purposes of the employment agreements, "cause" means (i) the executive officer's repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the executive officer's obligations and duties in the company, (2) the conviction of a felony, or any crime involving fraud or misrepresentation or

violation of applicable securities laws; (3) the executive officer's gross mismanagement of the business and affairs of the company or of its subsidiaries that directly results in a material loss to the company and for which the company has reasonable proof was committed by the executive officer; (4) material violation of any terms of the employment agreement or the restrictive covenants agreement between the executive officer and the company; or (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. In addition, 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 (3) relocation of the executive officer's, without consent. to a location more than thirty (30) kilometers from the original employment location, other than temporary relocations of no longer than six (6) calendar months.

In the event of termination of employment by reason of death or disability, the executive officer except for Dr. Du is entitled to receive the accrued compensation, a payment equal to one month's base salary and fringe benefits, plus any other additional compensation required by law. For purposes of the employment agreement, "disability" means the executive officer is incapacitated or disabled by accident, sickness or otherwise, so as to render him or her unable to 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.

As a condition to receiving payments during the severance period, the executive officer must execute a release of claims that is satisfactory to the Company.

Each executive officer has 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, for the term of his or her employment with us at Zai Lab (Hong Kong) Limited 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 or (ii) solicit for any employees of our company or orders from any person, firm or company which was at any time during the 12 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) Co., Ltd.

Executive officers working for Zai Labs (Shanghai), except Dr. Reinhart, are party to a service agreement with Zai Lab (Shanghai). Zai Lab (Shanghai) employment agreements provide that we engage each executive officer on 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) Co., Ltd. by providing the executive with 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 (iv) other circumstances prescribed by PRC laws or regulation. In addition, we may terminate the executive's employment without notice or payment if the executive (i) seriously or continuously violates, or violates several times the employment rules and policies of the company; (ii) commits serious dereliction in the performance of his or her duties, or practices graft, causing severe damage to the interests of the company; (iii) commits fraud or uses coercive measures or takes advantage of the company vulnerability to make it enter into this contract or to make amendments thereto against the company's will; (iv) is prosecuted for criminal liability, or is subject to re-education through labor in accordance with law; (iv) may be terminated as otherwise permitted by PRC laws. The executive officer may voluntarily terminate his or her contract without cause with 30 days' prior notice to us. The executive officer may also terminate employment immediately for "cause," which includes, among other things, being asked to perform tasks that are unsafe.

Each executive officer has 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 that for a certain period of time after his or her employment with us at Zai Lab (Shanghai) Co., Ltd., he or she will not (i) work for another company or individual that is in competition with us or (ii) manufacture any product or operate any business which is in competition with us.

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) Co., Ltd., 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, 2016, we paid aggregate salaries, bonuses and benefits (excluding equity-based grants) of approximately $1.4 million to our executive officers. 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. We do not separately set aside any amounts for pensions, retirement or other benefits for our executive officers, other than pursuant to relevant statutory requirements, and, in the case of executives who are not PRC citizens, health and life insurance. For information regarding equity-based grants to executive officers and directors, see "—Equity Incentive Plan." We did not pay any compensation to our non-executive directors.

Equity incentive plan

We currently have one omnibus equity incentive plan. Our shareholders originally adopted an equity incentive plan in September 2014, and it was subsequently superseded and replaced in its entirety by a plan approved by our shareholders in August 2015. We refer to this equity incentive plan, as amended from time to time, as our 2015 Omnibus Equity Incentive Plan. We believe the equity-based incentives provided in our 2015 Omnibus Equity Incentive Plan are vital to attract and retain the best available personnel for positions by providing incentives to our directors, employees and consultants to promote the success of our business.

The following describes the material terms of our 2015 Omnibus Equity Incentive Plan. This summary is not a complete description of all provisions of the 2015 Omnibus Equity Incentive Plan and is qualified in its entirety by reference to such plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Administration. Our board of directors is responsible for administering our 2015 Omnibus Equity Incentive Plan. As the plan administrator, our board of directors has the authority to, among other things, determine eligibility for awards to be granted, determine the size, terms and conditions of the awards, accelerate the vesting of or waive any restrictions applicable to the awards, interpret the terms and provisions of the 2015 Omnibus Equity Incentive Plan, and make all other determinations as it deems necessary or advisable to administer the 2015 Omnibus Equity Incentive Plan. The board of directors' decisions with respect to the 2015 Omnibus Equity Incentive Plan and any awards made under such plan are binding upon all participants.

Eligibility. Under the 2015 Omnibus Equity Incentive Plan, awards may be granted to a director, employee or consultant of our company and subsidiaries, as applicable. Options intended to qualify as "incentive stock options" under U.S. law may only be granted to an employee of our company or subsidiaries, as applicable.

Authorized shares. Subject to certain adjustments for stock splits, reorganizations, mergers, consolidations, split-up, and other changes in our corporate structure, the maximum number of ordinary shares that may be issued pursuant to the awards granted under the 2015 Omnibus Equity Incentive Plan is 44,218,603. If an award expires or becomes unexercisable without being exercised in full, or is forfeited or repurchased due to a failure to vest, the unpurchased shares subject to such awards will again become available for grant under the 2015 Omnibus Equity Incentive Plan.

Types of awards. The 2015 Omnibus Equity Incentive Plan provides for awards of stock options, share appreciation rights, restricted shares and restricted share units (the latter, "RSUs").

- *Stock options*. The exercise price for our ordinary shares to be issued pursuant to the exercise of stock options granted under the 2015 Omnibus Equity Incentive Plan is determined by our board of directors on the date of such grant, provided that such exercise price shall not be less than the fair market value of our ordinary shares on the date of such grant (110% in the case of incentive stock options), which will be determined by our board of directors in good faith. To exercise a vested award, the participant must submit a notice of exercise and full payment of the exercise price and applicable tax withholding in a form permitted under the plan. The term of each option may not extend beyond ten (10) years from the grant date.
- *Share appreciation rights*. The exercise price used to determine the amount payable to a participant receiving share appreciation rights under the 2015 Omnibus Equity Incentive Plan is determined by our board of directors, provided that such price my not be less than the fair market value of our ordinary shares on the date of such grant. Upon exercising of a vested share appreciation right, such participant is entitled to receive from us an amount equal to the difference between the fair market value of our ordinary share on the date of exercise over the exercise price, multiplied by the number of ordinary shares with respect to which such share appreciation right is exercised.
- *Restricted shares*. A restricted share granted under the 2015 Omnibus Equity Incentive Plan is subject to forfeiture, transfer restrictions and other restrictions during a certain period of restriction as determined by our board of directors. We keep any restricted shares granted under the 2015 Omnibus Equity Incentive Plan in escrow on behalf of the participants receiving such grant until the end of the applicable period of restriction, unless our board of directors decides to accelerate the time at which such restrictions will lapse or be removed. During the restriction period, participants holding shares of restricted stock will be entitled to receive dividends and distributions paid with respect to such shares under the administrator determines otherwise.

- *RSUs*. A RSU granted under the 2015 Omnibus Equity Incentive Plan entitles a participant receiving such grant to a payment in the form of cash, our ordinary shares or a combination of both upon the future vesting of such RSU. The form of payment and vesting conditions are determined by our board of directors.

Award agreements. Each award granted under the 2015 Omnibus Equity Incentive Plan will be evidenced by an award agreement providing for the number of ordinary shares subject to such award, restrictions and such other terms and conditions as our board of directors determines in its sole discretion.

Vesting schedule; termination of employment. Awards granted under the 2015 Omnibus Equity Incentive Plan are subject to vesting schedules as specified by the relevant award agreements.

In the event of a plan participant's termination of his or her employment with us other than for Cause, the ordinary shares that are not vested on the date of termination or unexercised will revert to the company and be available for grant under our 2015 Omnibus Equity Incentive Plan. In the event of a participant's termination for Cause, ordinary shares covered by any stock option under our 2015 Omnibus Equity Incentive Plan, whether vested or not, will revert to the company and be available for new or additional grants to participants. In addition, in the event of a participant's termination, voluntary or involuntary, we have the right to repurchase any unvested restricted shares at par value per ordinary share. A stock option must be exercised within thirty (30) days of employment termination (or such longer period specified in the award), but before the option's term expires.

Non-transferability of awards. Awards granted under our 2015 Omnibus Equity Incentive Plan may not be transferred other than by will or by the laws of descent or distribution and may only be exercised by the relevant participant receiving such award.

Change of control. If a merger or change of control of our company occurs, each outstanding award under the 2015 Omnibus Equity Incentive Plan may be treated in the following ways (or any combination of such ways) as our board determines in its sole discretion:

- assumed or substituted by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and type of shares and prices;
- terminated upon or immediately prior to the consummation of such merger or change in control upon written notice to participants;
- vested and become exercisable, realizable or payable, or restrictions deemed lapsed, in whole or in part; or
- terminated in exchange for cash and/or property or replaced with other rights or property.

For this purpose a "change of control" will occur if any one person, or more than one person acting as a group, (together, a "person") acquires ownership of the company's stock that, together with the stock held by such person constitutes more than 50% of the total voting power of the company's stock, excluding any change in stock ownership resulting from a private financing of the company approved by the company's board of directors. A change of control may also occur if, while the company has a class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, a majority of the members of our board of directors is replaced during any twelve month period by directors whose appointment was not endorsed by a majority of our board of directors at the time of such appointment. In addition, a change of control will occur if any person acquires (or has acquired during the 12 months ending on the date of the most recent acquisition by such person) assets from the company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all assets of the company immediately prior to such acquisition. Gross fair market value of the assets is determined without regard to any liabilities associates with the assets. Changes in the company's place of incorporation, or for the sole purpose of creating a holding company owned in substantially the same proportions by the persons who held the company's securities immediate before the transaction is not a change of control under the 2015 Omnibus Equity Incentive Plan.

Term. Unless earlier terminated, our 2015 Omnibus Equity Incentive Plan has a term of ten years.

Amendment and termination. Our board of directors may at any time amend, suspend or terminate the 2015 Omnibus Equity Option Plan.

Outstanding awards. As of May 15, 2017, there were 40,302,812 shares of our company subject to awards made under the 2015 Omnibus Equity Incentive Plan. The following table summarizes, as of that date, the outstanding share options, restricted shares and RSUs held by our directors and executive officers, as well as by their affiliates, under the 2015 Omnibus Equity Incentive Plan.

Name	Ordinary shares underlying outstanding awards, which represent options unless otherwise indicated	Purchase price ($/share)	Exercise price ($/share)	Date of grant(1)
Samantha Du	1,300,000	N/A	US$ 0.10	March 5, 2015
	10,435,000	N/A	US$ 0.10	October 22, 2015
	3,626,259	N/A	US$ 0.20	March 9, 2016
	5,533,108	N/A	US$ 0.29	August 25, 2016
Qi Liu	2,000,000	N/A	US$ 0.10	October 22, 2015
	200,000	N/A	US$ 0.29	August 25, 2016
Harald Reinhart	400,000	N/A	US$ 0.50	May 12, 2017
James Yan	2,000,000	N/A	US$ 0.10	October 22, 2015
	500,000	N/A	US$ 0.29	August 25, 2016
Ning Xu	1,270,000	N/A	US$ 0.10	March 5, 2015
	2,700,000	N/A	US$ 0.10	October 22, 2015
	250,000	N/A	US$ 0.20	March 9, 2016
	250,000	N/A	US$ 0.29	August 25, 2016
Marietta Wu	291,667	N/A	US$ 0.10	March 5, 2015(2)
	360,000	N/A	US$ 0.10	October 22, 2015(2)
	150,000	N/A	US$ 0.20	March 9, 2016(2)

* The share options, restricted shares and RSUs to acquire ordinary shares in the aggregate held by each of these directors and executive officers and their affiliates represent less than 1% of our total outstanding shares.

(1) Option expire on or before the 10-year anniversary of the grant date.

(2) Option expire on or before April 5, 2019

Security ownership of beneficial owners and management

We had 71,800,000 ordinary shares outstanding as of March 31, 2017. The following table and accompanying footnotes set forth information relating to the beneficial ownership of our ordinary shares as of March 31, 2017 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our directors;
- each of our 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. The percentage of shares beneficially owned prior to this offering is computed on the basis of 230,465,951 ordinary shares as of March 31, 2017, which reflects the assumed conversion of all of our outstanding shares of preferred shares into an aggregate of 158,665,951 ordinary shares. All of our preferred shares convert into ordinary shares on a one to one basis. The percentage of shares beneficially owned after this offering includes ordinary shares in the form of ADSs issued in connection with this offering, assuming the underwriters do not exercise their option to purchase additional ADSs.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary shares beneficially owned prior to this offering		Ordinary shares beneficially owned after this offering	
Name of beneficial owner†	**Number**	**Percent**	**Number**	**Percent**
Executive Officers and Directors:				
Samantha Du(1)	25,701,835	4.7%		
Qi Liu(2)	566,667	*		
Ning Xu(3)	1,323,000	*		
James Yan(4)	566,667	*		
Marietta Wu(5)	770,000	*		
Nisa Leung	—	—		
Jianming Yu	—	—		
All Executive Officers and Directors as a Group	**63,421,224**	**6.0%**		
Beneficial Owners of 5% or More of our Ordinary Shares:				
QM 11 Limited(6)	61,025,823	26.5%		
Maxway Investment Limited(7)	40,404,387	17.5%		
KPCB China Fund II, L.P.(8)	22,723,873	9.9%		
Sequoia Capital CV IV Holdco, Ltd.(9)	17,917,677	7.8%		

* The person beneficially owns less than 1% of our outstanding ordinary shares.

† The business address of all directors and officers is 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, 201210, China

(1) Includes 4,201,835 ordinary shares issuable upon exercise of options within 60 days of March 31, 2017.

(2) Includes 566,667 ordinary shares issuable upon exercise of options within 60 days of March 31, 2017.

(3) Includes 1,323,000 ordinary shares issuable upon exercise of options within 60 days of March 31, 2017.

(4) Includes 566,667 ordinary shares issuable upon exercise of options within 60 days of March 31, 2017.

(5) Includes 770,000 ordinary shares issuable upon exercise of options within 60 days of March 31, 2017.

(6) Consists of (i) 53,753,033 ordinary shares issuable upon conversion of Series A preferred shares and (ii) 7,272,790 ordinary shares issuable upon conversion of Series B preferred shares. The address for QM 11 Limited is Unit 1904 Gloucester Tower, The Landmark, Central, Hong Kong.

(7) Consists of 40,404,387 ordinary shares issuable upon conversion of Series B preferred shares. The address for Maxway Investment Limited is c/o Intertrust Corporate Services (Cayman) Limited, 190 Elgin Avenue, George Town, Grand Cayman, KY1-9005, Cayman Islands.

(8) Consists of 22,723,873 ordinary shares issuable upon conversion of Series A preferred shares. The address for KPCB China Fund II, L.P. is Scotia Centre, P.O. Box 268, George Town, Grand Cayman KY1-1104,Cayman Islands.

(9) Consists of 17,917,677 ordinary shares issuable upon conversion of Series A preferred shares. The address for Sequoia Capital CV IV Holdco, Ltd. is Codan Trust Company (Cayman) Limited, P.O. Box 2681, George Town, Cricket Square, Hutchins Drive, Cayman Islands.

As of March 31, 2017, we had two holders of record with addresses in the United States, and such holders held approximately 21.1% of our outstanding ordinary shares in the aggregate, and approximately 6.6% assuming the conversion of all of our outstanding shares of preferred shares into ordinary shares. None of the holders of our ordinary shares will have different voting rights from other holders of ordinary shares after the closing of this offering. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Related party transactions

The following is a description of related party transactions we have entered into since January 1, 2014 with any members of our board of directors or executive officers and beneficial holders of more than 5% of our ordinary shares:

Agreements and transactions with shareholders

Registration Rights Agreement

We have entered into a shareholders agreement in January 2016, or the Registration Rights Agreement, with certain of our shareholders. The Registration Rights Agreement provides that certain holders of our ordinary shares have the right to demand that we file a registration statement or request that their ordinary shares be covered by a registration statement that we are otherwise filing. The registration rights are described in more detail under “Description of Share Capital—Registration Rights.” All rights under the Registration Rights Agreement, other than the registration rights, will terminate upon the closing of this offering.

Convertible loan agreements and shareholder private placements

We entered into a (i) $500,000 convertible loan agreement with QM 11 Limited on March 24, 2014, (ii) $1,000,000 convertible loan agreement with Sequoia Capital CV IV Holdco, Ltd. on April 17, 2014, and (iii) $500,000 convertible loan agreement with KPCB China Fund II, L.P. on March 27, 2014. Each convertible loan agreement was converted into Series A-1 Preferred Shares on August 20, 2014.

On August 20, 2014, we closed a private placement transaction pursuant to which we issued an aggregate of 50,800,001 Series A-1 preferred shares for an aggregate cash consideration of $8,028,572. The following table sets for the number of shares of our Series A-1 preferred shares that we issued to our 5% stockholders and their affiliates in this transaction:

Investor	Shares of Series A-1 preferred shares	Purchase price ($)
QM 11 Limited	30,000,001(1)	5,714,286
KPCB China Fund II, L.P.	7,066,667(2)	800,000
Sequoia Capital CV IV Holdco, Ltd.	10,000,000(3)	714,286

(1) 3,333,334 of these Series A-1 Preferred Shares are issued pursuant to a convertible loan agreement converted from a principal amount of $500,000.

(2) 3,333,334 of these Series A-1 Preferred Shares are issued pursuant to a convertible loan agreement converted from a principal amount of $500,000.

(3) 6,666,667 of these Series A-1 Preferred Shares are issued pursuant to a convertible loan agreement converted from a principal amount of $1,000,000.

On April 30, 2015, we closed a private placement transaction pursuant to which we issued an aggregate of 57,719,866 Series A-2 preferred shares for an aggregate consideration of $20,828,572 of which $5,300,000 was unpaid. The following table sets for the number of shares of our Series A-2 preferred shares that we issued to our 5% stockholders and their affiliates in this transaction:

Investor	Shares of Series A-2 preferred shares	Purchase price ($)
QM 11 Limited	23,753,032	8,571,429
KPCB China Fund II, L.P.	22,723,733(1)	8,200,000
Sequoia Capital CV IV Holdco, Ltd.	7,917,677	2,857,143

(1) On September 30, 2015, we cancelled 7,066,527 of these Series A-2 Preferred Shares issued to KPCB China Fund II, L.P. and forgave the $2,550,000.000 unpaid capital balance.

On January 20, 2016, we closed a private placement transaction pursuant to which we sold an aggregate of 33,374,023 Series B-1 preferred shares for an aggregate consideration of $53,100,000. The following table sets for the number of shares of our Series B-1 preferred shares that we issued to our 5% stockholders and their affiliates in this transaction:

Investor	Shares of Series B-1 preferred shares	Purchase price ($)
QM 11 Limited	4,242,461	6,750,000
Maxway Investment Limited	23,569,226	37,500,000

On April 1, 2016, we closed a private placement transaction pursuant to which we sold an aggregate of 23,838,588 Series B-2 preferred shares for an aggregate consideration of $53,100,000. The following table sets for the number of shares of our Series B-2 preferred shares that we issued to our 5% stockholders and their affiliates in this transaction:

Investor	Shares of Series B-2 preferred shares	Purchase price ($)
QM 11 Limited	3,030,329	6,750,000
Maxway Investment Limited	16,835,161	37,500,000

Agreements with our directors and executive officers

Employment agreements

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see “Management—Employment Agreements with our Executive Officers.”

Indemnification agreements

In connection with this offering, we intend to enter 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.

Description of share capital

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

Our authorized share capital is $5,000.00 divided into ordinary shares and preferred shares. In respect of all of our ordinary shares and preferred shares we have power insofar as is permitted by law, to redeem or purchase any of our shares and to increase or reduce the said capital subject to the provisions of the Companies Law and the articles of association and to issue any part of our capital, whether original, redeemed or increased with or without any preference, priority or special privilege or subject to any postponement of rights or to any conditions or restrictions and so that unless the conditions of issue shall otherwise expressly declare every issue of shares whether declared to be preference or otherwise shall be subject to the powers under our memorandum and articles of association.

As of March 31, 2017 our authorized share capital consists of 338,563,198 Ordinary Shares of par value $0.00001 each, 50,800,001 Series A-1 preferred shares of par value $0.00001 each, 50,653,339 Series A-2 preferred shares of par value $0.00001 each, 33,374,023 Series B-1 preferred shares of par value $0.00001 each, and 23,838,588 Series B-2 preferred shares of par value $0.00001 each. As of March 31, 2017, there were 71,800,000 ordinary shares, 50,800,001 Series A-1 preferred shares, 50,653,339 Series A-2 preferred shares, 33,374,023 Series B-1 preferred shares and 23,838,588 Series B-2 preferred shares issued and outstanding. All of our issued and outstanding convertible preferred shares will automatically convert into 158,665,951 ordinary shares concurrently with the completion of this initial public offering. Following completion of this offering, our authorized capital will be $ divided into ordinary shares with a par value of $0.00001 per share.

We plan to adopt a third amended and restated memorandum and articles of association, which will become effective and replace the current second amended and restated memorandum and articles of association in its entirety immediately prior to the completion of this offering. We will issue ordinary shares represented by our ADSs in this offering. All options, regardless of grant dates, will entitle holders to an equivalent number of ordinary shares once the vesting and exercising conditions are met. The following are summaries of material provisions of our post-offering amended and restated memorandum and articles of association and the Companies Law insofar as they relate to the material terms of our ordinary shares that we expect will become effective upon the closing of this offering.

Ordinary shares

General. Upon the completion of this offering, our authorized share capital is US$ divided into ordinary shares, with a par value of $0.0001 each. Holders of ordinary shares will have the same rights except for voting and conversion rights. All of our outstanding ordinary shares are fully paid and non-assessable. Certificates representing the ordinary shares are issued in registered form. Our shareholders who are non-residents of the Cayman Islands may freely hold and transfer their ordinary shares.

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

Voting rights. In respect of all matters subject to a shareholders' vote, each ordinary share is entitled to one vote. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be

demanded by the chairman of such meeting or any one or more shareholders who together hold not less than 10% of the nominal value of the total issued voting shares of our company present in person or by proxy. Each holder of our ordinary shares is entitled to have one vote for each ordinary share registered in his or her name on our register of members.

A quorum required for a meeting of shareholders consists of one or more shareholders who hold at least one-third of all voting power of our share capital in issue at the date of the meeting present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. Shareholders' meetings may be held annually. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Extraordinary general meetings may be called by a majority of our board of directors or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than one-tenth of the aggregate voting power of our company. Advance notice of at least 10 days is required for the convening of our annual general meeting and other general meetings unless such notice is waived in accordance with our articles of association.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of not less than two-thirds of the votes attaching to all issued and outstanding shares cast at a meeting, while a special resolution also requires the affirmative vote of no less than two-thirds of the votes cast attaching to the issued and outstanding shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our post-offering amended and restated memorandum and articles of association.

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

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

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four;
- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Nasdaq Stock Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

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

The registration of transfers may, after compliance with any notice required of the Nasdaq Stock Market, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year as our board may determine.

Liquidation. On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares), assets available for distribution among the holders of ordinary shares shall be distributed among the holders of the ordinary shares on a pro rata basis. If our 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 our shareholders proportionately. Any distribution of assets or capital to a holder of an ordinary share will be the same in any liquidation event.

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

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

Variations of rights of shares. All or any of the special rights attached to any class of shares may, subject to the provisions of the Companies Law, be varied with the written consent of the holders of a majority of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Inspection of books and records. Holders of our ordinary shares have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we will provide our shareholders with annual audited financial statements. See “Where You Can Find Additional Information.”

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

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

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

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

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

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

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

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

Differences in corporate law

The Companies Law is modeled after that of English law but does not follow many recent English law statutory enactments. In addition, the Companies Law differs from laws applicable to United States corporations and their shareholders. Set forth below is a summary of the significant differences between the provisions of the Companies Law applicable to us and the laws applicable to companies incorporated in the State of Delaware.

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

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose, a subsidiary is a company of which at least 90% of the issued shares entitled to vote are owned by the parent company.

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

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

In addition, there are statutory provisions that facilitate the reconstruction and amalgamation of companies, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors

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

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

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

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

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

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a "fraud on the minority."

Indemnification of directors and executive officers and limitation of liability. Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our post-offering amended and restated memorandum and articles of association permit indemnification of officers and directors for losses, damages, costs and expenses incurred in their capacities as such unless such losses or damages arise from dishonesty or fraud of such directors or officers. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. In addition, we intend to enter into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our post-offering amended and restated memorandum and articles of association.

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

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

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he or she owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his or her position as director (unless the company permits him or her to do so) and a duty not to put himself or herself in a position where the interests of the company conflict with his or her personal interest or his or her duty to a third party. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his or her duties a greater degree of skill than may reasonably be expected from a person of his or her knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

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

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

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

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

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

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

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

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

Variation of rights of shares. Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and our post-offering amended and restated articles of association, if our share capital is divided into more than one class of shares, we may vary the rights

attached to any class with the written consent of the holders of a majority of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class.

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

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

History of securities issuances

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act. We believe that each of the following issuances was exempt from registration under the Securities Act in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions, Regulation D under the Securities Act, Rule 701 under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering. No underwriters were used in the below issuances.

1. On April 3, 2014, we issued 20,999,999 restricted ordinary shares and 500,000 ordinary shares to Samantha Du for an aggregate cash consideration of $50,210. On the same date, we issued 48,500,000 ordinary shares to Red Kingdom Investments Limited for an aggregate consideration of $141,971.
2. On August 20, 2014, we closed a private placement transaction pursuant to which we issued an aggregate of 50,800,001 Series A-1 preferred shares for an aggregate cash consideration of $8,028,572 and in consideration for the conversion of convertible loans amounting an aggregate consideration of $2,000,000.
3. On April 30, 2015, we issued a total of 57,719,866 Series A-2 preferred shares in connection with the second closing of the private placement transaction described above for an aggregate consideration of $20,828,572 of which $5,300,000 remained unpaid. On September 30, 2015 we cancelled 7,066,527 of these Series A-2 preferred shares and forgave the $2,550,000 unpaid capital balance.
4. On August 10, 2015, we issued 1,000,000 restricted ordinary shares to Peter Karl Wirth.
5. On December 31, 2015, we granted a warrant to purchase 2,770,851 Series A-2 preferred shares at the purchase price of $0.3609 per share to OrbiMed Asia Partners II, L.P. for a period commencing on April 1, 2016 and ending on the earlier of (i) the sixth anniversary of the date of issuance of this warrant or (ii) 90 calendar days prior to the date on which we consummate this offering. No consideration was received by us in connection with the issuance of the warrant. As of the date of this prospectus, no Series A-2 preferred shares have been purchased by OrbiMed Asia Partners II, L.P. pursuant to this warrant.
6. On January 20, 2016, we closed a private placement transaction pursuant to which we sold an aggregate of 33,374,023 Series B-1 preferred shares for an aggregate consideration of $53,100,000 in cash.
7. On April 1, 2016, we issued a total of 23,838,588 Series B-2 preferred shares in connection with the second closing of the private placement transaction described above for an aggregate consideration of $53,100,000 in cash.

8. On July 15, 2016 and August 25, 2016, we issued an additional 350,000 and 450,000 restricted ordinary shares to Peter Karl Wirth, respectively.

In addition to the above, since January 1, 2014, we have granted share options to purchase (i) an aggregate of 25,855,395 ordinary shares, each at an exercise price of $0.10 per share, (ii) an aggregate of 6,946,759 ordinary shares, each at an exercise price of $0.20 per share, and (iii) an aggregate of 10,567,208 ordinary shares, each at an exercise price of $0.29 per share, to our employees, consultants and directors. These grants were made pursuant to written compensatory plans or arrangements with our employees, consultants and directors in reliance upon the exemption provided by Rule 701 promulgated under the Securities Act or Section 4(a)(2) of the Securities Act for transactions by an issuer not involving a public offering or Regulation S under the Securities Act.

Registration rights

In connection with our issuance of Series B-1 and B-2 preferred shares, we and all of our then shareholders entered into a second amended and restated shareholders agreement in January 2016.

Under the shareholders agreement, our preferred shareholders are entitled to registration rights and certain preferential rights, including, among others, preferential and non-cumulative dividend rights, information rights, right of participation to purchase and subscribe for their respective pro rata portions of new securities to be issued, right of first refusal before any securities of the company may be sold or otherwise transferred or disposed of by any ordinary shareholder certain principal employees, co-sale rights in the event that any offered securities are not purchased by the preferred shareholders exercising their rights of first refusal, drag-along rights in the event that shareholders approve a drag-along transaction and preferred distribution rights in the event of a liquidation. Except for the registration rights and certain tax-related rights, all preferred shareholders' rights will automatically terminate upon the completion of this offering.

Pursuant to our shareholders' agreement, we have granted certain registration rights to our shareholders. Such registration rights would terminate with respect to a shareholder upon such time at which all registrable securities held by a shareholder proposed to be sold may be sold under Rule 144 of the Securities Act in any 90-day period without registration in compliance with Rule 144 of the Securities Act. Set forth below is a description of the registration rights granted under the agreement.

Demand registration rights. At any time after the earlier of (i) January 20, 2022 or (ii) the date six months following the consummation of this offering, upon a written request from the holders of at least 10% of the voting power of the registrable securities or the then outstanding or the ordinary shares and Series B preferred shares together, we must file a registration statement covering the offer and sale of the registrable securities held by the requesting shareholders and other holders who choose to participate in the offering in the event that the anticipated gross receipts from this offering are to exceed $10,000,000. Registrable securities include, among others, our ordinary shares issued or to be issued upon conversion of the preferred shares.

However, we are not obligated to proceed with a demand registration if we have, within the six-month period preceding the date of such request, already effected a registration under the Securities Act pursuant to the exercise of the holders' demand registration rights or Form F-3 registration rights, or in which the holders had an opportunity to participate in the piggyback registration rights, unless the registrable securities of the holders were excluded from such registration. We have the right to defer filing of a registration statement for up to 90 days if our board of directors determines in good faith that the filing of a registration statement would be materially detrimental to us and our shareholders, but we cannot exercise the deferral right more than once in any 12-month period. We are obligated to effect only three demand registrations on forms other than Form F-3 so long as such registrations have been declared or ordered effective.

F-3 registration rights. When we are eligible for registration on Form F-3, upon a written request from any holder all registrable securities, we must effect a registration on Form-3 and any related qualification or compliance covering the offer and sale of the registrable securities.

We are not obligated to effect a Form F-3 registration, among other things, if we have, within the 12-month period preceding the date of the request, already effected two registrations under the Securities Act or if the holders of Registrable securities proposed to sell at an aggregate price to the public less than $2,000,000. We have the right to defer filing of a registration statement for up to 90 days if our board of directors determines in good faith that the filing of a registration statement would be materially detrimental to us and our shareholders, but we cannot exercise the deferral right more than once in any 12-month period.

Piggyback registration rights. If we propose to file a registration statement under the Securities Act for purposes of effecting a public offering of our securities (including, but not limited to, registration statements relating to secondary offerings of our securities, but excluding registration statements relating to any employee benefit plan or a corporate reorganization), we must afford holders of registrable securities an opportunity to include in that registration all or any part of their registrable securities then held. We have the right to terminate or withdraw any registration initiated by us under the piggyback registration rights prior to the effectiveness of such registration whether or not any holder has elected to include securities in such registration. The underwriters of any underwritten offering have the right to limit the number of shares with registration rights to be included in the registration statement, subject to certain limitations.

Expenses of registration. We will pay all expenses relating to any demand, Form F-3, or piggyback registration except for the underwriting discounts and selling commissions applicable to the sale of registrable securities and certain other limited exceptions.

Description of American depositary receipts

, as depositary, will issue the ADSs which you will be entitled to receive in this offering. Each ADS will represent an ownership interest in ordinary shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary and yourself as an ADR holder. In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you. Unless specifically requested by you, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive which reflect your ownership of ADSs.

The depositary's office is located at .

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Cayman Islands law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all registered holders from time to time of ADSs issued under the deposit agreement. The obligations of the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the shares, you must rely on it to exercise the rights of a shareholder on your behalf. The deposit agreement and the ADSs are governed by New York law.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to the registration statement of which this prospectus forms apart. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the attached deposit agreement on the SEC's website at http://www.sec.gov.

Share dividends and other distributions

How will I receive dividends and other distributions on the shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after converting any cash received into U.S. dollars and, in all cases, making any necessary deductions provided for in the deposit agreement. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- **Cash.** The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. The depositary will hold any cash amounts it is unable to distribute in a non-interest-bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States. If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.
- **Shares.** In the case of a distribution in shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such shares. Only whole ADSs will be issued. Any shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.
- **Rights to receive additional shares.** In the case of a distribution of rights to subscribe for additional shares or other rights, if we provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not furnish such evidence, the depositary may:
    - sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or
    - if it is not practicable to sell such rights, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing.

We have no obligation to file a registration statement under the Securities Act in order to make any rights available to ADR holders.

- **Other distributions.** In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.

If the depositary determines that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period.

Deposit, withdrawal and cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance. In the case of the ADSs to be issued under this prospectus, we will arrange with the underwriters named herein to deposit such shares.

Shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of , as depositary for the benefit of holders of ADRs or in such other name as the depositary shall direct.

The custodian will hold all deposited shares (including those being deposited by or on our behalf in connection with the offering to which this prospectus relates) for the account of the depositary. ADR holders thus have no direct ownership interest in the shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited shares. The deposited shares and any such additional items are referred to as “deposited securities.”

Upon each deposit of shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary’s direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder’s name. An ADR holder can request that the ADSs not be held through the depositary’s direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary’s office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying shares to you or upon your written order. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of shares in connection with voting at a shareholders’ meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or

- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Record dates

The depositary may, after consultation with us if practicable, fix record dates for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of shares,
- to give instructions for the exercise of voting rights at a meeting of holders of shares,
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR, or
- to receive any notice or to act in respect of other matters.

all subject to the provisions of the deposit agreement.

Voting rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the shares which underlie your ADSs. As soon as practicable after receiving notice of any meeting or solicitation of consents or proxies from us, the depositary will distribute to the registered ADR holders a notice stating such information as is contained in the voting materials received by the depositary and describing how you may instruct the depositary to exercise the voting rights for the shares which underlie your ADSs. For instructions to be valid, the depositary must receive them in the manner and on or before the date specified. No voting instructions may be deemed given to the depositary to give a discretionary proxy to a person designated by us if no instructions are received by the depositary from you on or before the response date established by the depositary. The depositary will try, as far as is practical, subject to the provisions of and governing the underlying shares or other deposited securities, to vote or to have its agents vote the shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you instruct. The depositary will not itself exercise any voting discretion. Furthermore, neither the depositary nor its agents are responsible for any failure to carry out any voting instructions, for the manner in which any vote is cast or for the effect of any vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of, or solicitation of consents or proxies from, holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such holders with, or otherwise publicizes to such holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

Under our constituent documents the depositary would be able to provide us with voting instructions without having to personally attend meetings in person or by proxy. Such voting instructions may be provided to us via facsimile, email, mail, courier or other recognized form of delivery and we agree to accept any such delivery so long as it is timely received prior to the meeting. We will endeavor to provide the depositary with written notice

of each meeting of shareholders promptly after determining the date of such meeting so as to enable it to solicit and receive voting instructions. In general, the depositary will require that voting instructions be received by the depositary no less than five business days prior to the date of each meeting of shareholders. Under the post-offering amended and restated memorandum and articles of association that we expect to adopt, the minimum notice period required to convene a general meeting is seven calendar days. The depositary may not have sufficient time to solicit voting instructions, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Notwithstanding the above, we have advised the depositary that under the Cayman Islands law and our constituent documents, each as in effect as of the date of the deposit agreement, voting at any meeting of shareholders is by show of hands unless a poll is (before or on the declaration of the results of the show of hands) demanded. In the event that voting on any resolution or matter is conducted on a show of hands basis in accordance with our constituent documents, the depositary will refrain from voting and the voting instructions (or the deemed voting instructions, as set out above) received by the depositary from holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by holders of ADSs.

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and other communications

Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Fees and expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, $5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall be incurred by the ADR holders, by any party depositing or withdrawing shares or by any party surrendering ADSs or to whom ADSs are issued (including, without limitation, issuance

pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADRs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of $ per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of up to $ per ADS for any cash distribution made pursuant to the deposit agreement;
- a fee of up to $ per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of the depositary's agents (including, without limitation, the custodian and expenses incurred on behalf of holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the shares or other deposited securities, the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which charge shall be assessed on a proportionate basis against holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were shares and there would be a fee of five cents per ADS outstanding);
- stock transfer or other taxes and other governmental charges;
- cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of shares;
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- expenses of the depositary in connection with the conversion of foreign currency into U.S. dollars.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary. The charges described above may be amended from time to time by agreement between us and the depositary.

Our depositary has agreed to reimburse us for certain expenses we incur that are related to establishment and maintenance of the ADR program, including investor relations expenses and exchange application and listing fees. Neither the depositary nor we can determine the exact amount to be made available to us because (i) the number of ADSs that will be issued and outstanding, (ii) the level of fees to be charged to holders of ADSs and (iii) our reimbursable expenses related to the ADR program are not known at this time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from

distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of taxes

ADR holders must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. Additionally, if any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, including, without limitation, any Chinese Enterprise Income Tax owing if SAT Circular 82 or any other circular, edict, order or ruling, as issued and as from time to time amended, is applied or otherwise, such tax or other governmental charge shall be paid by the holder thereof to the depositary and by holding or having held an ADR the holder and all prior holders thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect thereof. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) to pay such taxes and distribute any remaining net proceeds to the ADR holders entitled thereto.

By holding an ADR or an interest therein, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

Reclassifications, recapitalizations and mergers

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

Amendment and termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least 30 days' notice of any amendment that imposes or increases any fees or charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders. Such notice need not describe in detail the specific amendments effectuated thereby, but must give ADR holders a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder is deemed to agree to such amendment and to be bound by the deposit agreement as so amended. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations, which amendment or supplement may take effect before a notice is given or within any other period of time as required for compliance. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

How may the deposit agreement be terminated?

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders unless a successor depositary shall not be operating under the deposit agreement within 45 days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 90th day after our notice of removal was first provided to the depositary. After termination, the depositary's only responsibility will be (i) to deliver deposited securities to ADR holders who surrender their ADRs, and (ii) to hold or sell distributions received on deposited securities. As soon as practicable after the expiration of six months from the termination date, the depositary will sell the deposited securities which remain and hold the net proceeds of such sales (as long as it may lawfully do so), without liability for interest, in trust for the ADR holders who have not yet surrendered their ADRs. After making such sale, the depositary shall have no obligations except to account for such proceeds and other cash.

Limitations on obligations and liability to ads holders

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;

- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial ownership of any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdrawal shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, ourselves and our respective agents. Neither we nor the depositary nor any such agent will be liable if:

- any present or future law, rule, regulation, fiat, order or decree of the United States, the Cayman Islands, the People's Republic of China or any other country, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our charter, any act of God, war, terrorism or other circumstance beyond our, the depositary's or our respective agents' control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);
- it exercises or fails to exercise discretion under the deposit agreement or the ADR;
- it performs its obligations under the deposit agreement and ADRs without gross negligence or bad faith;
- it takes any action or refrains from taking any action in reliance upon the advice of or information from legal counsel, accountants, any person presenting shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information; or
- it relies upon any written notice, request, direction or other document believed by it to be genuine and to have been signed or presented by the proper party or parties.

Neither the depositary nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs. We and our agents shall only be obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by any securities depository, clearing agency or settlement system in connection

with or arising out of book-entry settlement of deposited securities or otherwise. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of . The depositary and the custodian(s) may use third party delivery services and providers of information regarding matters such as pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide extraordinary services such as attendance at annual meetings of issuers of securities. Although the depositary and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services.

Additionally, none of us, the depositary or the custodian shall be liable for the failure by any registered holder of ADRs or beneficial owner therein to obtain the benefits of credits on the basis of non-U.S. tax paid against such holder's or beneficial owner's income tax liability. Neither we nor the depositary shall incur any liability for any tax consequences that may be incurred by holders or beneficial owners on account of their ownership of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any such vote is cast or for the effect of any such vote. Neither the depositary nor any of its agents shall be liable to registered holders of ADRs or beneficial owners of interests in ADSs for any indirect, special, punitive or consequential damages (including, without limitation, lost profits) of any form incurred by any person or entity, whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

In the deposit agreement each party thereto (including, for avoidance of doubt, each holder and beneficial owner and/or holder of interests in ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or the company directly or indirectly arising out of or relating to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory).

The depositary may own and deal in any class of our securities and in ADSs.

Disclosure of interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof. We reserve the right to instruct you to deliver your ADSs for cancellation and withdrawal of the deposited securities so as to permit us to deal with you directly as a holder of shares and, by holding an ADS or an interest therein, you will be agreeing to comply with such instructions.

Books of depositary

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed from time to time, when deemed expedient by the depositary.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Pre-release of ADSs

In its capacity as depositary, the depositary shall not lend shares or ADSs; provided, however, that the depositary may issue ADSs prior to the receipt of shares (each such transaction a “pre-release”). The depositary may receive ADSs in lieu of shares (which ADSs will promptly be canceled by the depositary upon receipt by the depositary). Each such pre-release will be subject to a written agreement whereby the person or entity (the “applicant”) to whom ADSs are to be delivered (a) represents that at the time of the pre-release the applicant or its customer owns the shares that are to be delivered by the applicant under such pre-release, (b) agrees to indicate the depositary as owner of such shares in its records and to hold such shares in trust for the depositary until such shares are delivered to the depositary or the custodian, (c) unconditionally guarantees to deliver to the depositary or the custodian, as applicable, such shares, and (d) agrees to any additional restrictions or requirements that the depositary deems appropriate. Each such pre-release will be at all times fully collateralized with cash, U.S. government securities or such other collateral as the depositary deems appropriate, terminable by the depositary on not more than five (5) business days’ notice and subject to such further indemnities and credit regulations as the depositary deems appropriate. The depositary will normally limit the number of ADSs involved in such pre-release at any one time to thirty percent (30%) of the ADSs outstanding (without giving effect to pre-released ADSs outstanding), provided, however, that the depositary reserves the right to change or disregard such limit from time to time as it deems appropriate. The depositary may also set limits with respect to the number of ADSs involved in pre-release with any one person on a case-by-case basis as it deems appropriate. The depositary may retain for its own account any compensation received by it in conjunction with the foregoing. Collateral provided in connection with pre-release transactions, but not the earnings thereon, shall be held for the benefit of the registered holders of ADRs (other than the applicant).

Appointment

In the deposit agreement, each registered holder of ADRs and each person holding an interest in ADSs, upon acceptance of any ADSs (or any interest therein) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs, and
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof.

Governing law

The deposit agreement and the ADRs shall be governed by and construed in accordance with the laws of the State of New York. In the deposit agreement, we have submitted to the jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Notwithstanding the foregoing, any action based on the deposit agreement or the transactions contemplated thereby may be instituted by the depositary and holders in any competent court in the Cayman Islands, Hong Kong, the People’s Republic of China and/or the United States or through the commencement of an English language arbitration either in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association or in Hong Kong following the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL).

Shares eligible for future sale

Before this offering, no public market existed in the United States for our ordinary shares or the ADSs. Upon completion of this offering, we will have ADSs outstanding, representing approximately % of our outstanding ordinary shares. All of the ADSs sold in this offering will be freely transferable by persons other than by our "affiliates" without restriction or further registration under the Securities Act. Sales of substantial amounts of our ADSs in the public market could adversely affect prevailing market prices of our ADSs. We intend to apply to list the ADSs on the Nasdaq Stock Market, but we cannot assure you that a regular trading market will develop for the ADSs. We do not expect that a trading market will develop for our ordinary shares not represented by the ADSs.

Lock-up agreements

We, our executive officers, directors and certain of our existing shareholders have agreed, for a period of 180 days after the date of this prospectus and subject to specified exceptions, not to (i) 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, or file with the Commission a registration statement under the Securities Act relating to, any ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for ordinary shares or ADSs, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares or ADSs or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of ordinary shares or ADSs or such other securities, in cash or otherwise, without the prior written consent of the representatives of the underwriters, other than the ADSs to be sold in this offering and any ordinary shares or ADSs issued upon the exercise of options granted under our stock plans.

In addition, through a letter agreement, we have instructed , as depositary, not to accept any deposit of any ordinary shares or issue any ADSs for 180 days after the date of this prospectus unless we consent to such deposit or issuance. We have also agreed not to provide such consent without the prior written consent of the representatives of the underwriters. The foregoing does not affect the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares.

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

Regulation S

Regulation S under the Securities Act provides an exemption from registration requirements in the United States for offers and sales of securities that occur outside the United States. Rule 903 of Regulation S provides the conditions to the exemption for a sale by an issuer, a distributor, their respective affiliates or anyone acting on their behalf, while Rule 904 of Regulation S provides the conditions to the exemption for a resale by persons other than those covered by Rule 903. In each case, any sale must be completed in an offshore transaction, as that term is defined in Regulation S, and no directed selling efforts, as that term is defined in Regulation S, may be made in the United States.

We are a foreign issuer as defined in Regulation S. As a foreign issuer, securities that we sell outside the United States pursuant to Regulation S are not considered to be restricted securities under the Securities Act, and are freely tradable without registration or restrictions under the Securities Act, unless the securities are held by your affiliates. Generally, subject to certain limitations, holders of our restricted shares who are not our who are our affiliates solely by virtue of their status as an officer or director of us may, under Regulation S, resell their restricted shares in an "offshore transaction" if none of the seller, its affiliate nor any person acting on their behalf engages in directed selling efforts in the United States and, in the case of a sale of our restricted shares by an officer or director who is an affiliate of us solely by virtue of holding such position, no selling commission, fee or other remuneration is paid in connection with the offer or sale other than the usual and customary broker's commission that would be received by a person executing such transaction as agent. Additional restrictions are applicable to a holder of our restricted shares who will be an affiliate of us other than by virtue of his or her status as an officer or director of us.

We are not claiming the potential exemption offered by Regulation S in connection with the offering of newly issued shares outside the United States and will register all of the newly issued shares under the Securities Act.

Rule 144

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

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

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

Rule 701

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

Taxation

Cayman Islands taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

People's Republic of China taxation

We are a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of China with a "de facto management body" within China is considered a "resident enterprise," and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State Administration of Taxation issued SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, all offshore enterprises controlled by a PRC enterprise or a PRC enterprise will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China only if all of the following conditions are met:

(i) the primary location of the day-to-day operational management is in the PRC;

(ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC;

(iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and

(iv) at least 50% of voting board members or senior executives habitually reside in China.

We believe that none of Zai Lab Limited and its subsidiaries outside of China is a PRC resident enterprise for PRC tax purposes. Zai Lab Limited is not controlled by a PRC enterprise or PRC enterprise group, and we do not believe that Zai Lab Limited meets all of the conditions above. Zai Lab Limited is a company incorporated outside China. As a holding company, some of its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside China. For the same reasons, we believe our other subsidiaries outside of China are also not PRC resident enterprises. 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 is a PRC resident enterprise for EIT purposes, we may be required to withhold tax at a rate of 10% on dividends we pay to our shareholders, including holders of our ADSs, that are non-resident enterprises. In addition, non-resident enterprise shareholders (including our ADS

holders) may be subject to a 10% PRC withholding tax on gains realized on the sale or other disposition of ADS or ordinary shares, if such income is treated as sourced from within China. Furthermore, gains derived by our non-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 dividends realized by non-PRC individuals, it will generally apply at a rate of 20%. The PRC tax liability may be reduced under applicable tax treaties. However, it is unclear whether non-PRC shareholders of Zai Lab Limited would be able to claim the benefits of any tax treaty between their country of tax residence and China in the event that Zai Lab Limited is treated as a PRC resident enterprise.

See “Risk Factors—Risks Related to Doing Business in China—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.”

Pursuant to the EIT Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in China, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) it must have directly owned such percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. Furthermore, the Administrative Measures for Non-Resident Enterprises to Enjoy Treatments under Tax Treaties (For Trial Implementation), which became effective in October 2009, require that non-resident enterprises must obtain approval from the relevant tax authority in order to enjoy the reduced tax rate. There are also other conditions for enjoying the reduced tax rate according to other relevant tax rules and regulations. Accordingly, our subsidiary Zai Lab (HongKong) Limited may be able to enjoy the 5% tax rate for the dividends it receives from its PRC incorporated subsidiaries Zai Lab (Shanghai) Co., Ltd. and Zai Lab (Suzhou) Co., Ltd., respectively, if they satisfy the conditions prescribed under SAT Circular 81 and other relevant tax rules and regulations and obtain the approvals as required. However, according to SAT Circular 81, if the relevant tax authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

If our Cayman Islands holding company, Zai Lab Limited, is not deemed to be a PRC resident enterprise, holders of our ADSs and ordinary shares who are not PRC residents will not be subject to PRC income tax on dividends distributed by us or gains realized from the sale or other disposition of our shares or ADSs.

Material United States federal income tax considerations

The following discussion, subject to the limitations set forth below, describes the material U.S. federal income tax consequences for a U.S. Holder (as defined below) of the acquisition, ownership and disposition of ADSs. This discussion is limited to U.S. Holders who are initial purchasers of ADSs pursuant to this offering and hold

such ADSs as capital assets (generally, property held for investment). For purposes of this summary, a "U.S. Holder" is a beneficial owner of an ADS that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States or any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) it has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court can exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

Except as explicitly set forth below, this summary does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders subject to special rules, including:

- banks or other financial institutions;
- insurance companies;
- real estate investment trusts;
- regulated investment companies;
- grantor trusts;
- tax-exempt organizations;
- persons holding ADSs through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- dealers or traders in securities, commodities or currencies;
- persons whose functional currency is not the U.S. dollar;
- certain former citizens and former long-term residents of the United States;
- persons holding ADSs as part of a position in a straddle or as part of a hedging, conversion or integrated transaction for U.S. federal income tax purposes; or
- direct, indirect or constructive owners of 10% or more of our total combined voting power.

In addition, this summary does not address the 3.8% Medicare contribution tax imposed on certain net investment income, the U.S. federal estate and gift tax or the alternative minimum tax consequences of the acquisition, ownership, and disposition of ADSs. We have not received nor do we expect to seek a ruling from the U.S. Internal Revenue Service, or the IRS, regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of ADSs.

This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the PRC and the United States, or the U.S.-PRC Tax Treaty, each as available and in effect on the date hereof, all of which are subject to change or differing interpretations, possibly with retroactive effect,

which could affect the tax consequences described herein. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership should consult its own tax advisors as to the U.S. federal income tax consequences of acquiring, owning and disposing of ADSs.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEIR SITUATIONS AS WELL AS THE APPLICATION OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S. OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.

ADSs

A U.S. Holder of ADSs will generally be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that such ADSs represent. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depositary or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of non-U.S. withholding taxes (if any), and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

Taxation of dividends

As described in “Dividend Policy” above, we do not currently anticipate paying any distributions on our ADSs in the foreseeable future. However, subject to the discussion below in “—Passive Foreign Investment Company Considerations,” to the extent there are any distributions made with respect to our ADSs, the gross amount of any distribution on the ADSs (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder’s adjusted tax basis in the ADSs and thereafter as capital gain. However, because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax accounting principles, U.S. Holders should expect to treat distributions paid with respect to the ADSs as dividends. Dividends paid to corporate U.S. Holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. This discussion assumes that distributions on the ADSs, if any, will be paid in U.S. dollars.

Dividends paid to a non-corporate U.S. Holder by a “qualified foreign corporation” may be subject to reduced rates of U.S. federal income taxation if certain holding period and other requirements are met. A qualified foreign corporation generally includes a foreign corporation (other than a PFIC) if (1) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (2) it is eligible for benefits under a comprehensive U.S. income tax treaty that includes an exchange of information program and which the U.S. Treasury Department has determined is satisfactory for these purposes.

We have applied to list the ADSs on the Nasdaq Stock Market, which is an established securities market in the United States. Provided that such listing is approved, IRS guidance indicates that the ADSs will be readily tradable for these purposes.

The United States does not have a comprehensive income tax treaty with the Cayman Islands. However, in the event that we were deemed to be a PRC resident enterprise under the EIT Law (see "—People's Republic of China taxation" above), although no assurance can be given, we might be considered eligible for the benefits of the U.S.-PRC Tax Treaty, and if we were eligible for such benefits, dividends paid on the ADSs, regardless of whether the ADSs are readily tradable on an established securities market in the United States, would be eligible for the reduced rates of U.S. federal income taxation, subject to applicable limitations. U.S. Holders should consult their own tax advisors regarding the availability of the reduced tax rates on dividends in light of their particular circumstances.

Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

In the event that we were deemed to be a PRC resident enterprise under the EIT Law (see "—People's Republic of China taxation" above), ADS holders might be subject to PRC withholding taxes on dividends paid with respect to ADSs. In that case, subject to certain conditions and limitations, such PRC withholding tax may be treated as a foreign tax eligible for credit against a U.S. Holder's U.S. federal income tax liability under the U.S. foreign tax credit rules. For purposes of calculating the U.S. foreign tax credit, dividends paid on the ADSs will be treated as income from sources outside the United States and will generally constitute passive category income. If a U.S. Holder is eligible for U.S.-PRC Tax Treaty benefits, any PRC taxes on dividends will not be creditable against such U.S. Holder's U.S. federal income tax liability to the extent such tax is withheld at a rate exceeding the applicable U.S.-PRC Tax Treaty rate. An eligible U.S. Holder who does not elect to claim a foreign tax credit for PRC tax withheld may instead be eligible to claim a deduction, for U.S. federal income tax purposes, in respect of such withholding but only for the year in which such U.S. Holder elects to do so for all creditable foreign income taxes. The U.S. foreign tax credit rules are complex. U.S. Holders should consult their own tax advisors regarding the foreign tax credit or deduction rules in light of their particular circumstances.

Taxation of capital gains

Subject to the discussion below in "—Passive foreign investment company considerations" below, upon the sale, exchange, or other taxable disposition of ADSs, a U.S. Holder generally will recognize gain or loss on the taxable sale or exchange in an amount equal to the difference between the amount realized on such sale or exchange and the U.S. Holder's adjusted tax basis in the ADSs. The initial tax basis of ADSs to a U.S. Holder will generally be the U.S. Holder's U.S. dollar purchase price for the ADS.

Subject to the discussion below in "—Passive foreign investment company considerations" below, such gain or loss will be capital gain or loss. Under current law, capital gains of non-corporate U.S. Holders derived with respect to capital assets held for more than one year are generally eligible for reduced rates of taxation. The deductibility of capital losses is subject to limitations. Capital gain or loss, if any, recognized by a U.S. Holder generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders are encouraged to consult their own tax advisors regarding the availability of the U.S. foreign tax credit in consideration of their particular circumstances.

If we were treated as a PRC resident enterprise for EIT Law purposes and PRC tax were imposed on any gain (see "—People's Republic of China taxation" above), and if a U.S. holder is eligible for the benefits of the U.S.-PRC Tax Treaty, the holder may be able to treat such gain as PRC source gain under the treaty for U.S. foreign tax credit purposes. A U.S. Holder will be eligible for U.S.-PRC Tax Treaty benefits if (for purposes of the

treaty) such holder is a resident of the United States and satisfies the other requirements specified in the U.S.-PRC Tax Treaty. Because the determination of treaty benefit eligibility is fact-intensive and depends upon a holder's particular circumstances, U.S. Holders should consult their tax advisors regarding U.S.-PRC Tax Treaty benefit eligibility. U.S. Holders are also encouraged to consult their own tax advisors regarding the tax consequences in the event PRC tax were to be imposed on a disposition of ADSs, including the availability of the U.S. foreign tax credit and the ability and whether to treat any gain as PRC source gain for the purposes of the U.S. foreign tax credit in consideration of their particular circumstances.

Passive foreign investment company considerations

Status as a PFIC

The rules governing PFICs can have adverse tax effects on U.S. Holders. We generally will be classified as a PFIC for U.S. federal income tax purposes if, for any taxable year, either: (1) 75% or more of our gross income consists of certain types of passive income, or (2) the average value (determined on a quarterly basis), of our assets that produce, or are held for the production of, passive income (including cash) is 50% or more of the value of all of our assets.

Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

Whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year and which depends on the composition of our income and the composition and value of our assets for the relevant taxable year. The fair market value of our assets for purposes of the PFIC rules (including goodwill) may be determined in large part by reference to the quarterly market price of our ADSs, which is likely to fluctuate significantly after the offering. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash proceeds from the offering in our business.

Because we hold, and will continue to hold after this offering, a substantial amount of passive assets, including cash, and because the value of our assets (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early stage of our drug candidates, we cannot give any assurance that we will not be a PFIC for the current or any future taxable year.

If we are a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless the U.S. Holder makes the "deemed sale election" described below. Prospective investors should consult their own tax advisors regarding our PFIC status for the current or any future taxable years.

U.S. federal income tax treatment of a shareholder of a PFIC

If we are a PFIC for any taxable year during which a U.S. Holder owns ADSs, the U.S. Holder, absent certain elections (including the mark-to-market and QEF elections described below), generally will be subject to adverse rules (regardless of whether we continue to be a PFIC) with respect to (1) any "excess distributions" (generally, any distributions received by the U.S. Holder on its ADSs in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for its ADSs) and (2) any gain realized on the sale or other disposition, including in certain circumstances a pledge, of its ADSs.

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income and (c) the amount allocated to each other taxable year during the U.S. Holder's holding period in which we were a PFIC (i) will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and (ii) will be subject to an interest charge at a statutory rate with respect to the resulting tax attributable to each such other taxable year.

If we are a PFIC, a U.S. Holder will generally be treated as owning a proportionate amount (by value) of stock or shares owned by us in any direct or indirect subsidiaries that are also PFICs and will be subject to similar adverse rules with respect to any distributions we receive from, and dispositions we make of, the stock or shares of such subsidiaries. U.S. Holders are urged to consult their tax advisors about the application of the PFIC rules to any of our subsidiaries.

If we are classified as a PFIC and then cease to be so classified, a U.S. Holder may make an election (a "deemed sale election") to be treated for U.S. federal income tax purposes as having sold such U.S. Holder's ADSs on the last day of our taxable year during which we were a PFIC. A U.S. Holder that makes a deemed sale election would then cease to be treated as owning stock in a PFIC by reason of ownership of our ADSs. However, gain recognized as a result of making the deemed sale election would be subject to the adverse rules described above and loss would not be recognized.

PFIC "mark-to-market" election

In certain circumstances if we are a PFIC for any taxable year, a U.S. Holder can be subject to rules different from those described above by making a mark-to-market election with respect to its ADSs, provided that the ADSs are "marketable." ADSs will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury Regulations. ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter. A "qualified exchange" includes a national securities exchange that is registered with the SEC.

Under current law, the mark-to-market election may be available to U.S. Holders of ADSs if the ADSs are listed on the Nasdaq Stock Market (which constitutes a qualified exchange) and such ADSs are "regularly traded" for purposes of the mark-to-market election (for which no assurance can be given).

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the U.S. Holder's ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in its ADSs. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in its ADSs over the fair market value of its ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. The adjusted tax basis of a U.S. Holder's ADSs will be adjusted to reflect amounts included in gross income or allowed as a deduction because of such mark-to-market election. If a U.S. Holder makes an effective mark-to-market election, gains from an actual sale or other disposition of ADSs in a year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of ADSs will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If we are a PFIC for any taxable year in which a U.S. Holder owns ADSs but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

A mark-to-market election is not permitted for the shares of any of our subsidiaries that are also classified as PFICs. Prospective investors should consult their own tax advisors regarding the availability of, and the procedure for making, a mark-to-market election, and whether making the election would be advisable, including in light of their particular circumstances.

PFIC "QEF" election

In some cases, a shareholder of a PFIC can avoid the interest charge and the other adverse PFIC consequences described above by obtaining certain information from the PFIC and by making a QEF election to be taxed currently on its share of the PFIC's undistributed income. We do not, however, expect to provide the information regarding our income that would be necessary in order for a U.S. Holder to make a QEF election with respect to its ADSs if we were classified as a PFIC.

PFIC information reporting requirements

If we are a PFIC in any year with respect to a U.S. Holder, such U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ADSs, and certain U.S. Holders will be required to file an annual information return (also on IRS Form 8621) relating to their ownership of our ADSs.

THE U.S. FEDERAL INCOME TAX RULES RELATING TO PFICS ARE COMPLEX. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

U.S. Backup Withholding and Information Reporting

Backup withholding and information reporting requirements may apply to distributions on, and proceeds from the sale or disposition of, ADSs that are held by U.S. Holders. The payor will be required to backup withhold tax on payments made within the United States, or by a U.S. payor to a U.S. intermediary (and certain subsidiaries thereof), on the ADSs to a U.S. Holder, other than an exempt recipient, if the U.S. Holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding requirements. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability (if any) or refunded provided the required information is furnished to the IRS in a timely manner.

Certain U.S. Holders of specified foreign financial assets with an aggregate value in excess of the applicable dollar threshold are required to report information relating to their holding of ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by certain financial institutions) with their tax return for each year in which they hold ADSs. U.S. Holders should consult their own tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of ADSs.

THE ABOVE DISCUSSION DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. PROSPECTIVE INVESTORS ARE STRONGLY URGED TO CONSULT THEIR OWN TAX ADVISORS ABOUT THE TAX CONSEQUENCES OF AN INVESTMENT IN THE ADSs.

Underwriting

We are offering the ADSs described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Leerink Partners LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ADSs listed next to its name in the following table:

Name	Number of ADSs
J.P. Morgan Securities LLC	
Citigroup Global Markets Inc.	
Leerink Partners LLC	
Total	

The underwriters are committed to purchase all the ADSs offered by us if they purchase any ADSs. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the ADSs directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per ADS. Any such dealers may resell ADSs to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. After the initial offering of the ADSs to the public, the offering price and other selling terms may be changed by the underwriters. Sales of ADSs made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional ADSs from us to cover sales of ADSs by the underwriters which exceed the number of ADSs specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional ADSs. If any ADSs are purchased with this option to purchase additional ADSs, the underwriters will purchase ADSs in approximately the same proportion as shown in the table above. If any additional ADSs are purchased, the underwriters will offer the additional ADSs on the same terms as those on which the ADSs are being offered.

The underwriting fee is equal to the public offering price per ADS less the amount paid by the underwriters to us per ADS. The underwriting fee is $ per ADS. The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	Without option to purchase additional ADSs	With full option to purchase additional ADSs exercise
Per ADS	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any ADSs or securities convertible into or exchangeable or exercisable for any ADSs, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any ADSs or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of ADSs or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Leerink Partners LLC for a period of 180 days after the date of this prospectus other than the ADSs to be sold hereunder.

Our directors and executive officers, and certain of our significant shareholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Leerink Partners LLC, (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any ADSs or any securities convertible into or exercisable or exchangeable for our ADSs (including, without limitation, ADSs or such other securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) or (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 such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ADSs 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 any security convertible into or exercisable or exchangeable for our ADSs.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We will apply to have our ADSs approved for listing/quotation on the Nasdaq Stock Market under the symbol “ZLAB”.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling ADSs in the open market for the purpose of preventing or retarding a decline in the market price of the ADSs while this offering is in progress. These stabilizing transactions may include making short sales of the ADSs, which involves the sale by the underwriters of a greater number of ADSs than they are required to purchase in this offering, and purchasing ADSs on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional ADSs referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional ADSs, in whole or in part, or by purchasing ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ADSs

available for purchase in the open market compared to the price at which the underwriters may purchase ADSs through the option to purchase additional ADSs. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase ADSs in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase ADSs in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those ADSs as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs, and, as a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Stock Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our ADSs. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded ADSs of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our ADSs, or that the ADSs will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”), with effect from and including the date on which the Prospectus

Directive is implemented in that Relevant Member State, no offer of ADSs may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;

B. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the underwriters; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of ADSs shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive and each person who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive.

In the case of any ADSs being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ADSs to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "**offer of ADSs to the public**" in relation to any ADSs in any Relevant Member State means the communication in any form and by means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase ADSs, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended, including by Directive 2010/73/EU), and includes any relevant implementing measure in the Relevant Member State.

Notice to prospective investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the ADSs in the United Kingdom.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Canada

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration

Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ADSs or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

Notice to prospective investors in the United Arab Emirates

The ADSs have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the "Corporations Act");

- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a "retail client" (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The ADSs may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the ADSs may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any ADSs may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the ADSs, you represent and warrant to us that you are an Exempt Investor.

As any offer of ADSs under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the ADSs you undertake to us that you will not, for a period of 12 months from the date of issue of the ADSs, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The ADSs have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the ADSs nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The ADSs have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the ADSs has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore

Notice to prospective investors in Bermuda

ADSs may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority ("CMA") pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended (the "CMA Regulations"). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorised financial adviser.

Notice to prospective investors in the British Virgin Islands

The ADSs are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on our behalf. The ADSs may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), "BVI Companies"), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to prospective investors in China

This Prospectus does not constitute a public offer of ADSs, whether by sale or subscription, in the People's Republic of China (the "PRC"). The ADSs are not being offered or sold directly or indirectly in the PRC to or for the benefit of, legal or natural persons of the PRC.

Further, no legal or natural persons of the PRC may directly or indirectly purchase any of the ADSs or any beneficial interest therein without obtaining all prior PRC's governmental approvals that are required, whether statutorily or otherwise. Persons who come into possession of this document are required by the issuer and its representatives to observe these restrictions.

Notice to prospective investors in Korea

The ADSs have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the ADSs have been and will be offered in Korea as a private placement under the FSCMA. None of the ADSs may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). Furthermore, the purchaser of the ADSs shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the ADSs. By the purchase of the ADSs, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the ADSs pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the ADSs has been or will be registered with the Securities Commission of Malaysia ("Commission") for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the ADSs, as principal, if the offer is on terms that the ADSs may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent

in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the ADSs is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

The ADSs have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorised to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the ADSs in Taiwan.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, the ADSs are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions applies:

i. the offer, transfer, sale, renunciation or delivery is to:

(a) persons whose ordinary business is to deal in securities, as principal or agent;

(b) the South African Public Investment Corporation;

(c) persons or entities regulated by the Reserve Bank of South Africa;

(d) authorised financial service providers under South African law;

(e) financial institutions recognised as such under South African law;

(f) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorised portfolio manager for a pension fund or collective investment scheme (in each case duly registered as such under South African law); or

(g) any combination of the person in (a) to (f); or

ii. the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000.

No “offer to the public” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the “South African Companies Act”)) in South Africa is being made in connection with the issue of the ADSs. Accordingly, this document does not, nor is it intended to, constitute a “registered prospectus” (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. Any issue or offering of

the ADSs in South Africa constitutes an offer of the ADSs in South Africa for subscription or sale in South Africa only to persons who fall within the exemption from “offers to the public” set out in section 96(1)(a) of the South African Companies Act. Accordingly, this document must not be acted on or relied on by persons in South Africa who do not fall within section 96(1)(a) of the South African Companies Act (such persons being referred to as “SA Relevant Persons”). Any investment or investment activity to which this document relates is available in South Africa only to SA Relevant Persons and will be engaged in South Africa only with SA relevant persons.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Legal matters

We are being represented by Ropes & Gray LLP with respect to certain legal matters as to United States federal securities and New York State law. The underwriters are being represented by Davis Polk & Wardwell LLP with respect to certain legal matters as to United States federal securities and New York State law. One of Davis Polk & Wardwell LLP's partners is the spouse of Nisa Leung, who is one of our directors and a Managing Partner at Quiming Venture Partners which beneficially owns approximately 26.5% of our ordinary shares prior to this offering. The validity of the ordinary shares represented by the ADSs offered in this offering will be passed upon for us by Travers Thorp Alberga. Certain legal matters as to PRC law will be passed upon for us by Zhong Lun Law Firm and for the underwriters by Fangda Partners. Ropes & Gray LLP may rely upon Travers Thorp Alberga with respect to matters governed by Cayman Islands law and Zhong Lun Law Firm with respect to matters governed by PRC law. Davis Polk & Wardwell LLP may rely upon Fangda Partners with respect to matters governed by PRC law.

Experts

The consolidated financial statements as of December 31, 2015 and 2016, and for each of the two years in the period ended December 31, 2016, and the related financial statement schedule included in this prospectus have been audited by Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements and financial statement schedule are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The offices of Deloitte Touche Tohmatsu Certified Public Accountants LLP are located at Bund Center, 30th Floor 222 Yan An Road East, Shanghai, the People's Republic of China.

Enforcement of civil liabilities

We are incorporated in the Cayman Islands to take advantage of certain benefits associated with being a Cayman Islands exempted company, such as:

- political and economic stability;
- an effective judicial system;
- a favorable tax system;
- the absence of exchange control or currency restrictions; and
- the availability of professional and support services.

However, certain disadvantages accompany incorporation in the Cayman Islands. These disadvantages include, but are not limited to:

- the Cayman Islands has a less developed body of securities laws as compared to the United States and these securities laws provide significantly less protection to investors as compared to the United States; and
- Cayman Islands companies may not have standing to sue before the federal courts of the United States.

Our constituent documents do not contain provisions requiring that disputes, including those arising under the securities laws of the United States, between us, our officers, directors and shareholders, be arbitrated.

Substantially all of our operations are conducted in China, and substantially all of our assets are located in China. All of our directors and executive officers are nationals or residents of jurisdictions other than the United

States and most of their assets are located outside the United States. As a result, it may be difficult for a shareholder to effect service of process within the United States upon these persons, or to enforce against us or them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

We have appointed , located at as our agent upon whom process may be served in any action brought against us under the securities laws of the United States.

Travers Thorp Alberga, our legal counsel as to Cayman Islands law, and Zhong Lun Law Firm, our legal counsel as to PRC law, have advised us, respectively, that there is uncertainty as to whether the courts of the Cayman Islands and China, respectively, would:

- recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States; or
- entertain original actions brought in each respective jurisdiction against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

There is uncertainty with regard to Cayman Islands law relating to whether a judgment obtained from the United States courts under civil liability provisions of the securities laws will be determined by the courts of the Cayman Islands as penal or punitive in nature. If such a determination is made, the courts of the Cayman Islands will not recognize or enforce the judgment against a Cayman Islands company. Because the courts of the Cayman Islands have yet to rule on whether such judgments are penal or punitive in nature, it is uncertain whether they would be enforceable in the Cayman Islands. Travers Thorp Alberga has advised us that although there is no statutory enforcement in the Cayman Islands of judgments obtained in the federal or state courts of the United States, a judgment in personam obtained in such jurisdiction will be recognized and enforced in the courts of the Cayman Islands at common law, without any re-examination of the merits of the underlying dispute, by an action commenced on the foreign judgment debt in the Grand Court of the Cayman Islands, provided such judgment:

- is given by a competent foreign court with jurisdiction to give the judgment;
- imposes a specific positive obligation on the judgment debtor (such as an obligation to pay a liquidated sum or perform a specified obligation);
- is final and conclusive;
- is not in respect of taxes, a fine or a penalty; and
- was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

Zhong Lun Law Firm has further advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other form of reciprocity with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in China will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC law or national sovereignty, security or social public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States or in the Cayman Islands. Under the PRC Civil Procedures Law, foreign

shareholders may originate actions based on PRC law against a company in China for disputes if they can establish sufficient nexus to the PRC for a PRC court to have jurisdiction, and meet other procedural requirements, including, among others, the plaintiff must have a direct interest in the case, and there must be a concrete claim, a factual basis and a cause for the suit. However, it would be difficult for foreign shareholders to establish sufficient nexus to China by virtue only of holding our ADSs or ordinary shares.

In addition, it will be difficult for U.S. shareholders to originate actions against us in China in accordance with PRC laws because we are incorporated under the laws of the Cayman Islands and it will be difficult for U.S. shareholders, by virtue only of holding our ADSs or ordinary shares, to establish a connection to China for a PRC court to have jurisdiction as required under the PRC Civil Procedures Law.

Expenses relating to this offering

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of ordinary shares being registered. All amounts are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority filing fee and The Nasdaq Stock Market listing fee.

Item	Amount to be paid
SEC registration fee	*
FINRA filing fee	*
The Nasdaq Stock Market listing fee	*
Blue sky fees and expenses	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer Agent fees and expenses	*
Miscellaneous expenses	*
Total	*

* To be completed by amendment

Where you can find more information

We have filed with the SEC a registration statement on Form F-1 under the Securities Act with respect to the ADSs offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and the ADSs offered hereby, please refer to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

We are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we are required to file reports, including annual reports on Form 20-F, and other information with the SEC. As a foreign private issuer, we are exempt from the rules of the Exchange Act prescribing the furnishing and content of proxy statements to shareholders and Section 16 short-swing profit reporting for our officer, directors and holders of more than 10% of our ordinary shares.

ZAI Lab Limited

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Report of independent registered public accounting firm

To the Board of Directors and Shareholders of Zai Lab Limited

We have audited the accompanying consolidated balance sheets of Zai Lab Limited (the “Company”) and its subsidiaries (collectively referred to as the “Group”) as of December 31, 2015 and 2016, and the related consolidated statements of operations, comprehensive loss, changes in shareholders’ deficit, and cash flows for each of the two years in the period ended December 31, 2016 and related financial statement schedule included in Schedule I. These consolidated financial statements and financial statement schedule are the responsibility of the Group’s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Group is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2015 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China

May 30, 2017

ZAI Lab Limited
Consolidated balance sheets
(In U.S. dollars ("$") except for number of shares)

	Note	As of December 31, 2015 $	2016 $
Assets			
Current assets:			
Cash and cash equivalents	3	13,160,696	83,948,770
Prepayments and other current assets		69,020	143,527
Total current assets		13,229,716	84,092,297
Cost method investment		—	500,000
Prepayments for Equipment		—	1,417,029
Property and equipment	4	707,584	1,246,058
Intangible assets		2,525	7,000
Long term deposits		—	267,980
Value added tax recoverable		—	1,376,921
Total assets		13,939,825	88,907,285
Liabilities, mezzanine equity and shareholders' deficits			
Current liabilities:			
Accounts payable		1,453,054	523,338
Warrant liabilities	7	1,980,000	3,900,000
Other payables	6	507,931	750,118
Total current liabilities		3,940,985	5,173,456
Deferred subsidy income		61,599	778,434
Total liabilities		4,002,584	5,951,890
Commitments and Contingencies (Note 15)			
Mezzanine equity			
Series A1 convertible preferred shares (par value US$0.00001 per share; 50,800,001 shares authorized, issued and outstanding as of December 31, 2015 and 2016)	7	10,028,572	10,028,572
Series A2 convertible preferred shares (par value US$0.00001 per share; 50,653,339 shares authorized, issued and outstanding as of December 31, 2015 and 2016)	7	18,278,572	18,278,572
Series B1 convertible preferred shares (par value US$0.00001 per share; 33,374,023 shares authorized, issued and outstanding as of 2016)	7	—	53,100,000
Series B2 convertible preferred shares (par value US$0.00001 per share; 23,838,588 shares authorized, issued and outstanding as of December 31, 2016)	7	—	53,100,000
Total mezzanine equity		28,307,144	134,507,144

The accompanying notes are an integral part of these consolidated financial statements.

ZAI Lab Limited
Consolidated balance sheets
(In U.S. dollars ("$") except for number of shares)

	As of December 31,	
	2015	2016
	$	$
Shareholders' deficits		
Ordinary shares (par value of US$0.00001 per share; 500,000,000 shares authorized, 53,311,111 and 57,943,056 shares issued and outstanding as of December 31,2015 and 2016, respectively)	533	579
Subscription receivable	(1)	(5)
Additional Paid-in Capital	4,388,410	9,313,646
Accumulated deficits	(22,655,225)	(60,167,437)
Accumulated other comprehensive loss	(103,620)	(698,532)
Total shareholders' deficits	(18,369,903)	(51,551,749)
Total liabilities, mezzanine equity and shareholders' deficits	13,939,825	88,907,285

The accompanying notes are an integral part of these consolidated financial statements.

ZAI Lab Limited
Consolidated statements of operations
(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2015	2016
	$	$
Operating expenses:		
Research and development	(13,587,145)	(32,149,157)
General and administrative	(2,762,292)	(6,380,144)
Loss from operations	(16,349,437)	(38,529,301)
Interest income	5,005	403,266
Fair value of warrants	(1,980,000)	(1,920,000)
Other income	341,112	2,533,966
Other expense	(38,417)	(143)
Loss before income tax	(18,021,737)	(37,512,212)
Income tax expense	—	—
Net loss	(18,021,737)	(37,512,212)
Net loss attributable to ordinary shareholders	(18,021,737)	(37,512,212)
Net loss per share attributable to ordinary shareholders-basic and diluted	(0.35)	(0.66)
Weighted-average shares used in calculating net loss per ordinary share-basic and diluted	52,161,918	56,634,142

The accompanying notes are an integral part of these consolidated financial statements.

ZAI Lab Limited
Consolidated statements of comprehensive loss
(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2015	2016
	$	$
Net loss	(18,021,737)	(37,512,212)
Other comprehensive loss, net of tax of nil:		
Foreign currency translation adjustments	(98,893)	(594,912)
Comprehensive loss	(18,120,630)	(38,107,124)

The accompanying notes are an integral part of these consolidated financial statements.

ZAI Lab Limited
Consolidated statements of shareholders' deficits
(In U.S. dollars ("$") except for number of shares)

	Ordinary shares		Additional paid in capital	Subscription receivables	Accumulated deficits	Accumulated other comprehensive loss	Total
	Number of shares	Amount					
		$	$	$	$	$	$
Balance at January 1, 2015	49,000,000	490	1,687,048	—	(4,633,488)	(4,727)	(2,950,677)
Issuance of ordinary shares upon vesting of restricted shares	4,311,111	43	(42)	(1)	—	—	—
Share-based compensation	—	—	2,701,404	—	—	—	2,701,404
Net loss	—	—	—	—	(18,021,737)	—	(18,021,737)
Foreign currency translation	—	—	—	—	—	(98,893)	(98,893)
Balance at December 31, 2015	53,311,111	533	4,388,410	(1)	(22,655,225)	(103,620)	(18,369,903)
Issuance of ordinary shares upon vesting of restricted shares	4,631,945	46	(42)	(4)	—	—	—
Share-based compensation	—	—	4,925,278	—	—	—	4,925,278
Net loss	—	—	—	—	(37,512,212)	—	(37,512,212)
Foreign currency translation	—	—	—	—	—	(594,912)	(594,912)
Balance at December 31, 2016	57,943,056	579	9,313,646	(5)	(60,167,437)	(698,532)	(51,551,749)

The accompanying notes are an integral part of these consolidated financial statements.

ZAI Lab Limited
Consolidated statements of cash flows
(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2015	2016
	$	$
Operating activities		
Net loss	(18,021,737)	(37,512,212)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation of property and equipment	125,774	198,224
Amortization of intangible assets	733	781
Share-based compensation	2,701,404	4,925,278
Loss on disposal of property and equipment	38,417	—
Fair value of warrants	1,980,000	1,920,000
Changes in operating assets and liabilities:		
Prepayments and other current assets	33,713	(74,507)
Long term deposits	—	(267,980)
Value added tax recoverable	—	(1,376,921)
Accounts payable	1,287,687	(929,716)
Payroll payable and other payables	327,500	242,187
Deferred subsidy income	61,599	716,835
Net cash used in operating activities	(11,464,910)	(32,158,031)
Cash flows from investing activities:		
Purchase of cost method investment	—	(500,000)
Purchases of property and equipment	(738,470)	(2,223,882)
Purchase of intangible assets	—	(5,615)
Net cash used in investing activities	(738,470)	(2,729,497)
Cash flows from financing activities:		
Proceed from issuance of convertible preferred shares and warrants	18,278,572	106,200,000
Net cash provided by financing activities	18,278,572	106,200,000
Effect of foreign exchange rate changes on cash and cash equivalents	(66,770)	(524,398)
Net increases in cash and cash equivalents	6,008,422	70,788,074
Cash and cash equivalents—beginning of the year	7,152,274	13,160,696
Cash and cash equivalents—end of the year	13,160,696	83,948,770

The accompanying notes are an integral part of these consolidated financial statements

ZAI Lab Limited
Notes to the consolidated financial statements
For the years ended December 31, 2015 and 2016

(In U.S. dollars ("$") except for number of shares)

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 infectious disease therapies that address areas of large unmet medical needs in the China market, including in the fields of oncology, autoimmune and anti-infective therapies.

As at December 31, 2016, 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	April 29, 2013	100%	Operating company for business development and R&D activities
ZAI Lab (Shanghai) Co., Ltd.	The People's Republic of China ("PRC" or "China")	January 6, 2014	100%	Development and commercialisation of innovative medicines
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

2. Summary of significant accounting policies

(a) Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

(b) Principles of consolidation

The consolidated financial statements include 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 consolidated financial statements 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 estimating the useful lives of long-lived assets, assessing the impairment of long-lived assets, valuation of ordinary shares, 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 U.S. dollars 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 year. 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’ deficits 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. Nonmonetary assets and liabilities are remeasured into the applicable functional currencies at historical exchange rates. Transactions in currencies other than the applicable functional currencies during the year 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 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.

(f) Cost method investment

For investments for which the Group does not have significant influence or control, the cost method of accounting is used. Under the cost method, the Group carries the investment at cost and recognizes income to the extent of dividends received from the distribution of the equity investee’s post-acquisition profits. As of December 31, 2015 and 2016, investments in cost method investees accounted for under the cost method were nil and $500,000.

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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, 2015 and 2016.

(g) Prepayments for equipment

The prepayments for equipment purchase are recorded in long term prepayments considering the prepayments are all related to property and equipment.

(h) 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
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.

(i) Long term deposits

Long term deposits represent amounts paid in connection with the Group's long-term lease agreements.

(j) 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.

(k) Intangible assets

Intangible assets mainly consist of externally purchased software which are amortized over five years on a straight-line basis. As of December 31, 2015 and 2016, the original value of the Group's intangible assets is $3,523 and $8,684 with accumulated amortization of $998 and $1,684.

(l) 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

(In U.S. dollars ("$") except for number of shares)

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, 2015 and 2016, there was no impairment of the value of the Group's long-lived assets.

(m) 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, for example, 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 and cash equivalents, prepayments and other current assets, accounts payable, warrant liabilities, payroll payables and other payables. As of December 31, 2015 and 2016, the carrying values of cash and cash equivalents, prepayments and other current assets, accounts payable, payroll payables and other payables approximated their fair values due to the short-term maturity of these instruments. The warrant liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. The Group determined the fair values of the warrant liabilities with the assistance of an independent third party valuation firm.

Liabilities measured at fair value on a recurring basis as of December 31, 2015 are summarized below:

	Level 1	Level 2	Level 3
	$	$	$
Warrant liabilities	—	—	1,980,000

Liabilities measured at fair value on a recurring basis as of December 31, 2016 are summarized below:

	Level 1	Level 2	Level 3
	$	$	$
Warrant liabilities	—	—	3,900,000

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The Group has measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of the years ended December 31, 2015 and 2016.

The Group used the binomial model to estimate the fair value of warrant liabilities using the following assumptions:

	December 31, 2015	December 31, 2016
Risk-free rate of return	2.9%	2.9%
Vesting date	April 1,2016	April 1,2016
Maturity date	December 31,2021	December 31,2021
Estimated volatility rate	70%	70%
Exercise price	0.36	0.36
Fair value of underlying preferred shares price	0.90	1.64

The model requires the input of highly subjective assumptions including the risk-free rate of return, expected vesting date, maturity date, estimated volatility rate and fair value of underlying preferred share's price. The risk-free rate for periods within the contractual life is based on the US treasury bonds with maturity similar to the maturity of the warrants as of valuation dates plus a China country risk premium. On April 1, 2016, the investment amount met the $7,000,000 threshold, therefore, the vesting date was on April 1, 2016. For maturity date, the terms state that it shall be the earlier of 6 years from grant and 90 days before the IPO date. Prior to 2017, the Group did not have a concrete plan to undertake an IPO, and as such, the maturity date was estimated to be December 31, 2021. For expected volatilities, the Group has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Group. The estimated fair value of the preferred shares was determined with assistance from an independent third party valuation firm. The Group's management is ultimately responsible for the determination of the estimated fair value of its preferred shares.

The significant unobservable inputs used in the fair value measurement of the warrant liabilities include risk-free rate of return, interval between vesting date and maturity date, estimated volatility rate and fair value of underlying preferred shares. Significant decreases in interval between vesting date and maturity date, estimated volatility rate and fair value of underlying preferred shares would result in a significantly lower fair value measurement. Significant increases in risk-free rate of return would result in a significantly lower fair value measurement.

(n) Revenue recognition

The Group has not yet generated any revenues from the sale of goods or from the rendering of services.

Prior to the adoption of ASC 606, the Group will recognize any revenues when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed or determinable, and there is reasonable assurance that the related amounts are collectible in accordance with ASC 605, Revenue Recognition.

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(o) Research and development expenses

Elements of research and development expenses primarily include (i) payroll and other related costs of personnel engaged in research and development activities, (ii) in-licensed patent rights fee of exclusive development rights of drugs granted to the Group, (iii) costs related to preclinical testing of the Group's technologies under development and clinical trials such as payments to contract research organizations ("CROs"), investigators and clinical trial sites that conduct our clinical studies (iv)costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (v) 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 conditions enabling capitalization of development costs as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

The Group also has obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones, which will be recorded as research and development expenses. The Group has not included these commitments on our balance sheet because the commitments are cancellable if the milestones are not completed and achievement and timing of these milestones are not fixed or determinable.

(p) Government grants

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 $298,072 and $2,065,510 were included in other income for the years ended December 31, 2015 and 2016, respectively. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Company may be required to refund the subsidy. Cash grants of $61,599 and $778,434 were recorded in deferred subsidy income as of December 31, 2015 and 2016 respectively, which will be recognized when the government specified performance obligation is satisfied.

(q) Leases

Leases are 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: a) ownership is transferred to the lessee by the end of the lease term, b) there is a bargain purchase option, c) the lease term is at least 75% of the property's estimated remaining economic life or d) the present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date. A capital lease is accounted for as if there was an acquisition of an asset and an incurrence of an obligation at the inception of the lease. The Group has no capital leases for the years presented.

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over 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.

(r) 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.

(s) Stock-based compensation

Awards Granted to Employees

The Group grants share options to eligible employees, management and directors and accounts for these share based awards in accordance with ASC 718 *Compensation-Stock Compensation.*

Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses a) immediately at grant date if no vesting conditions are required; or b) using graded vesting method over the requisite service period, which is the vesting period.

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, with the assistance of an independent third party valuation firm, determined the fair value of the stock options granted to employees. The binomial option pricing model was applied in determining the estimated fair value of the options granted to employees.

Awards Granted to Non-Employees

The Group has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 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.

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(t) Income taxes

The Group uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and 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.

(u) 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.

The Group’s convertible preferred shares are participating securities as the preferred shares participate in undistributed earnings on an as-if-converted basis. Accordingly, the Group uses the two-class method whereby undistributed net income is allocated on a pro rata basis to each participating share to the extent that each class may share income for the period. Undistributed net loss is not allocated to preferred shares because they are not contractually obligated to participate in the loss allocated to the ordinary shares.

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 convertible preferred shares, warrants, stock options and non-vested restricted shares, which could potentially dilute basic earnings per share in the future. To calculate the number of shares for diluted income per share, the effect of the convertible redeemable preferred shares and warrants is computed using the as-if-converted method; the effect of the stock options and non-vested restricted shares is computed using the treasury stock method.

(v) Segment information

In accordance with ASC 280, *Segment Reportin*g, 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 the PRC, no geographical segments are presented.

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(w) Concentration of risks

Concentration of suppliers

The following suppliers accounted for 10% or more of research and development expenses for the years ended December 31, 2015 and 2016:

	For year ended December 31,	
	2015	2016
	$	$
A	5,703,000	*
B	*	14,625,500

* Represents less than 10% of research and development expenses for the years ended December 31, 2015 and 2016.

Concentration of credit risk

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents and prepayments for equipment. The carrying amounts of cash and cash equivalents represent the maximum amount of loss due to credit risk. As of December 31, 2015 and 2016, all of the Group's cash and cash equivalents 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. With respect to the prepayment to suppliers, the Company performs on-going credit evaluations of the financial condition of these suppliers.

Foreign currency risk

Renminbi ("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 RMB3,541,812 and RMB44,156,161, which were denominated in RMB, as of December 31, 2015 and 2016, respectively, representing 4% and 8% of the cash and cash equivalents as of December 31, 2015 and 2016, respectively.

(w) Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)", to clarify the principles of recognizing revenue and create common revenue recognition guidance between U.S. GAAP and International Financial Reporting Standards ("IFRS"). An entity has the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application. ASU 2014-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2016, and early adoption is not permitted. In August 2015, the FASB updated this standard to ASU 2015-14, the amendments in this Update defer the effective date

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of Update 2014-09 so that the Update should be applied to annual reporting periods beginning after December 15, 2017 and earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.

In May 2016, FASB issued ASU 2016-12 "Revenue from Contracts with Customers (Topic 606)": Narrow-Scope Improvements and Practical Expedients. The amendments in this Update do not change the core principle of the guidance in Topic 606. Rather, the amendments in this Update affect only the narrow aspects of Topic 606. The areas improved include: (1) Assessing the Collectability Criterion in Paragraph 606-10-25-1(e) and Accounting for Contracts That Do Not Meet the Criteria for Step 1; (2) Presentation of Sales Taxes and Other Similar Taxes Collected from Customers; (3) Noncash Consideration; (4) Contract Modifications at Transition; (5) Completed Contracts at Transition; and (6) Technical Correction. The effective date and transition requirements for the amendments in this Update are the same as the effective date and transition requirements for Topic 606 (and any other Topic amended by Update 2014-09).

The Group is in a development stage, with no revenues to date, and will evaluate the application of this ASU, but as a result has not yet determined the potential effects it may have on the Company's financial statements.

In November 2015, FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*, which requires deferred income tax liabilities and assets to be classified as noncurrent on the balance sheet rather than being separated into current and noncurrent. The guidance is effective for public entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption being permitted. The Group has adopted this guidance during the year ended December 31, 2016, retrospectively. The adoption of this guidance did not have a material effect on the Group's consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"),* which requires that equity investments, except for those accounted for under the equity method or those that result in consolidation of the investee, be measured at fair value, with subsequent changes in fair value recognized in net income. However, an entity may choose to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. ASU 2016-01 also impacts the presentation and disclosure requirements for financial instruments. ASU 2016-01 is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted only for certain provisions. The Group is in the process of evaluating the impact of adoption of this guidance on the Group's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842),* which requires lessees to recognize most leases on the balance sheet. This ASU requires lessees to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Lessees are permitted to make an accounting policy election to not recognize the asset and liability for leases with a term of twelve months or less. The ASU does not significantly change the lessees' recognition, measurement and presentation of expenses and cash flows from the previous accounting standard. Lessors' accounting under the ASC is largely unchanged from the previous accounting standard. In addition, the ASU expands the disclosure requirements of lease arrangements. Lessees and lessors

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will use a modified retrospective transition approach, which includes a number of practical expedients. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. The Group is currently evaluating this ASU to determine the full impact on its consolidated financial statements, as well as the impact of adoption on policies, practices and systems. As of December 31, 2016, the Group has $2.1 million of future minimum operating lease commitments that are not currently recognized on its consolidated balance sheets (see Note 15). Therefore, the Group would expect changes to its consolidated balance sheets for the recognition of these and any additional leases entered into in the future upon adoption.

In March 2016, the FASB issued ASU 2016-09, which simplifies several aspects of the accounting for employee share-based payment transactions for both public and non-public entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. For public entities, the ASU is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. Early adoption will be permitted in any interim or annual period for which financial statements have not yet been issued or have not been made available for issuance. The Group has elected to early adopt this standard on a modified retrospective basis at the beginning of the period presented as the Group elected to account for forfeitures when they occur to reduce the complexity in the accounting of share based compensation.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230)*. The update is intended to improve financial reporting in regards to how certain transactions are classified in the statement of cash flows. This update requires that debt extinguishment costs be classified as cash outflows for financing activities and provides additional classification guidance for the statement of cash flows. The update also requires that the classification of cash receipts and payments that have aspects of more than one class of cash flows to be determined by applying specific guidance under generally accepted accounting principles. The update also requires that each separately identifiable source or use within the cash receipts and payments be classified on the basis of their nature in financing, investing or operating activities. The update is effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Group is in the process of evaluating the impact of adoption of this guidance on the consolidated financial statements.

In October 2016, FASB issued ASU 2016-16, *Income Taxes (Topic 740)*. Under the new standard, an entity is to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The new standard does not include new disclosure requirements; however, existing disclosure requirements might be applicable when accounting for the current and deferred income taxes for an intra-entity transfer of an asset other than inventory. The new standard is effective for annual periods beginning after December 15, 2017, including interim reporting periods within those annual periods. The ASU is not expected impact the Group's consolidated balance sheet upon adoption.

In October 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash*. The update applies to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. The update addresses diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows, and requires that a statement of cash

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flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The update is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The updates should be applied using a retrospective transition method to each period presented. The Group currently does not have restricted cash balances.

3. Cash and cash equivalents

	December 31,	
	2015	2016
	$	$
Cash at bank and in hand	13,160,696	36,531,272
Cash Equivalents	—	47,417,498
	13,160,696	83,948,770
Denominated in:		
US$	12,344,841	77,463,141
RMB (note (i))	545,431	6,365,311
Australia dollar ("A$")	270,424	120,318
	13,160,696	83,948,770

Notes:

(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. Property and equipment

Property and equipment consist of the following:

	December 31,	
	2015	2016
	$	$
Office equipment	50,514	49,432
Electronic equipment	33,224	66,271
Vehicle	—	76,636
Laboratory equipment	481,432	593,582
Leasehold improvements	214,730	465,428
Construction in progress	—	252,509
	779,900	1,503,858
Less accumulated depreciation	(72,316)	(257,800)
Property and equipment, net	707,584	1,246,058

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Depreciation expenses for the years ended December 31, 2015 and 2016 were $125,774 and $198,224, respectively.

5. Income tax

Cayman islands

ZAI Lab Limited is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, ZAI Lab Limited is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Australia

ZAI Lab (AUST) Pty., Ltd. incorporated in Australia is subject to corporate income tax at a rate of 30%. ZAI Lab (AUST) Pty., Ltd. has no taxable income for all periods presented and therefore, no provision for income taxes is required.

Hong Kong

ZAI Lab (Hong Kong) Limited is incorporated in Hong Kong. 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. The applicable tax rate is 16.5% in Hong Kong. For the years ended December 31, 2015 and 2016, The 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

ZAI Lab (Shanghai) Co., Ltd and ZAI Lab (Suzhou) Co., Ltd. are both subject to the statutory rate of 25% for the years ended December 31, 2015 and 2016 in accordance with the Enterprise Income Tax law (the "EIT Law").

There is no provision for income taxes because the Company and all of its owned subsidiaries are in a current loss position for all the periods presented.

Loss before income taxes consists of:

	Year ended December 31,	
	2015	2016
	$	$
Cayman	2,036,806	2,454,660
PRC	4,938,688	26,111,094
HK	9,869,007	8,010,908
AUST	1,177,236	935,550
	18,021,737	37,512,212

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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, 2015 and 2016 are as follows:

	2015	2016
	$	$
Statutory income tax rate	25%	25%
Share-based Compensations	(3.68%)	(2.92%)
Non-deductible expenses	(7.19%)	(1.59%)
Effect of different tax rate of subsidiary operation in other jurisdiction	(7.15%)	(3.33%)
Changes in valuation allowance	(6.98%)	(17.16%)
Effective income tax rate	—	—

The principal components of the deferred tax assets and liabilities are as follows:

	2015	2016
	$	$
Deferred tax assets:		
Depreciation of property and equipment, net	2,415	3,892
Accrued expenses	72,408	—
Government grants	16,025	166,336
Net operating loss forward	1,729,009	8,086,361
Less: valuation allowance	(1,819,857)	(8,256,589)
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 2015 and 2016, the Group has determined that the deferred tax assets on temporary differences and net operating loss carry forward are related to certain other 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, 2015 and 2016. Amounts of operating loss carry forwards were $7,969,098 and $34,716,071 for the year ended December 31, 2015 and 2016, which are expected to be expired from 2019 to 2021.

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Movement of the valuation allowance is as follows:

	December 31,	
	2015	2016
	$	$
Balance as of January 1	(561,672)	(1,819,857)
Additions	(1,258,185)	(6,436,732)
Balance as of December 31	(1,819,857)	(8,256,589)

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.

6. Other payables

	December 31,	
	2015	2016
	$	$
Payroll	350,514	573,802
Other taxes payable	—	23,721
Other payables(note (i))	157,417	152,595
	507,931	750,118

Notes:

(i) Other payables are mainly payables related to legal advisory fee and travel expense.

7. Convertible preferred shares and warrants

In August, 2014 and April, 2015, the Company issued 37,466,668 Series A1 convertible preferred shares ("Series A1 Preferred Shares") and 50,653,339 Series A2 convertible preferred shares ("Series A2 Preferred Shares") with a par value $0.00001 per share to a group of investors for a cash consideration of $8,028,572 or $0.2143 per share and $18,278,572 or $0.3609 per share, respectively. In August 2014, $2,000,000 in convertible loans issued in March and April of 2014 to certain investors who purchased Series A1 Preferred Shares were converted into 13,333,333 Series A1 Preferred Shares in connection with the offering at a per share price of $0.15.

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In January and April, 2016, the Company issued 33,374,023 Series B1 convertible preferred shares (“Series B1 Preferred Shares”) and 23,838,588 Series B2 convertible preferred shares (“Series B2 Preferred Shares”) with a par value of $0.00001 per share to a group of investors including existing preferred share investors for a cash consideration of $53,100,000 or $1.5911 per share and $53,100,000 or $2.2275 per share, respectively.

On December 31, 2015, as an inducement to participate in the contemplated issuance of Series B1 Preferred Shares and Series B2 Preferred Shares, the Company entered into an agreement with one investor to issue warrants to purchase up to 2,770,851 Series A2 Preferred Shares at $0.3609 per share, as adjusted from time to time pursuant to the agreement. The fair value of the warrants of $1,980,000 was expensed on the date of issuance (as opposed to being treated as a cost of equity issuance because the warrant would have become exercisable after the passage of time in the absence of an equity offering).

The key terms of the Series A1, A2, B1 and B2 Preferred Shares (collectively “Preferred Shares”) are as follows:

Conversion rights

Each holder of Preferred Shares shall have the right, at such holder’s sole discretion, to convert all or any portion of the Preferred Shares into ordinary shares based on a one-for-one basis at any time. The initial conversion price is the issuance price of Preferred Shares, subject to adjustment in the event of (1) stock splits, share combinations, share dividends and distribution, recapitalizations and similar events, and (2) issuance of new securities at a price per share less than the conversion price in effect on the date of or immediately prior to such issuance. In that case, the conversion price shall be reduced concurrently to the subscription price of such issuance.

The Preferred Shares will be automatically converted into ordinary shares at the then applicable conversion price upon the earlier of (1) the closing of a Qualified Initial Public Offering, or (2) the date specified by written consent or agreement of majority holders of Preferred Shares.

Voting rights

The Preferred Shareholders are entitled to vote with ordinary shareholders on an as-converted basis. The holders of the Preferred Shares also have certain veto rights including, but not limited to, an increase or decrease in the total number of directors and change of board composition, appointment or removal of senior management, approval of business plan and operating budget, dividend declaration, any merger, split, reorganization or consolidation.

Dividends

The Preferred Shareholders may be entitled to receive dividends accruing at the rate of 8% per annum. In addition, Preferred Shareholders are also entitled to dividends on the Company’s ordinary shares on an as if converted basis and must be paid prior to any payment on ordinary shares. All dividends shall be payable only when, as, and if declared by the Board of Directors and shall be noncumulative.

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Liquidation preference

Series A1 Preferred Shares and Series A2 Preferred Shares

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series A1 and Series A2 Preferred Shares are entitled to receive, prior to any distribution to the holders of ordinary shares, an amount per share equal to the Series A original issue price, plus accrued but unpaid dividends (the “Preference Amount”).

Series B1 Preferred Shares and Series B2 Preferred Shares

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series B1 and Series B2 Preferred Shares are entitled to receive, prior to any distribution to the holders of ordinary shares, an amount per share equal the Series B original issue price plus five percent (5%) simple interest on such Series B issue price accrued annually from the applicable Series B issue date, plus accrued but unpaid dividends.

In the event insufficient funds are available to pay in full the Preference Amount in respect of each preferred shareholders, the sequence of liquidation right of all series of preferred shares was as follows:

(1) Series B1 and B2 Preferred Shares

(2) Series A1 and A2 Preferred Shares

After the Preference Amount has been paid, any remaining funds or assets legally available for distribution shall be distributed pro rata among the preferred shareholders together with ordinary shares.

A liquidation event includes, (i) any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary; the exclusive licensing of all or substantially all of the Group Companies’ intellectual property, taken as a whole, to a third party; (ii) any sale of all or substantially all of the assets of the Group to a third party unaffiliated with any member of the Group; or (iii) the transfer (whether by merger, reorganization or other transaction) in which a majority of the outstanding voting power of the Company is transferred (excluding any sale of shares by the Company for capital raising purposes).

The key terms of the warrants are as follows:

Vesting date

The warrant was vested on April 1, 2016.

Exercise period

If not previously exercised, the warrants shall expire on the earlier of (i) the sixth (6th) anniversary of the issue date or (ii) ninety (90) days prior to the date on which the Company consummates an initial public offering.

The Company has classified the Preferred Shares as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event (i.e. a liquidation event). The holders of the Preferred

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Shares have a liquidation preference and will not receive the same form of consideration upon the occurrence of the conditional event as the ordinary shareholders would. The holders of Preferred Shares have the ability to convert the instrument into the Company's ordinary shares. The conversion option of the convertible preferred shares do not qualify for bifurcation accounting because the conversion option is clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily convertible into cash.

The Group has determined that there was no beneficial conversion feature ("BCF") attributable to the Preferred Shares, as the effective conversion price was greater than the fair value of the ordinary shares on the respective commitment date. The Group will re-evaluate whether additional BCF is required to be recorded upon the modification to the effective conversion price of the Preferred Shares, if any.

The Company concluded that the Preferred Shares are not redeemable currently, and is not probable that the Preferred Shares will become redeemable because the likelihood of a liquidation event is remote. Therefore, no adjustment will be made to the initial carrying amount of the Preferred Shares until it is probable that they will become redeemable.

The warrants are freestanding instruments and are recorded as liabilities in accordance with ASC480. The Series B1 and B2 Preferred Shares were initially recorded as mezzanine equity equal to the proceeds received of $106.2 million in total. The warrants are initially recognized at fair value, with subsequent changes in fair value recorded in losses. For the year ended December 31, 2016, the Company recognized a loss from the increase in fair value of the warrants of $1.92 million.

8. Net loss per share

Basic and diluted net loss per share for each of the years presented are calculated as follow:

	For the year ended December 31,	
	2015	2016
	$	$
Numerator:		
Net loss attributable to ordinary shareholders	(18,021,737)	(37,512,212)
Denominator:		
Weighted average number of ordinary shares-basic and diluted	52,161,198	56,634,142
Net loss per share-basic and diluted	(0.35)	(0.66)

The Group has determined that its convertible preferred shares are participating securities as the preferred shares participate in undistributed earnings on an as-if-converted basis. The holders of the preferred shares are entitled to receive dividends on a pro rata basis, as if their shares had been converted into ordinary shares. Accordingly, the Group uses the two-class method of computing net income per share, for ordinary and preferred shares according to participation rights in undistributed earnings, However, undistributed net loss is only allocated to ordinary shareholders because holders of preferred shares are not contractually obligated to share losses.

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As a result of the Group's net loss for the two years ended December 31, 2015 and 2016, Series A1, A2, B1 and B2 preferred shares, share options, non-vested restricted shares and warrants 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,	
	2015	2016
Number of Series A1 Shares outstanding	50,800,001	50,800,001
Number of Series A2 Shares outstanding	50,653,339	50,653,339
Number of Series B1 Shares outstanding	—	33,374,023
Number of Series B2 Shares outstanding	—	23,838,588
Share options	25,855,395	43,368,862
Non-vested restricted shares	17,688,889	13,856,945
Warrants	2,770,851	2,770,851

9. Related party transactions

The table below sets forth the related party transactions and the relationship with the Group as of December 31, 2016:

Company Name	Relationship with the group
Qiagen (Suzhou) Translational Medicine Co., Ltd.	Significant influence held by Samantha Du's immediate family

(a) The Group entered into the following transactions between its related party:

	Year ended December 31,	
	2015	2016
	$	$
Research and development expense	96,656	—

(b) The Group had the following balances with its related party:

	December 31,	
	2015	2016
	$	$
Accounts payable	27,865	—

10. Share-based compensation

Share options

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "Plan") which is administered by the Board of Directors. Under the 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 24,845,671 ordinary shares of the Group (“Option Pool”). On October 22, 2015, March 9, 2016 and August 25, 2016, the Board of Directors approved the increase in the Option Pool to 44,218,603 ordinary shares. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting one year after the grant date and the remainder of the awards vesting on a monthly basis thereafter.

In March and October 2015, the Group granted 5,222,695 and 20,632,700 share options to certain of the Group’s management and employees at an exercise price of $0.1 per share, respectively. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting one year after the grant date and the remainder of the awards vesting on a monthly basis thereafter.

In March 2016, the Group granted 6,946,759 share options to certain of the Group’s management and employees at an exercise price of $0.2 per share. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting anniversary year after the grant date.

In August 2016, the Group granted 10,562,208 share options to certain of the Group’s management and employees at an exercise price of $0.29 per share, respectively. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting on the anniversary of the grant date each year.

In August and December 2016, the Group granted 2,500 and 2,500 share options to certain individual advisors of the Group at an exercise price of $0.29 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.

The binomial option-pricing model was applied in determining the estimated fair value of the options granted. The model requires the input of highly subjective assumptions including the estimated expected stock price volatility and, the exercise multiple for which employees are likely to exercise share options. For expected volatilities, the Group has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Group. For the exercise multiple, the Group has no historical exercise patterns as reference, thus the exercise multiple is based on management’s estimation, which the Group believes is representative of the future exercise pattern of the options. The risk-free rate for periods within the contractual life of the option is based on the US treasury bonds with maturity similar to the maturity of the options as of valuation dates plus a China country risk premium. The estimated fair value of the ordinary shares, at the option grant dates, was determined with assistance from an independent third party valuation firm. The Group’s management is ultimately responsible for the determination of the estimated fair value of its ordinary shares.

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The following table presents the assumptions used to estimate the fair values of the share options granted in the years presented:

	March, 2015	October, 2015	March, 2016	August, 2016	December, 2016
Risk-free rate of return	3.1%	3.1%	2.8%	2.5%	3.4%
Contractual life of option	10 years	10 years	10 years	10 years	10 years
Estimated volatility rate	70%	70%	70%	70%	70%
Expected dividend yield	0%	0%	0%	0%	0%
Fair value of underlying ordinary shares	0.27	0.32	1.19	1.34	1.34

A summary of option activity under the Plan during the years ended December 31, 2015 and 2016 is presented below:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
		$	Years	$
Outstanding at January 1, 2015	—	—	—	—
Granted	25,855,395	0.10	—	—
Outstanding at December 31, 2015	25,855,395	0.10	9.68	18,874,438
Granted	17,513,967	0.25	—	—
Forfeited	(500)	0.29	—	—
Outstanding at December 31, 2016	43,368,862	0.16	9.00	53,677,170
Vested and Exercisable as of December 31, 2016	6,642,240	0.10	8.63	8,634,911
Vested or expected to vest as of December 31, 2016	43,368,862	0.16	9.00	53,677,170

The weighted-average grant-date fair value of the options granted in 2015 and 2016 was $0.27 and $1.16 per share. The Group recorded compensation expense related to the option of $419,709 and $3,524,733 for the year ended December 31, 2015 and 2016, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	2015	2016
	$	$
Year ending December 31:		
General and administrative	124,871	1,472,993
Research and development	294,838	2,051,740
Total	419,709	3,524,733

As of December 31, 2016, there was $23,286,577 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 4.0 years.

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Non-vested restricted shares

On April 3, 2014, the Company entered into a restricted share arrangement with Samantha Du, founder and Chairman and Chief Executive Officer of the Company (the "CEO") to secure her services, pursuant to which all of her 21,000,000 ordinary shares of the Company became subject to transfer restrictions. In addition, the restricted shares shall initially be unvested and subject to repurchase by the Company at par value upon voluntary or involuntary termination of employment by the CEO (the "Repurchase Right"). One fifth of the restricted shares shall vest and be released from the restrictions and Repurchase Right on each yearly anniversary from the date of the agreement. The CEO retains the voting rights of such non-vested restricted shares and any additional securities or cash received as the result of ownership of such shares, such as a share dividend, become subject to restriction in the same manner. This arrangement has been accounted for as a performance-based plan. Accordingly, the Group measured the fair value of the non-vested restricted shares as of April 3, 2014 and is recognizing the amount as compensation expense over the five year deemed service period using a graded vesting attribution model for each separately vesting portion of the non-vested restricted shares.

On August 10, 2015, the Company entered into an restricted share arrangement with an individual advisor to secure their services, for 1,000,000 ordinary shares authorized for grant. In general, restrictions limit the sale or transfer of these shares during a three year period, and restrictions lapse proportionately over the three year period. During the three year period the Company upon voluntary or involuntary termination of service agreement by the individual advisor will repurchase unvested restricted shares at par (the "Repurchase Right"). On July 15, 2016 and August 25, 2016, 350,000 and 450,000 ordinary shares were authorized for grant to the individual advisor with the same Repurchase Right. The Repurchase Right terminates over the three years commencing August 10, 2015, July 15, 2016 and August 25, 2016 in 36 equal monthly instalments thereafter. Any additional securities or cash received as the result of ownership of such shares, such as dividends, become subject to restriction in the same manner. For all restricted shares, the individual advisor has delegated his voting rights to the CEO of the Company. This arrangement has been accounted for as a performance-based plan. Accordingly, the Group measures the service expense based on the fair value at the date the services are completed which is monthly.

The following table summarized the Group's non-vested restricted share activity in 2016.

	Numbers of non-vested restricted shares	Weighted average fair value
Non-vested as of January 1, 2016	17,688,889	0.14
Granted	800,000	1.34
Vested	(4,631,944)	0.21
Non-vested as of December 31, 2016	13,856,945	0.22

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As of December 31, 2016, there was $1,367,014 of total unrecognized compensation expense related to non-vested Restricted Shares. The Group recorded compensation expense related to the restricted shares of $476,806 and $954,660 for the year ended December 31, 2015 and 2016, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	2015	2016
	$	$
Year ending December 31:		
General and administrative	210,000	210,000
Research and development	266,806	744,660
Total	476,806	954,660

Ordinary shares issued to Red Kingdom Investment Limited ("Red Kingdom")

Red Kingdom is a company incorporated in the British Virgin Islands in August 2013 and owned by a group of senior management including the CEO of the Company and advisors of the Group and third party investors. Red Kingdom has no activities and does not have employees. All the shareholders of the Red Kingdom have delegated their voting rights to the CEO of the Company.

On April 3, 2014, the Company issued 48,500,000 shares to Red Kingdom which are corresponding to the total outstanding shares of Red Kingdom for total consideration of $141,971. One share of Red Kingdom is entitled to indirectly all of the economic rights associated with the underlying ordinary shares of the Company. Of these shares, 47,085,000 shares were held by members of senior management and certain advisors of the Group, who paid par value.

In April and May 2014, Red Kingdom entered into restricted share arrangements with the members of senior management of the Group to secure their services, pursuant to which all of their 38,755,000 ordinary shares of the Red Kingdom became subject to transfer restrictions (the "Restricted Shares"). In addition, the Restricted Shares shall initially be unvested and subject to repurchase by Red Kingdom at par value upon voluntary or involuntary termination of employment by those senior management (the "Repurchase Right"). One fifth of the Restricted Shares shall vest and be released from the restrictions and Repurchase Right on each yearly anniversary from the date of the agreement. Any additional securities or distributions received associated with the Restricted Shares shall become subject to the same restrictions. The Repurchase Right shall terminate upon the earlier to occur of: (i) the cancelation of the Repurchase Right upon vesting, (ii) immediately prior to the consummation of an initial public offering of the securities of the Company, or (iii) a Change of Control. Accordingly, the Group measured the fair value of the non-vested Restricted Shares at grant date and recognizes the amount as compensation expense over the five year deemed service period using a graded vesting attribution model on a straight-line basis.

In April 2014, Red Kingdom entered into a restricted share arrangement with one of its advisors whereby all of their 2,100,000 ordinary shares of Red Kingdom became subject to transfer restrictions (the "Advisor Restricted Shares"). Such shares shall initially be unvested and subject to repurchase by Red Kingdom at par value during the 5 year period following the date of the agreement. The Advisor Restricted Shares shall vest and

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be released from the Repurchase Right at the rate of twenty percent (20%) of the total number of Advisor Restricted Shares as each the contractually agreed milestones within each year (collectively, the "Milestones") are determined to have been achieved by the Company. Accordingly, the Group measures the service expense based on the fair value of the Restricted Shares when the milestones are achieved.

The 6,230,000 shares of the Company that issued to Red Kingdom corresponding to the shares of Red Kingdom held by advisors of the Group, purchased for par value in 2014 are not subject to the transfer restrictions or other repurchase rights, and so were considered vested immediately at the date of grant and expensed.

On December 15, 2015, 11,526,000 unvested Restricted Shares granted to the CEO were deemed vested by the Company and the unrecognized share-based compensation of $1,152,600 as of the modification date was immediately recognized as compensation expense in the consolidated statements of operations.

The following table summarized the non-vested Restricted Shares activities of Red Kingdom in 2016.

	Numbers of non-vested restricted shares	Weighted average grant date fair value
Non-vested as of January 1, 2016	21,160,000	0.10
Vested	(4,450,000)	0.10
Non-vested as of December 31, 2016	16,710,000	0.10

As of December 31, 2016, there was $1,136,753 of total unrecognized compensation expense related to non-vested Restricted Shares. The Group recorded compensation expense related to the restricted shares of $1,804,889 and $445,885 for the year ended December 31, 2015 and 2016, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	2015	2016
	$	$
Year ending December 31:		
General and administrative	697,206	364,723
Research and development	1,107,683	81,162
Total	1,804,889	445,885

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11. Accumulated other comprehensive loss

The movement of accumulated other comprehensive loss is as follows:

	Foreign currency translation adjustments
	$
Balance as of January 1, 2015	(4,727)
Other comprehensive loss	(98,893)
Balance as of December 31, 2015	(103,620)
Other comprehensive loss	(594,912)
Balance as of December 31, 2016	(698,532)

12. Licenses and collaborative arrangements

License and collaboration agreement with Bristol-Myers Squibb Company ("BMS")

In March 2015, the Group entered into a collaboration and license agreement with BMS, under which the Group obtained an exclusive license under certain patents and know-how of BMS to develop, manufacture, use, sell, import and commercialize brivanib, BMS's proprietary multi-targeted kinase inhibitor, in mainland China, Hong Kong and Macau, or the licensed territory, in the licensed field of diagnosis, prevention, treatment or control of oncology indications, with the right to expand the 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.

BMS has the option to elect to co-promote the licensed products in the licensed territory. If BMS exercises its co-promotion option, BMS will pay the Group an option exercise fee, and the Group will share with BMS the operating profits and losses of the licensed products in the licensed territory. If BMS does not exercise its co-promotion option, the Group will pay BMS milestone payments for the achievement of certain development and sales milestone events, and also tiered royalties at certain percentage rates on the net sales of the licensed products in the 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.

The Group also has the right to opt-out of the commercialization of the licensed products in its licensed territory under certain conditions. If the Group elects to opt-out, BMS will have the right to commercialize the licensed products in the Group's licensed territory and will pay the Group royalties on the net sales of the licensed products in its licensed territory. BMS has the option to use the data generated by the Group from the Group's development of the licensed products to seek regulatory approval of the licensed products outside the Group's licensed territory, and if BMS exercises such option, BMS will be obligated to make certain payments to the Group, including upfront, milestone and royalty payments.

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The agreement may be 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, the Group has 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.

License and collaboration agreement with Sanofi

In July 2015, the Group entered into a license agreement with Sanofi, under which the Group obtained an exclusive and worldwide license under certain patents and know-how of Sanofi to develop, manufacture, use, sell, import and commercialize Sanofi's ALK inhibitor SAR 348830, or the licensed compound (also known as ZL-2302), for any oncology indications in humans. Sanofi retains the non-exclusive right to use the licensed compound to conduct internal research.

Under the terms of the agreement, the Group made upfront payments to Sanofi totalling $0.5 million which were recorded as research and development expenses in 2015. If the Group successfully develops and commercializes the licensed product, the Group will make milestone payments to Sanofi for the achievement of certain development milestone events. In addition, the Group will pay to Sanofi tiered royalties at certain percentage rates of 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 country-by-country basis. If the Group sublicenses, transfers or assigns (other than through a change of control transaction) the right to the licensed product to third parties, the Group is also required to pay to Sanofi a share of its sublicense income.

The Group at any time has the right to terminate this agreement for any reason or no reason at all by providing Sanofi with prior written notice.

License and collaboration agreement with UCB Biopharma Sprl ("UCB")

In September 2015, the Group entered into a license agreement with UCB, under which the Group obtained an exclusive and worldwide license under certain patents and know-how of UCB to develop, manufacture, use, sell, import and commercialize UCB's proprietary antibody UCB3000 or the licensed compound (also known as ZL-1101), for the treatment, prevention and diagnosis of any human diseases. UCB retains the non-exclusive right to use the licensed compound for its own research purposes.

Under the terms of the agreement, the Group made upfront payments to UCB totalling $0.8 million which was recorded as a research and development expense in 2015. If the Group successfully develops and commercializes the licensed products, the Group will make milestone payments to UCB for the achievement of certain development and sales milestone events. In addition, the Group will pay to UCB royalties at certain percentage rates 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 country-by-country basis. If the Group sublicenses the right to the licensed product to third parties, the Group is also required to pay to UCB a share of its sublicense income.

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The Group has the right to terminate this agreement by providing UCB with prior written notice.

License and collaboration agreement with Hanmi Pharm, Co., Ltd.(“Hanmi”)

In November 2015, the Group entered into a collaboration and license agreement with Hanmi under which the Group obtained an exclusive right of license under certain patents and know-how of Hanmi to develop, manufacture, use, sell, import and commercialize Hanmi’s EGFR mutation specific TKI HM61713, or the licensed compound (also known as ZL-2303) for the treatment, diagnosis or prevention of any diseases or conditions in human. Hanmi retains the non-exclusive right to use the licensed compound for its own research purposes. Hanmi has the right of first negotiation to acquire the rights to the licensed products back from the Group upon successful completion of certain clinical development work.

Under the terms of the agreement, the Group made upfront payments amounted $6.0 million and $1.0 million to Hanmi in 2015 and 2016, respectively. If the Group successfully develop and commercialize the licensed products, the Group will make milestone payments to Hanmi for the achievement of certain development milestone events. In addition, the Group will pay to Hanmi royalties at certain percentage rates on the net sales of the licensed products in its licensed territory, until date of expiration of the latest of valid claim that claims the composition-of-matter of the licensed product, the expiration date of any regulatory data exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product.

The Group has the right to terminate this agreement by providing Hanmi with prior written notice.

License and collaboration agreement with Tesaro Inc., (“Tesaro”)

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, niraparib, 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). Tesaro has the option to elect to co-promote the licensed products in the Group’s licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $15.0 million to Tesaro which was recorded as a research and development expense in 2016. If the Group successfully develops and commercializes the licensed products, the Group will make a milestone payment to Tesaro for the achievement of a certain development milestone event. In addition, if Tesaro does not exercise its co-promotion option, the Group will pay Tesaro milestone payments for the achievement of certain sales milestone events, and also tiered royalties at certain percentages of 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 by providing Tesaro with prior written notice.

ZAI Lab Limited
Notes to the consolidated financial statements
For the years ended December 31, 2015 and 2016
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License and collaboration agreement with GlaxoSmithKline (China) R&D Co., Ltd ("GSK China")

In October 2016, the Group entered into a license and transfer agreement with GSK China, an affiliate of GSK, under which GSK China transferred to the Group its rights under certain patents, know-how, inventory and regulatory materials to develop, manufacture, use and commercialize FUGAN and GRAPE, two formulations comprising extracts from traditional Chinese herbs, for the treatment, diagnosis and prevention of human diseases. In connection with such transfer, GSK China also assigned to the Group its agreements with Chengdu Bater Pharmaceutical Co., Ltd, or Bater, and Traditional Chinese Medical Hospital, Xinjiang Medical University, or Xinjiang, relating to FUGAN and GRAPE.

Under the terms of the agreement, the Group made an upfront payment to GSK China of $0.7 million (RMB4.5 million) which was recorded as a research and development expense in 2016. The Group will make milestone payments to GSK China for the achievement of certain development milestone events. In addition, the Group will pay to GSK China tiered royalties at certain percentage rates on the net sales of FUGAN and GRAPE. The Group also assumed the obligation to make milestone payments under the assigned agreements with Bater and Xinjiang for milestones achieved after the assignment of the agreements to the Group.

If the Group sublicenses, sells or otherwise divests the patents and know-how acquired from GSK China to third parties before the completion of a certain development phase, the Group is also required to pay to GSK China a share of its income attributed to such sublicense, sale, or divesture.

The Group may not terminate the agreement before the completion of the Phase II Study of fugan unless for causes beyond the reasonable control of the Group. Subject to the completion of the Phase II Study of fugan, the Group has the right to terminate the agreement upon prior written consent.

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. The Group hasn't made any milestone payment under these agreements for the years ended December 31, 2014, 2015 and 2016, respectively, because none of the milestones were achieved. 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 $300.0 million 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.

13. 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.

ZAI Lab Limited
Notes to the consolidated financial statements
For the years ended December 31, 2015 and 2016
(In U.S. dollars ("$") except for number of shares)

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 subsidiary was established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2015 and 2016, no appropriation to statutory reserves was made because the PRC subsidiary 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 subsidiary is 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 subsidiary from transferring funds to the Group in the form of dividends, loans and advances. As of December 31, 2015 and 2016, amounts restricted are the paid-in capital of the Group's PRC subsidiaries, which amounted to $5,699,980 and $39,215,714, respectively.

14. 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 subsidiary 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 $79,878 and $288,666 for the years ended December 31, 2015 and 2016, respectively.

15. Commitments and Contingencies

(A) Operating lease commitments

The Group leases office facilities under non-cancellable operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases, and the terms of the leases do not contain rent escalation, contingent rent, renewal, or purchase options.

There are no restrictions placed upon the Group by entering into these leases. Total expenses under these operating leases were $148,274 and $285,742 for the years ended December 31, 2015 and 2016, respectively.

ZAI Lab Limited
Notes to the consolidated financial statements
For the years ended December 31, 2015 and 2016
(In U.S. dollars ("$") except for number of shares)

Future minimum lease payments under non-cancellable operating lease agreements at December 31, 2016 were as follows:

	Year ended December 31,
	$
2017	712,301
2018	659,810
2019	548,923
2020	198,451
2021 and thereafter	—
Total lease commitment	2,119,485

(B) Purchase commitments

As of December 31, 2016, the Group's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statement was $3,396,524 which is expected to be incurred within one year.

(C) 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 12).

16. Subsequent events

On April 21, 2017, the Group entered into a license and collaboration agreement with Paratek Bermuda Ltd. for the development, manufacture and commercialization of omadacycline in China, Hong Kong, Macau and Taiwan.

In May 2017, the Group granted 949,883 share options to certain of the Group's management and employees at an exercise price of $0.5 per share. These options 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 the anniversary date of the grant. The Group also granted 27,500 share options to certain individual advisors of the Group at an exercise price of $0.5 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 on the anniversary date of the grant.

On May 29, 2017, pursuant to the board resolution, the Repurchase Right to all the remaining non-vested shares of the Chief Executive Officer which are subject to the restricted share arrangement dated April 3, 2014 was terminated.

Additional financial information of parent company - Financial statements schedule I
ZAI Lab Limited
Financial information of parent company
Condensed statements of operations and comprehensive income (loss)

(In U.S. dollars ("$") except for number of shares)

	As of December 31,	
	2015	2016
	$	$
Assets		
Current assets:		
Cash and cash equivalents	3,114,070	24,813,050
Total current assets	3,114,070	24,813,050
Investment in subsidiaries	8,803,171	62,042,345
Total assets	11,917,241	86,855,395
Liabilities, mezzanine equity and shareholders' deficits		
Liabilities		
Current liabilities:		
Warrant liabilities	1,980,000	3,900,000
Total liabilities	1,980,000	3,900,000
Mezzanine equity		
Series A1 convertible preferred shares (par value US$0.00001 per share; 50,800,001 shares authorized, issued and outstanding as of December 31, 2015 and 2016)	10,028,572	10,028,572
Series A2 convertible preferred shares (par value US$0.00001 per share; 50,653,339 shares authorized, issued and outstanding as of December 31, 2015 and 2016)	18,278,572	18,278,572
Series B1 convertible preferred shares (par value US$0.00001 per share; 33,374,023 shares authorized, issued and outstanding as of 2016)	—	53,100,000
Series B2 convertible preferred shares (par value US$0.00001 per share; 23,838,588 shares authorized, issued and outstanding as of December 31, 2016)	—	53,100,000
Total mezzanine equity	28,307,144	134,507,144
Shareholders' deficits		
Ordinary shares (par value of US$0.00001 per share; 500,000,000 shares authorized, 53,311,111 and 57,943,056 shares outstanding as of December 31, 2015 and 2016, respectively)	533	579
Subscription receivable	(1)	(5)
Additional Paid-in Capital	4,388,410	9,313,646
Accumulated deficits	(22,655,225)	(60,167,437)
Additional other comprehensive loss	(103,620)	(698,532)
Total shareholders' deficits	(18,369,903)	(51,551,749)
Total liabilities, mezzanine equity and shareholders' deficits	11,917,241	86,855,395

Additional financial information of parent company - Financial statements schedule I
ZAI Lab Limited
Financial information of parent company
Condensed statements of operations and comprehensive income (loss)

(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2015	**2016**
	$	**$**
Operating Expenses:		
General and administrative	(56,806)	(534,660)
Loss from operations	(56,806)	(534,660)
Changes in fair value of warrants	(1,980,000)	(1,920,000)
Equity in loss of subsidiaries	(15,984,931)	(35,057,552)
Loss before income tax	(18,021,737)	(37,512,212)
Income tax expense	—	—
Net loss attributable to ordinary shareholders	(18,021,737)	(37,512,212)
Net loss	(18,021,737)	(37,512,212)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustment	(98,893)	(594,912)
Comprehensive loss	(18,120,630)	(38,107,124)

Additional financial information of parent company - Financial statements schedule I
ZAI Lab Limited
Financial information of parent company
Condensed statements of cash flows

(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,	
	2015	2016
	$	$
Operating activities		
Net loss	(18,021,737)	(37,512,212)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Share based compensation	56,806	534,660
Change of fair value of warrants	1,980,000	1,920,000
Equity in loss of subsidiaries	15,984,931	35,057,552
Net cash provided by operating activities	—	—
Cash flows from investing activities:		
Investment in subsidiaries	(21,500,000)	(84,501,020)
Net cash used in investing activities	(21,500,000)	(84,501,020)
Cash flows from financing activities:		
Proceed from issuance of convertible preferred shares	18,278,572	106,200,000
Net cash provided by financing activities	18,278,572	106,200,000
Effect of foreign exchange rate changes on cash and cash equivalent	—	—
Net (decrease) increase in cash and cash equivalents	(3,221,428)	21,698,980
Cash and cash equivalents—beginning of the year	6,335,498	3,114,070
Cash and cash equivalents—end of the year	3,114,070	24,813,050

Additional financial information of parent company - Financial statements schedule I
ZAI Lab Limited
Financial information of parent company
Notes to schedule I

(In U.S. dollars (“$”) except for number of shares)

1) Schedule I has been provided pursuant to the requirements of Rule 12-04(a) and 5-04(c) of Regulation S-X, which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.

2) The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements except that the equity method has been used to account for investments in its subsidiaries. For the parent company, the Company records its investments in subsidiaries under the equity method of accounting as prescribed in ASC 323, Investments-Equity Method and Joint Ventures. Such investments are presented on the Condensed Balance Sheets as ‘‘Investment in subsidiaries’’. Ordinarily under the equity, an investor in an equity method investee would cease to recognize its share of the losses of an investee once the carrying value of the investment has been reduced to nil absent an undertaking by the investor to provide continuing support and fund losses. For the purpose of this Schedule I, the parent company has continued to reflect its share, based on its proportionate interest, of the losses of subsidiaries regardless of the carrying value of the investment even though the parent company is not obligated to provide continuing support or fund losses.

3) As of December 31, 2015 and 2016, there were no material contingencies, significant provisions of long term obligations, mandatory dividend or redemption requirements of redeemable stocks or guarantees of the Company.

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Through and including , 2017 (25 days after the commencement of this offering), all dealers that effect transactions in our ordinary shares or ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

Zai Lab Limited

American depositary shares

Representing ordinary shares

J.P. Morgan **Citigroup** **Leerink Partners**

, 2017

Part II
Information not required in prospectus

Item 6. Indemnification of directors and officers

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime.

The post-offering amended and restated articles of association that we expect to adopt to become effective immediately prior to the completion of this offering provide that we shall indemnify our directors and officers (each an indemnified person) against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such indemnified person, other than by reason of such person's own dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

Pursuant to the indemnification agreements the form of which is filed as Exhibit 10.16 to this registration statement, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or officer.

The underwriting agreement, the form of which will be filed as Exhibit 1.1 to this registration statement, will also provide for indemnification by the underwriters of us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, but only to the extent that such liabilities are caused by information relating to the underwriters furnished to us in writing expressly for use in this registration statement and certain other disclosure documents.

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

Item 7. Recent sales of unregistered securities

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act. We believe that each of the following issuances was exempt from registration under the Securities Act in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions, Regulation D under the Securities Act, Rule 701 under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering. No underwriters were used in the below issuances.

1. On April 3, 2014, we issued 20,999,999 restricted ordinary shares and 500,000 ordinary shares to Samantha Du for an aggregate cash consideration of $50,210. On the same date, we issued 48,500,000 ordinary shares to Red Kingdom Investments Limited for an aggregate consideration of $141,971.

2. On August 20, 2014, we closed a private placement transaction pursuant to which we issued an aggregate of 50,800,001 Series A-1 preferred shares for an aggregate cash consideration of $8,028,572 and in consideration for the conversion of convertible loans amounting an aggregate consideration of $2,000,000.

3. On April 30, 2015, we issued a total of 57,719,866 Series A-2 preferred shares in connection with the second closing of the private placement transaction described above for an aggregate consideration of $20,828,572 of which $5,300,000 remained unpaid. On September 30, 2015 we cancelled 7,066,527 of these Series A-2 preferred shares and forgave the $2,550,000 unpaid capital balance.
4. On August 10, 2015, we issued 1,000,000 restricted ordinary shares to Peter Karl Wirth, which were credited as full paid.
5. On December 31, 2015, we granted a warrant to purchase 2,770,851 Series A-2 preferred shares at the purchase price of $0.3609 per share to OrbiMed Asia Partners II, L.P. for a period commencing on April 1, 2016 and ending on the earlier of (i) the sixth anniversary of the date of issuance of this warrant or (ii) 90 calendar days prior to the date on which we consummate this offering. No consideration was received by us in connection with the issuance of the warrant. As of the date of this prospectus, no Series A-2 preferred shares have been purchased by OrbiMed Asia Partners II, L.P. pursuant to this warrant.
6. On January 20, 2016, we closed a private placement transaction pursuant to which we sold an aggregate of 33,374,023 Series B-1 preferred shares for an aggregate consideration of $53,100,000 in cash.
7. On April 1, 2016, we issued a total of 23,838,588 Series B-2 preferred shares in connection with the second closing of the private placement transaction described above for an aggregate consideration of $53,100,000 in cash.
8. On July 15, 2016 and August 25, 2016, we issued an additional 350,000 and 450,000 restricted ordinary shares to Peter Karl Wirth, respectively, which were credited as fully paid.

In addition to the above, since January 1, 2014, we have granted share options to purchase (i) an aggregate of 25,855,395 ordinary shares, each at an exercise price of $0.10 per share, (ii) an aggregate of 6,946,759 ordinary shares, each at an exercise price of $0.20 per share, and (iii) an aggregate of 10,567,208 ordinary shares, each at an exercise price of $0.29 per share, to our employees, consultants and directors. These grants were made pursuant to written compensatory plans or arrangements with our employees, consultants and directors in reliance upon the exemption provided by Rule 701 promulgated under the Securities Act or Section 4(a)(2) of the Securities Act for transactions by an issuer not involving a public offering or Regulation S under the Securities Act.

Item 8. Exhibits and financial statement schedules

(a) Exhibits

Exhibit number	Exhibit title
1.1*	Form of Underwriting Agreement
3.1*	Third Amended and Restated Memorandum and Articles of Association of Zai Lab Limited
4.1*	Form of Deposit Agreement
4.2*	Form of American Depositary Receipt (included in Exhibit 4.1)
4.3*	Registrant's Specimen Certificate for Ordinary Shares
5.1*	Form of opinion of Travers Thorp Alberga regarding the validity of the ordinary shares being registered
8.1*	Opinion of Travers Thorp Alberga regarding certain Cayman Islands tax matters (included in Exhibit 5.1)

Exhibit number	Exhibit title
8.2*	Opinion of Zhong Lun Law Firm regarding certain PRC tax matters (included in Exhibit 99.2)
10.1*#	Zai Lab Limited 2015 Equity Incentive Plan
10.2*+	Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd. dated September 29, 2016
10.3*+	License Agreement by and between Bristol-Myers Squibb Company and Zai Lab (Hong Kong) Limited dated March 9, 2015
10.4*+	Collaboration and License Agreement by and between Paratek Bermuda Ltd and Zai Lab (Shanghai) Co., Ltd. dated April 21, 2017
10.5*+	License and Transfer Agreement by and between GlaxoSmithKline (China) R&D Co., Ltd and Zai Lab (Shanghai) Co., Ltd. dated October 18, 2016
10.6*+	Assignment and Assumption Agreement by and among GlaxoSmithKline (China) R&D Co., Ltd, Zai Lab (Shanghai) Co., Ltd. and Chengdu Bater Pharmaceutical Co., Ltd. dated October 13, 2016
10.7*+	Assignment and Assumption Agreement by and among GlaxoSmithKline (China) R&D Co., Ltd, Zai Lab (Shanghai) Co., Ltd. and Traditional Chinese Medical Hospital, Xinjiang Medical University dated October 14, 2016
10.8*+	License Agreement by and between Sanofi and Zai Lab (Hong Kong) Limited dated July 22, 2015
10.9*#	Form of Executive Employment Agreement for Zai Lab (Hong Kong) Limited executive officers
10.10*#	Form of Executive Employment Agreement for Zai Lab (Shanghai) Co., Ltd. executive officers
10.11*	Form of Indemnification Agreement for Directors and Officers
21.1*	Subsidiaries of the registrant
23.1*	Consent of Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent accounting firm, regarding the consolidated financial statements of Zai Lab Limited
23.2*	Consent of Travers Thorp Alberga (included in Exhibit 5.1)
23.3*	Consent of Zhong Lun Law Firm (included in Exhibit 99.2)
24.1*	Power of Attorney (included on signature page)
99.1*	Code of Ethics
99.2*	Opinion of Zhong Lun Law Firm regarding certain PRC law matters

* To be filed by amendment.

\+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the Securities and Exchange Commission.

\# Management contract or compensatory plan or arrangement.

(b) Financial statement schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 9. Undertakings

The undersigned Registrant hereby undertakes:

(1) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(4) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of , on , 2017.

ZAI LAB LIMITED

By: _____
Name:
Title:

* * *

Power of attorney

The undersigned directors and officers of Zai Lab Limited hereby appoint each of , as attorney-in-fact for the undersigned, with full power of substitution and resubstitution, for and in the name, place and stead of the undersigned, to sign and file with the Securities and Exchange Commission under the Securities Act of 1933 any and all amendments (including post-effective amendments) and exhibits to this registration statement on Form F-1 (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933) and any and all applications and other documents to be filed with the Securities and Exchange Commission pertaining to the registration of the securities covered hereby, with full power and authority to do and perform any and all acts and things whatsoever requisite and necessary or desirable, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____	Chief Executive Officer, Director (Principal Executive Officer)	, 2017
_____	Chief Financial Officer (Principal Financial Officer)	, 2017
_____	Director	, 2017
_____	Director	, 2017
_____	Director	, 2017

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Signature of authorized representative in the United States

Pursuant to the Securities Act of 1933, the undersigned, the duly authorized representative in the United States of Zai Lab Limited, has signed this registration statement or amendment thereto in on , 2017.

(Authorized U.S. Representative)

By: _____

Name:
Title:

Exhibit index

Exhibit number	Exhibit title
1.1*	Form of Underwriting Agreement
3.1*	Third Amended and Restated Memorandum and Articles of Association of Zai Lab Limited
4.1*	Form of Deposit Agreement
4.2*	Form of American Depositary Receipt (included in Exhibit 4.1)
4.3*	Registrant's Specimen Certificate for Ordinary Shares
5.1*	Form of opinion of Travers Thorp Alberga regarding the validity of the ordinary shares being registered
8.1*	Opinion of Travers Thorp Alberga regarding certain Cayman Islands tax matters (included in Exhibit 5.1)
8.2*	Opinion of Zhong Lun Law Firm regarding certain PRC tax matters (included in Exhibit 99.2)
10.1*#	Zai Lab Limited 2015 Equity Incentive Plan
10.2*+	Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd. dated September 29, 2016
10.3*+	License Agreement by and between Bristol-Myers Squibb Company and Zai Lab (Hong Kong) Limited dated March 9, 2015
10.4*+	Collaboration and License Agreement by and between Paratek Bermuda Ltd and Zai Lab (Shanghai) Co., Ltd. dated April 21, 2017
10.5*+	License and Transfer Agreement by and between GlaxoSmithKline (China) R&D Co., Ltd and Zai Lab (Shanghai) Co., Ltd. dated October 18, 2016
10.6*+	Assignment and Assumption Agreement by and among GlaxoSmithKline (China) R&D Co., Ltd, Zai Lab (Shanghai) Co., Ltd. and Chengdu Bater Pharmaceutical Co., Ltd. dated October 13, 2016
10.7*+	Assignment and Assumption Agreement by and among GlaxoSmithKline (China) R&D Co., Ltd, Zai Lab (Shanghai) Co., Ltd. and Traditional Chinese Medical Hospital, Xinjiang Medical University dated October 14, 2016
10.8*+	License Agreement by and between Sanofi and Zai Lab (Hong Kong) Limited dated July 22, 2015.
10.9*#	Form of Executive Employment Agreement for Zai Lab (Hong Kong) Limited executive officers
10.10*#	Form of Executive Employment Agreement for Zai Lab (Shanghai) Co., Ltd. executive officers
10.11*	Form of Indemnification Agreement for Directors and Officers
21.1*	Subsidiaries of the registrant
23.1*	Consent of Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent accounting firm, regarding the consolidated financial statements of Zai Lab Limited
23.2*	Consent of Travers Thorp Alberga (included in Exhibit 5.1)
23.3*	Consent of Zhong Lun Law Firm (included in Exhibit 99.2)
24.1*	Power of Attorney (included on signature page)
99.1*	Code of Ethics
99.2*	Opinion of Zhong Lun Law Firm regarding certain PRC law matters

* To be filed by amendment.

\+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the Securities and Exchange Commission.

\# Management contract or compensatory plan or arrangement.