
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **July 24, 2018**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification No.)

**c/o Maurant Ozannes Corporate Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands**

(Address of principal executive offices) (Zip Code)

+1 (345) 949 4123
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

BeiGene, Ltd. (the “Company”) recently filed an application (the “Listing Application”) with the Stock Exchange of Hong Kong Limited (“HKEx”) in connection with a proposed listing (the “Listing”) of the Company’s ordinary shares, par value US\$0.0001 per share, on the Main Board of the HKEx. In the Listing Application, the Company discloses that it expects cash and cash equivalents, restricted cash and short-term investments balance as of June 30, 2018 to decrease by approximately 5.0% to 5.8% from March 31, 2018, after giving effect to approximately US\$42 million of proceeds from the drawdown of a bank loan by a subsidiary of the Company for the continued construction of the Company’s biologics manufacturing facility in Guangzhou, China. The Company further discloses that it expects its net product revenue for the three months ended June 30, 2018 to increase by approximately 33.0% to 38.0% from the three months ended March 31, 2018. The Company’s independent registered public accountants have not audited, reviewed or performed any procedures with respect to this financial data and accordingly do not express an opinion or any other form of assurance with respect thereto. This data could change as a result of further review.

The information in Item 2.02 of this Current Report on Form 8-K is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.**Business Updates**

The Listing Application also contains an updated description of certain aspects of the Company’s business as well as updated Company risk factor disclosure. Accordingly, the Company is filing this information for the purpose of supplementing and updating the business and risk factor disclosures contained in its prior public filings with the U.S. Securities and Exchange Commission (“SEC”). The updated disclosures are filed herewith as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

There is no assurance that such Listing will take place or as to when the Listing may take place.

This communication is neither an offer to sell nor a solicitation of an offer to buy, nor shall there be any offer, solicitation or sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	BeiGene, Ltd. materials dated July 24, 2018
99.2	BeiGene, Ltd. materials dated July 24, 2018

Forward Looking Statements

This Current Report on Form 8-K and certain of the materials filed or furnished herewith contain forward-looking information about the Company within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein and therein which do not describe historical facts, including, among others, statements relating to the Company’s expectations regarding the completion of the Listing and statements in the materials filed herewith identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans,” “will,” “outlook” and similar expressions are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others, (1) the possibility that the Company will be unable to consummate the proposed Listing; (2) market conditions; (3) that the cost of the Listing to the Company will be more than planned; and (4) other risks identified in the Company’s SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and subsequent filings with the SEC, including this Current Report on Form 8-K. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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Exhibit Index

Exhibit No.	Description
99.1	BeiGene, Ltd. materials dated July 24, 2018
99.2	BeiGene, Ltd. materials dated July 24, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 24, 2018

BEIGENE, LTD.

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Senior Vice President, General Counsel

BUSINESS

Overview

We are a commercial-stage biotechnology company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer. Our internally-developed lead drug candidates are currently in late-stage clinical trials, and we are marketing three in-licensed drugs in China from which we have been generating product revenue since September 2017. Our mission is to become a global leader in the discovery, development and commercialization of innovative therapies.

We started as a research and development company in Beijing in 2010 focusing on developing best-in-class oncology therapeutics. Over the last eight years, we have developed into a fully-integrated global biotechnology company with a broad portfolio consisting of six internally-developed, clinical-stage drug candidates, including three late-stage clinical drug candidates. We have also in-licensed five drugs and drug candidates, including three marketed drugs in China and two clinical-stage drug candidates for which we have obtained development and commercialization rights in China and other selected countries in the Asia-Pacific region.

Our Core Product Candidates include the following:

- Zanutrutinib (BGB-3111) — a potentially best-in-class investigational small molecule inhibitor of BTK, that is currently being evaluated in a broad pivotal clinical program in China and in other markets, including the United States and the European Union, which we refer to as globally, for which we expect to file for approval in China in 2018 initially for the treatment of MCL, and submit an NDA in the first half of 2019 an NDA to the FDA to pursue an accelerated approval for the treatment of WM;
- Tislelizumab (BGB-A317) — an investigational humanized monoclonal antibody against the immune checkpoint receptor PD-1 that is currently being evaluated in a broad pivotal clinical program globally and in China, for which we expect to file for approval in China in 2018 initially for the treatment of cHL; and
- Pamiparib (BGB-290) — an investigational small molecule inhibitor of the PARP1 and PARP2 enzymes that is being evaluated in two pivotal clinical trials in China, with a global Phase 3 trial planned for which we are screening patients in preparation for the first dosing.

We are preparing to launch the two lead product candidates from our internal pipeline, zanutrutinib and tislelizumab, which we believe will address major unmet medical needs and have significant commercial potential.

In addition to our three late-stage clinical drug candidates, our pipeline also includes three internally-developed drug candidates in Phase 1 clinical development: lifirafenib (BGB-283), an investigational RAF dimer inhibitor, BGB-A333, an investigational humanized monoclonal antibody against the immune checkpoint receptor ligand PD-L1, and BGB-A425, an investigational humanized monoclonal antibody against TIM-3.

We entered into a strategic collaboration with Celgene Corporation in August 2017, in which we obtained an exclusive license to market in China Celgene's approved cancer therapies ABRAXANE®, REVLIMID® and VIDAZA®, as well as rights in China to develop and commercialize avadomide (CC-122), an investigational next-generation Cereblon modulator currently in clinical development by Celgene outside of China for lymphoma and hepatocellular carcinomas, or HCC. As part of the

BUSINESS

collaboration, we also granted Celgene an exclusive right to develop and commercialize tislelizumab for solid tumors in the United States, Europe, Japan and the rest of world other than Asia, for which we received US\$263 million in upfront license fees and a US\$150 million equity investment and are eligible to receive up to US\$980 million in milestone payments and royalties on future sales.

Our portfolio also includes sitravatinib, an in-licensed, investigational, spectrum-selective kinase inhibitor in clinical development by Mirati Therapeutics, Inc., or Mirati, for the treatment of non-small cell lung cancer, or NSCLC, and other tumors, for which we are planning to initiate clinical development in China.

We have strong internal capabilities spanning research, clinical development, manufacturing and commercialization. We have advanced six internally-developed candidates into clinical trials, including three into pivotal trials. With more than 500 clinical development personnel in China, the United States, Australia and Switzerland as of July 20, 2018, we have built internal clinical development capabilities globally which we believe provide a competitive advantage over other biotechnology companies in China. We have an 11,000-square meter facility in Suzhou for the manufacture of small molecule drugs at commercial scale and biologics drugs at pilot scale. We are currently building a 24,000-liter commercial-scale biologics manufacturing factory in Guangzhou. We also have a growing commercial team in China, which provides us with the initial commercial platform for the planned launches of our internally-developed drug candidates as well as current and potentially future in-licensed drug candidates.

We have formed collaborations with other biotechnology companies aiming to capture opportunities in China and the broader Asia-Pacific region by leveraging our global clinical development capabilities and China commercial capabilities, as evidenced by our collaborations with Celgene and Mirati.

We believe we are well-positioned to capture the significant market opportunities in China, including those created by recent regulatory reforms and new reimbursement policies in China. China is the second largest pharmaceutical market in the world based on revenue, and the oncology sector grew at a 13.7% CAGR from 2013 to 2017, according to the Frost and Sullivan Report. We believe that there is a large and growing opportunity for novel cancer therapeutics in China based on significant unmet medical need, a large target patient population, expanding reimbursement coverage, and increasing treatment affordability and willingness to pay. In addition, the CDA has undertaken significant regulatory reforms that are designed to accelerate the development of new innovative drugs and allow China to be an integral part of global drug development. In addition, innovative oncology drugs have been included in the most recent NDRL, reducing out-of-pocket expenses for patients. We believe that access to the large number of patients in China during clinical development as well as commercialization creates new opportunities for us. Leveraging our strong China presence and commitment to global standards of innovation and quality, we believe we have a unique ability to effectively take advantage of these opportunities.

BUSINESS

Our Strengths

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

Fully-Integrated Biotechnology Company with Broad Capabilities in China and Globally

Initially started as a research and development company in Beijing in 2010, we have since become a fully-integrated global biotechnology company with broad capabilities spanning research, clinical development, manufacturing and commercialization.

Research. As of July 20, 2018, we had a team of approximately 200 researchers based in Beijing. Our scientific advisory board, which may from time to time provide us with assistance upon our request, is comprised of world-renowned experts with extensive expertise in cancer drug research and development, and is led by Dr. Xiaodong Wang, founding director of China's National Institute of Biological Sciences in Beijing, and member of the U.S. National Academy of Sciences and the Chinese Academy of Sciences. In addition, we have built strong working relationships with key Chinese cancer centers, which give us access to patient biopsy samples that allow us to develop an extensive collection of proprietary cancer models. In eight years, our research team has generated six internally-developed candidates that we have advanced into clinical trials, including three which are currently in pivotal trials.

Clinical Development. We believe clinical development capabilities are critical to success in our industry. We have built internal clinical development capabilities globally, which we believe provide a competitive advantage over other biotechnology companies in China. As of July 20, 2018, we had over 200 clinical development staff in the United States and over 300 in China and the broader Asia-Pacific region. We believe that this global capability enables us to take advantage of significant regulatory reforms in China by integrating China and global clinical development, which allows access to a patient base that is as large as the United States and Europe combined. As of July 5, 2018, we had more than 50 clinical trials ongoing or planned for initiation, including 14 pivotal or potentially registration-enabling trials, with more than 3,000 patients and healthy subjects already enrolled in these trials. These trials include clinical sites in the United States, Australia, New Zealand, China and other Asian countries, as well as Europe. We believe that our broad global clinical development program will translate into significant commercial opportunities. In addition, we believe that our investment in research and development of US\$269 million during 2017 was the largest in oncology and one of the largest by a China-based biopharmaceutical company.

Manufacturing. We have an 11,000-square meter facility in Suzhou for the manufacture of small molecule drugs at commercial scale and biologics drugs at pilot scale. The facility was designed to comply with GMP requirements in China, the European Union and the United States. In January 2018, the facility received a manufacturing license from the Jiangsu Food and Drug Administration, in preparation for the commercial manufacture of zanubrutinib in China. We have another

BUSINESS

100,000-square meter facility under construction in Guangzhou for the manufacture of biologics at commercial scale. This facility is planned to have a 24,000-liter capacity, and over US\$300 million in funding has been committed for the construction of this facility. We expect the first phase of the facility to be completed in 2019. We also have a commercial supply partner, Boehringer Ingelheim, under an exclusive multi-year arrangement to manufacture our biologic drug candidate, tislelizumab, in its manufacturing facility in Shanghai as part of a MAH trial project.

Commercialization. In connection with our collaboration with Celgene, we obtained Celgene's commercial operations in China and an exclusive license to market three of Celgene's cancer therapies, ABRAXANE®, REVLIMID® and VIDAZA®. This collaboration provided us with commercial infrastructure and a marketed drug portfolio in China. We believe that our commercial team has established and maintains strong relationships with leading hospitals and medical professionals. We also believe that we have built relationships with key opinion leaders, or KOLs, in oncology through our years of research and clinical development efforts. Recently, we have strengthened our commercial leadership by adding Dr. Xiaobin Wu, who was the Country Manager of Pfizer China and Regional President of Pfizer Essential Health for Greater China, Ivan Yifei Zhu, who was the Vice President of Sales and Marketing at Janssen China, Vivian Xin Bian, who was the Vice President of Innovative Products Division at Janssen China. We believe these commercial leadership additions will further help build our commercial team and drive future product launches. We believe these efforts position us well for the planned launches of our internally-developed drug candidates as well as current and potentially future in-licensed drug candidates.

Two Late-Stage Clinical Drug Candidates with Significant Commercial Potential

We believe that our two lead drug candidates have significant commercial potential and we are well-positioned to realize these product-based opportunities.

Zanubrutinib. We believe that our lead drug candidate, zanubrutinib, is a potentially best-in-class BTK inhibitor based on the clinical data to date. Zanubrutinib has demonstrated higher selectivity against BTK and higher exposure than the first approved BTK inhibitor IMBRUVICA®, or ibrutinib, in pre-clinical models. As of July 5, 2018, we had enrolled more than 1,200 patients in clinical trials of zanubrutinib. The preliminary data reported to date demonstrated favorable response rates, quality and durability in various B-cell malignancies, such as WM and CLL/SLL.

We are running a broad pivotal clinical program globally and in China, including a global Phase 3 head-to-head trial against ibrutinib in WM, a global Phase 3 trial in treatment-naïve CLL/SLL, a global pivotal Phase 2 trial in combination with obinutuzumab in FL, and three China pivotal Phase 2 trials in MCL, CLL/SLL and WM, respectively, in which the global Phase 3 WM trial and the three China pivotal Phase 2 trials have completed enrollment.

BUSINESS

We have received results from independent review of the Phase 2 study in Chinese patients with R/R MCL. The overall response met the pre-specified criteria for a positive trial. We had a pre-NDA meeting with the CDA earlier this year and based on the feedback we received from the meeting, we currently believe that, subject to the successful completion and satisfactory results of the trials, we are on track to file the NDA for the treatment of R/R MCL in 2018.

In July 2018, zanubrutinib was granted Fast Track Designation by the FDA for the treatment of patients with WM. Based on our discussions with the FDA, internal review of available data from our global Phase 1 trial of zanubrutinib in patients with WM, and supported by the Fast Track Designation, we are preparing to submit in the first half of 2019 an NDA to pursue an accelerated approval of zanubrutinib for patients with WM based on results from the global Phase 1 study. The FDA's Fast Track program is intended to expedite or facilitate the process for reviewing new drugs that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition. A drug candidate with a Fast Track designation may be eligible for more frequent communications with the FDA, eligibility for Accelerated Approval and Priority Review (if relevant criteria are met), and rolling review of the NDA.

BTK inhibitors reported approximately US\$3.2 billion in global sales in 2017 and are projected to reach US\$17.8 billion in 2030 according to the Frost & Sullivan Report. According to the same report, the class of BTK inhibitors is projected to represent a US\$1.6 billion market in China in 2030. We believe there is significant market opportunity given the potentially best-in-class profile and the broad pivotal clinical program that we are currently conducting for zanubrutinib.

Tislelizumab. Tislelizumab is an investigational humanized PD-1 monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. Tislelizumab is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of solid tumors and hematologic cancers. As of July 5, 2018, we had enrolled more than 1,500 patients in clinical trials of tislelizumab. The preliminary data reported to date demonstrated that tislelizumab was generally well-tolerated and exhibited anti-tumor activity in a variety of tumor types. We had a pre-NDA meeting with the CDA, and based on the feedback we received from the meeting, we believe we are on track to file the NDA in China in 2018 initially for the treatment for HL.

We believe that PD-1/PD-L1 antibody therapies represent a large market opportunity, particularly in the favorably evolving China market. According to the Frost & Sullivan Report, the worldwide annual sales of the PD-1/PD-L1 class reached US\$10.1 billion in 2017 and are projected to amount to US\$78.9 billion worldwide and US\$15.1 billion in China in 2030. We believe the China market is particularly attractive, as currently available clinical data suggest that some of the most prevalent cancers in China, such as lung, gastric, liver and esophageal cancers, are responsive to these PD-1/PD-L1 antibody therapies.

We believe that we are uniquely positioned to capture this market opportunity because of our broad clinical development program and growing commercial capabilities in China. As of July 20, 2018, we had initiated four global pivotal or potentially registration-enabling trials of tislelizumab that are intended to support regulatory submissions globally and in China, and two pivotal trials in China, and we and Celgene expect to commence additional pivotal trials in 2018 and 2019. In China, we are also screening patients in preparation for the first dosing in a new pivotal trial, the Phase 3 trial combined with chemotherapy as a first-line treatment for patients with advanced non-squamous NSCLC. We believe that our broad pivotal clinical program will enable wide reimbursement coverage for patients in China and allow us to maximize the commercial opportunities for tislelizumab. In addition, we believe that our strategic partnership with Celgene will further expand our development programs and help maximize the commercial potential for tislelizumab across product combinations and global markets.

Robust Pipeline of Internally-Developed and In-Licensed Product Candidates

Beyond zanubrutinib and tislelizumab, we have an extensive pipeline of internally-developed and in-licensed product candidates that we are developing as monotherapies and in combination with other therapies. We have the internal capacity to develop both biologic and small-molecule drugs. Our recent collaboration with Mirati for sitravatinib provides an example of our ability to supplement internal research and development through external collaboration.

Pamiparib. We believe that pamiparib, a PARP1 and PARP2 inhibitor, has the potential to be differentiated from other PARP inhibitors because of its potential brain penetration, high selectivity, strong DNA-trapping activity and good oral bioavailability, based on pre-clinical data. In Phase 1/2 trials to date, it was demonstrated that pamiparib was generally well-tolerated and showed promising anti-tumor activity in ovarian cancer, and initial data from the dose-escalation portion of the Phase 1 trial of tislelizumab in combination with pamiparib suggested that the combination was generally well-tolerated and showed anti-tumor activity in multiple solid tumor types. We currently have a pivotal Phase 2 trial in China in patients with germline BRCA-mutated ovarian cancer and a Phase 3 trial in China as a potential maintenance therapy in patients with platinum-sensitive ovarian cancer. We are also screening patients in preparation of the first dosing of a global Phase 3 maintenance trial in patients with platinum-sensitive GC.

Other early-stage assets. We are pursuing the clinical development of other early-stage drug candidates, advancing pre-clinical drug candidates toward clinical trials and developing additional novel drug candidates. For example, three internally-developed drug candidates, lifirafenib, BGB-A333, and BGB-A425 are in Phase 1 clinical development. Sitravatinib is in clinical development by Mirati for the treatment of NSCLC and other tumors, and avadomide (CC-122) is currently in clinical development by Celgene for lymphomas and HCC.

BUSINESS

Experienced Management Team with Diverse Backgrounds and Skill Sets

We have assembled an experienced management team with geographically diverse backgrounds and skillsets to lead our company. Our Co-Founder, Xiaodong Wang, Ph.D., is a highly respected cancer scientist, a member of the U.S. National Academy of Sciences and the Chinese Academy of Sciences, and head of China's National Institute of Biological Sciences. John Oyler, our Co-Founder, Chief Executive Officer and Chairman of the Board is a serial entrepreneur with a track record of successfully starting and managing companies in several industries including biotechnology. Dr. Xiaobin Wu, our General Manager of China and President, was the Country Manager of Pfizer China and Regional President of Pfizer Essential Health for Greater China and has 17 years of experience leading China operations of multinational companies. Our management team has experience successfully translating scientific visions into tangible drug candidates, solving complex issues in clinical development, progressing drug candidates through regulatory approval, and commercializing innovative therapies.

Our Strategy

Our mission is to become a global leader in the discovery, development and commercialization of innovative therapies. In the near term, we plan to focus on pursuing the following significant opportunities:

Globally Develop and Commercialize Zanubrutinib, a Potentially Best-in-Class BTK Inhibitor

Zanubrutinib is an investigational small molecule inhibitor of BTK that is currently being evaluated both as a monotherapy and in combination with other therapies to treat various lymphomas. Our clinical experience to date suggests a potentially best-in-class profile. To pursue this opportunity, we are conducting a broad pivotal clinical program globally and in China, including a global Phase 3 trial head-to-head against ibrutinib in WM, a global Phase 3 trial in treatment-naïve CLL/SLL, a global pivotal Phase 2 trial in combination with obinutuzumab in FL, and three China pivotal Phase 2 trials in MCL, CLL/SLL and WM, respectively. Subject to the successful completion and satisfactory results of the trials, we expect to file for approval in China in 2018 for the treatment of R/R MCL and accelerated approval in the U.S. for the treatment of WM in the first half of 2019.

Develop and Commercialize Our Investigational Checkpoint Inhibitor, Tislelizumab, in a Rapidly and Favorably Evolving China Market

We believe that there is a large and growing opportunity for novel cancer therapeutics in China and that the market opportunity for PD-1/PD-L1 antibody therapies may be especially attractive, as this class of agents has demonstrated anti-tumor activity in all four of the most common tumors in China: lung, gastric, liver and esophageal cancers. We believe that we are uniquely positioned to capture this opportunity with our strategic collaboration with Celgene, our strong presence in China, and our integrated global and China clinical development capabilities. We have initiated global Phase 3 trials to evaluate tislelizumab as a potential second- or third-line treatment compared to docetaxel

in patients with NSCLC; as a potential first-line treatment compared to sorafenib in patients with HCC; and as a potential second-line treatment compared to investigator-chosen chemotherapy in patients with esophageal squamous cell carcinoma, or ESCC. We also have a global Phase 2 trial in patients with previously treated advanced HCC, as well as a global Phase 2 trial in patients with relapsed or refractory mature T- and NK-cell lymphomas. We and our strategic collaborator Celgene expect to commence additional global pivotal trials in 2018 and 2019. Moreover, we have two additional China pivotal trials ongoing, and subject to the successful completion and satisfactory results of the trials, we expect to file for approval in China for the treatment of cHL in 2018. We are also screening patients in preparation for the first dosing in a new pivotal trial, the Phase 3 trial combined with chemotherapy as a first-line treatment for patients with advanced non-squamous NSCLC.

Build A Leadership Position by Further Expanding Our Capabilities

Although we believe that we have significant integrated capabilities in research and clinical development, manufacturing and commercialization, we plan to continue to strengthen and expand our platform. In particular, we plan to significantly expand our commercial capabilities in China in preparation for the potential launch of our drug candidates and to support our existing marketed drugs. We have an established commercial team in China, which provides coverage of large hospitals and physician clients. As a result of the improving reimbursement environment in China, which is expected to provide access to innovative medicines for a significantly larger number of patients, we believe that the scale of our commercial organization and the breadth of our market coverage will become even more important. We plan to invest in expanding our teams of sales and marketing, market access, medical and scientific affairs, compliance, and other supporting functions. We aim to become a leading organization in the commercialization of oncology drugs in China. Outside of China, we also plan to build commercial capabilities in the hematology-oncology area ahead of the potential launch of zanubrutinib. In addition, we plan to continue to invest in building our global clinical development capabilities, which we believe will provide a competitive advantage in allowing us to conduct pivotal trials to support approvals globally and in China.

Take Advantage of Significant Regulatory Reforms in China to Accelerate Global Drug Development

Historically, the regulatory environment in China has been considered highly challenging, with clinical development significantly delayed and regulatory approvals taking much longer than in the United States and Europe. To address these challenges, the CDA has issued a series of reform policies and opinions, which, among many things, are expected to expand access to clinical patients and expedite development and approval by removing delays and creating an environment with international quality standards for drug development, manufacturing and commercialization in China. We expect that these regulatory reforms will allow clinical trials in China to play a major role in global drug development programs. We also believe that the ability to effectively operate in China and integrate trials conducted in China with those in the rest of the world will be of increasing strategic importance. We are already taking advantage of these opportunities by conducting and leading dual-purpose global / China registration trials under our collaboration with Celgene.

BUSINESS

Expand Our Product Portfolio and Pipeline Through Collaborations with Other Biopharmaceutical Companies to Complement Our Internal Research

We expect to further expand our portfolio of drugs and drug candidates, in oncology as well as potentially in other therapeutic areas, through internal research and external collaborations. We intend to pursue collaborations with other biopharmaceutical companies both in China and globally by leveraging our strong clinical development capabilities. We have pursued and plan to continue to pursue business development opportunities, such as our collaboration with Mirati, in which development in China is expected to contribute to, and potentially accelerate, the global development program. We believe that there will be increasing interest by international biopharmaceutical companies in seeking collaborations in Asia, particularly in oncology, where clinical recruitment is a major bottleneck in new drug development.

Our Pipeline and Commercial Products

The following table summarizes the status of our pipeline and commercial products:

Program (Target)	Commercial Rights	Dose Esc		Dose Exp		Pivotal		Lead Indications
		Phase 1a	Phase 1b	Phase 2*	Phase 2*	Phase 3	Phase 3	
zanubrutinib (BGB-3111, BTK)	Worldwide							• WM, 1L CLL/SLL • R/R MCL, R/R CLL/SLL, WM (pivotal Phase 2)
zanubrutinib + CAZEPYR [†] (BTK + CD20)	Worldwide							• R/R FL (pivotal Phase 2)
tislelizumab (BGB-A317, PD-1)	Worldwide for harm malignancy, Asia ex-Japan for solid tumors [†]							• 2L NSCLC, 1L HCC, 2L ESCC • R/R d-L, 2L+ UC (pivotal Phase 2) • 2L/3L HCC (pivotal Phase 2) • R/R NKT-cell lymphoma
tislelizumab + pamiparib (PD-1 + PARP)	Worldwide							• Solid tumors
tislelizumab + zanubrutinib (PD-1 + BTK)	Worldwide							• B-cell malignancies
pamiparib (BGB-290, PARP)	Worldwide [‡]							• 2L, platinum-sensitive OC maintenance • 3L gBRCA+ OC (pivotal Phase 2) • Solid tumors
pamiparib + TMZ (PARP + Chemo)	Worldwide [‡]							• Solid tumors
pamiparib + RT/TMZ (PARP + RT/Chemo)	Worldwide [‡]							• Glioblastoma
lifiralenib (BGB-283, RAF Dimer)	Worldwide [‡]							• B-Raf- or K-RAS/N-RAS-mutated solid tumors • B-Raf- or K-RAS/N-RAS-mutated solid tumors
BGB-A333 + tislelizumab (PD-L1 +/- PD-1)	Worldwide							• Solid tumors
BGB-A425 (TGF- β)	Worldwide							• Solid tumors
REVLIMID [®] (IMiD) ^{***}	China							• R/R MM (marketed), NDMM (marketed), R/R N-HL (Phase 3)
ABRAXANE [®] (Albumin-bound paclitaxel)	China							• Breast cancer
VIDAZA [®] (hypomethylating agent)	China							• MDS, AML, with 20-30% bone marrow blasts, CMML
irradonide (CC-122, CELMoD)	China							• NHL
sitravatinib (multi-kinase inhibitor)	Asia ex-Japan, AU, NZ [‡]							• NSCLC

*Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or 3 clinical trials. **Confirmatory clinical trials post approval are required for accelerated approvals. ***Received approval as a combination therapy with doxorubicin. † Celgene has the right to develop and commercialize tislelizumab in solid tumors in the United States, European Union, Japan and the rest-of-world outside of Asia. ‡ Limited collaboration with Merck KGaA. † Partnership with Mirati Therapeutics, Inc.

Abbreviations: Dose Esc = dose escalation; Dose Exp = dose expansion; WM = Waldenström's macroglobulinemia; 1L = first line; CLL = chronic lymphocytic leukemia; SLL = small lymphocytic lymphoma; R/R = relapsed / refractory; MCL = mantle cell lymphoma; FL = follicular lymphoma; 2L = second line; NSCLC = non-small cell lung cancer; HCC = hepatocellular carcinoma; ESCC = esophageal squamous cell carcinoma; HL = Hodgkin's lymphoma; UC = urothelial carcinoma; 3L = third

BUSINESS

line treatment; gBRCA = germline BRCA; OC = ovarian cancer; TMZ = temozolomide; RT = radiotherapy; IMiD = immunomodulatory drugs; MM = multiple myeloma; ND = newly diagnosed; NHL = non-Hodgkin's lymphoma; MDS = myelodysplastic syndrome; AML = acute myeloid leukemia; CMMoL = chronic myelomonocytic leukemia; DLBCL = diffuse large B-cell lymphoma;

* Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or 3 clinical trials.

** Confirmatory clinical trials post-approval are required for accelerated approvals.

*** REVLIMID® approved as a combination therapy with dexamethasone.

¹ Celgene has the right to develop and commercialize tislelizumab in solid tumors in the United States, Europe, Japan and the rest-of-world outside of Asia.

² Limited collaboration with Merck KGaA.

³ Partnership with Mirati Therapeutics, Inc.

Our drug candidates are subject to NDA approval by the relevant authorities, such as the FDA and the CDA, before commercialization in the relevant jurisdictions. Please refer to the section titled “Regulations — U.S. Regulation — U.S. Government Regulation and Product Approval” and “— PRC Regulation — PRC Drug Regulation” for details. As of the date of this [REDACTED], we believe that we have not received any material comments or concerns raised by the CDA that we are not able to address in a timely manner, and we believe we are on track to file the NDAs related to our Core Product Candidates as described in the section titled “— Our Clinical-Stage Drug Candidates.”

Our Clinical-Stage Drug Candidates

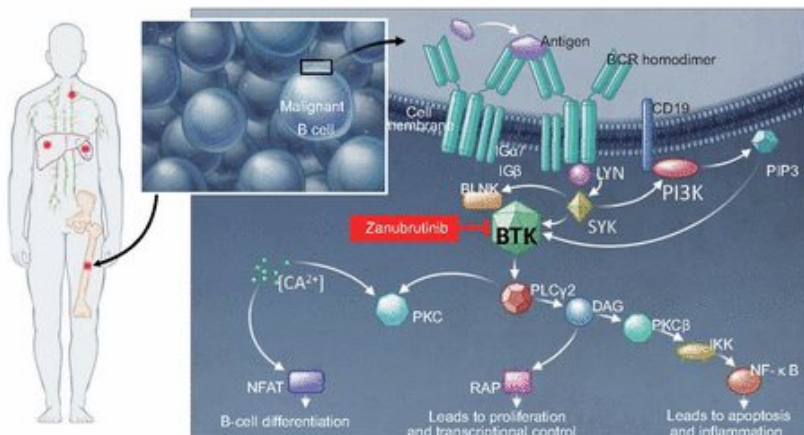
Zanubrutinib (BGB-3111), a BTK Inhibitor

Zanubrutinib is an investigational small molecule inhibitor of BTK that is currently being evaluated in a broad pivotal clinical program globally and in China as a monotherapy and in combination with other therapies to treat various lymphomas. Zanubrutinib has demonstrated higher selectivity against BTK than IMBRUVICA® (ibrutinib), an approved BTK inhibitor, based on our biochemical assays, higher exposure than ibrutinib based on their respective Phase 1 experience in separate studies, and sustained 24-hour BTK occupancy in both the peripheral blood and lymph node compartments.

Mechanism of Action

BTK is a key component of the BCR signaling pathway and is an important regulator of cell proliferation and cell survival in various lymphomas. BTK inhibitors block BCR-induced BTK activation and its downstream signaling, leading to growth inhibition and cell death in certain malignant white blood cells called B-cells. Zanubrutinib is an orally active inhibitor that covalently binds to BTK, resulting in irreversible inactivation of the enzyme.

BTK Inhibitor Mechanism of Action



BCR=B-cell antigen receptor, BLNK=B cell linker, BTK=Bruton's tyrosine kinase, CA2+=calcium, CD19=cluster of differentiation 19, DAG=1,2 di-acyl glycerol, IKK=I kappa B kinase, LYN=LYN proto-oncogene, Src family tyrosine kinase, NFκB=nuclear factor kappa B, NFAT=nuclear factor of activated T cells, PI3K=phosphatidylinositol-4,5-bisphosphate 3-kinase, PIP3=phosphatidylinositol (3,4,5) trisphosphate, PKC=protein kinase C, PLC=phospholipase C, RAP=Rap GTP-binding protein also known as Ras-related protein, SYK=spleen tyrosine kinase. Hendriks RW. *Nature Chem Biol.* 2011;7(1):4-5.

Market Opportunity and Competition

Lymphomas are blood-borne cancers involving lymphatic cells of the immune system. They can be broadly categorized into NHL and HL. Depending on the origin of the cancer cells, lymphomas can also be characterized as B-cell or T-cell lymphomas. B-cell lymphomas make up approximately 85% of NHLs and comprise a variety of specific diseases involving B-cells at differing stages of maturation or differentiation. According to statistics from the SEER program of the U.S. National Cancer Institute, there were 72,240 new NHL cases and 20,140 deaths, and 20,110 new CLL, cases and 4,660 deaths in 2017 in the United States. According to a published study (Chen et al., *Cancer Statistics in China, 2015*, *CA Cancer J. Clin.* 2016; 66(2):115-32), which we refer to as Chen et al. 2016, and GLOBOCAN 2012 analyses on cancer statistics in China, there are an estimated 42,000 to 88,000 new lymphoma cases and 26,000 to 53,000 deaths in China each year.

Conventional methods of treating lymphomas vary according to the specific disease or histology, but generally include chemotherapy, antibodies directed at CD20, and, less frequently, radiation. Recently, significant progress has been made in the development of new therapies for lymphomas, including BTK inhibitors, PI3K inhibitors, idelalisib, copanlisib and the Bcl-2 inhibitor, venetoclax. Most recently, a cell-based therapy, YESCARTA®, was approved for the treatment of diffuse large B-cell lymphoma, or DLBCL. YESCARTA® is a CD 19 directed genetically modified autologous T-cell immuno-oncology therapy.

BUSINESS

The BTK inhibitor ibrutinib was first approved by the FDA in 2013 for the treatment of patients with MCL, who have received at least one prior therapy. Since 2013, ibrutinib has received supplemental FDA approvals for the treatment of patients with CLL, CLL patients with 17p deletion, patients with WM, patients with MZL, who have received at least one prior anti-CD20-based therapy, and patients with chronic graft versus host disease after failure of one or more lines of systemic therapy. Ibrutinib is also approved by the EMA for the treatment of patients with MCL, CLL or WM. Ibrutinib has been approved in over 80 countries and regions, and it was approved and launched in China at the end of 2017. In 2017, global revenues for BTK inhibitors were approximately US\$3.2 billion. Another BTK inhibitor, CALQUENCE® (acalabrutinib) was approved by the FDA in 2017 under accelerated approval for the treatment of patients with MCL who have received at least one prior therapy. The table below summarizes the China competitive landscape of zanubrutinib, according to the Frost & Sullivan Report.

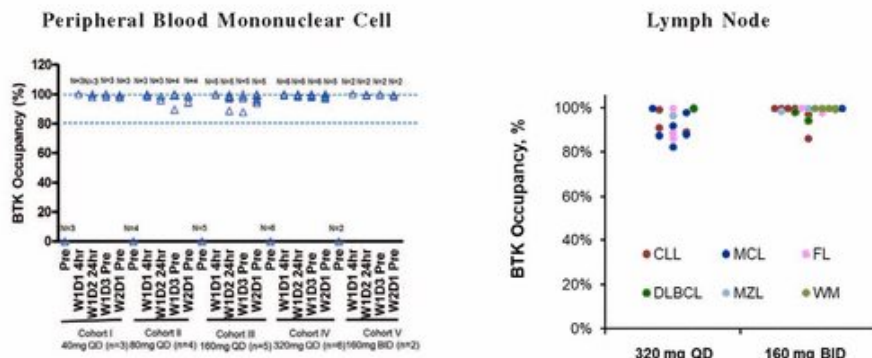
BTK Competitive Landscape in China (Late-Stage)							
Mechanism: Bruton's tyrosine kinase plays a role in signaling through the B-cell surface receptors which results in activation of pathways necessary for B-cell trafficking, chemotaxis, and adhesion. Nonclinical studies show that BTK inhibition could inhibit malignant B-cell proliferation and survival.							
Products (generic name)	Products (brand name)	Company	CDA Status	Lead Indications	Reimbursement	U.S. Patent Exclusivity	Generic Versions
ibrutinib	IMBRUVICA®	Pharmaceuticals, J&J, AbbVie	Approved (2017.11)	R/R CLL/SLL and R/R MCL	Zhejiang CII	2027	NA
zanubrutinib (BGB-3111)	NA	BeiGene	Pivotal PhII	R/R MCL, R/R CLL/SLL, WM	NA	2034	NA
acalabrutinib	CALQUENCE®	Acerta, AstraZeneca	CTA submitted (2018.6)	Early phase	NA	2032	NA

Abbreviations: CII = Critical Illness Insurance; CTA = Clinical trial application; NA = not applicable

Summary of Clinical Results

As of July 5, 2018, we have enrolled more than an aggregate of 1,200 patients in clinical trials of zanubrutinib, including trials of zanubrutinib in combination with other therapies, which we refer to as combination trials. A multi-center, open-label Phase 1 trial is being conducted in Australia, New Zealand, the United States, South Korea and European countries to assess the safety, tolerability, pharmacokinetic properties and preliminary activity of zanubrutinib as a monotherapy in patients with different subtypes of B-cell malignancies, such as WM, CLL/SLL, FL, and MCL. The initial results of the dose-escalation phase and dose-expansion phase of this trial, as shown in the chart below, demonstrated that, consistent with zanubrutinib's pharmacokinetic profile, complete and sustained 24-hour BTK occupancy in the blood was observed in all tested patients, starting at the lowest dose of 40 mg once daily. In addition, sustained full BTK occupancy was observed in the lymph nodes especially for the 160 mg twice daily dosing regimen. There is no guarantee that these results will be reproduced in pivotal trials.

Clinical Trial Data Show Sustained Full BTK Occupancy



Note:

Data from 20 patients.
W1D1 stands for week 1 day 1;
W1D2 stands for week 1 day 2;
W1D3 stands for week 1 day 3;
W2D1 stands for week 2 day 1;
Pre stands for pre-dose

Note:

QD means once daily,
BID means twice daily.
Paired lymph node biopsies were
collected during screening or pre-dose
on day 3.

Waldenstrom's Macroglobulinemia

On June 15, 2018, we presented data from our Phase 1 trial in patients with WM at the 23rd Congress of the EHA in Stockholm, Sweden. As of the data cutoff of November 3, 2017, 67 WM patients were enrolled in the study. At the time of the data cutoff, 59 patients remained on study treatment. Responses were determined according to the modified Sixth International Workshop on WM Criteria.

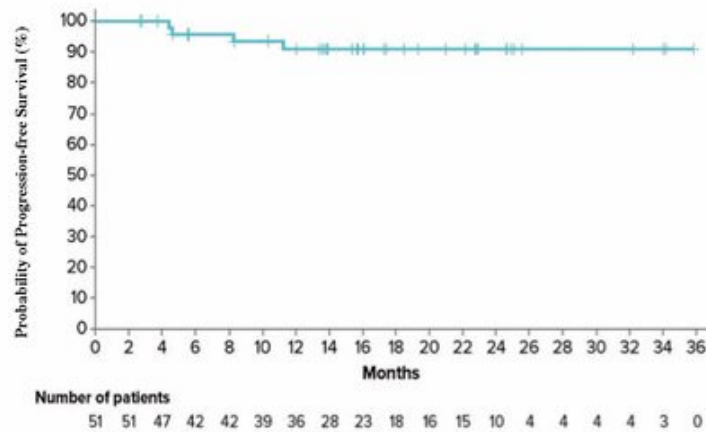
Zanubrutinib was observed to be generally well-tolerated with no discontinuation for zanubrutinib-related toxicity. AEs were generally mild in severity and self-limited. The most frequent AEs (>15%, all grade 1-2 but one) of any attribution among 67 patients evaluable for safety were petechia/purpura/contusion (37%), upper respiratory tract infection (34%), constipation (18%) and diarrhea (18%). Grade 3-4 AEs of any attribution reported in two or more patients included anemia (7%), neutropenia (6%), basal cell carcinoma (3%), hypertension (3%), squamous cell carcinoma (3%), pyrexia (3%), pneumonia (3%), major hemorrhage (3%), and actinic keratosis (3%). Serious AEs, or SAEs, were seen in 22 patients (33%), with events in five patients (7%) considered possibly related to zanubrutinib treatment: febrile neutropenia, colitis, atrial fibrillation, hemothorax (spontaneous) and headache. Among AEs of special interest, four patients (6%) experienced atrial fibrillation (all grade 1 or 2) and two patients experienced major hemorrhage. Four patients (6%) discontinued study treatment due to AEs, including fatal worsening bronchiectasis, prostate cancer, gastric adenocarcinoma, and acute myeloid leukemia. Two patients (3%) discontinued study treatment due to disease progression as assessed by investigator and one patient remains on treatment post disease progression.

BUSINESS

At the time of the data cutoff, 51 patients were evaluable for response, excluding those with less than 12 weeks of follow-up (n=13) and those with IgM less than 5 g/L at baseline (n=3). Of the 51 patients evaluable for efficacy, 12 were treatment naïve and 39 patients were relapsed or refractory to prior treatment. The overall response rate, or ORR, was 92% (47/51), and the major response rate was 80%, with 43 percent of patients achieving a very good partial responses, or VGPR, (defined as a >90% reduction in baseline IgM levels and improvement of extramedullary disease by CT scan). The 12-month progression-free survival (PFS) was estimated at 91%, and the median PFS had not yet been reached with 16.9 months median follow-up. Median time to response (partial response or higher) was 88 days (range, 77-279). The median IgM decreased from 32.5 g/L (range, 5.3-88.5) at baseline to 4.9 g/L (range, 0.1-57). Of 22 patients with hemoglobin <10 g/dL at baseline, the median increased from 8.7 g/dL (range, 6.3-9.8) to 13.8 g/dL (range, 7.7-15.8). While the presence of MYD88L265P appears to be associated with response and depth of response with zanubrutinib treatment, significant activity was also observed in patients with MYD88WT (ORR 83%, major response rate 50%, VGPR rate 17%).

The table below shows the progression-free survival data of WM patients treated with zanubrutinib:

Progression-Free Survival in Evaluable Patients (n=51)



1

Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma

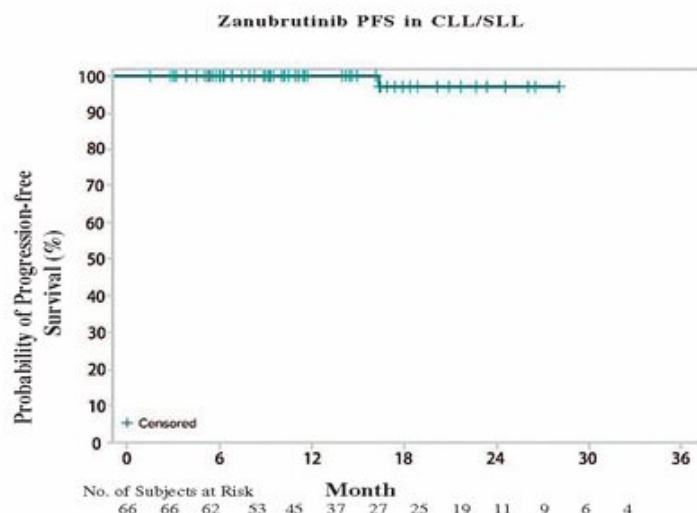
On June 14, 2017 at the 14th International Conference on Malignant Lymphoma in Lugano, Switzerland, we presented the data in patients with CLL/SLL from the same trial. As of the data cutoff of March 31, 2017, 69 patients with CLL or SLL (18 treatment naïve, or TN, 51 R/R) were enrolled in the trial.

Zanubrutinib was shown to be generally well-tolerated in CLL/SLL. The most frequent AEs (≥10%) of any attribution were petechiae/purpura/contusion (46%), fatigue (29%), upper respiratory

tract infection (28%), cough (23%), diarrhea (22%), headache (19%), hematuria (15%), nausea (13%), rash (13%), arthralgia (12%), muscle spasms (12%) and urinary tract infection (12%). All of these events were grade 1 or 2 except for one case of grade 3 purpura (subcutaneous hemorrhage), which was the only major bleeding event. Additional AEs of interest included one case of each grade 2 diarrhea and grade 2 atrial fibrillation. A total of 18 SAEs occurred in 13 patients, with no SAE occurring in more than one patient. Only one patient discontinued treatment due to an AE, a grade 2 pleural effusion.

At the time of the data cutoff, 66 patients (16 TN and 50 R/R) had more than 12 weeks of follow-up and were evaluable for efficacy, and three other patients had less than 12 weeks of follow-up. After a median follow-up of 10.5 months (2.2–26.8 months), the ORR was 94% (62/66) with complete responses, or CRs, in 3% (2/66), PRs in 82% (54/66), and PRs with lymphocytosis, or PR-Ls, in 9% (6/66) of patients. Stable disease, or SD, was observed in 5% (3/66) of patients. The patient with pleural effusion discontinued treatment prior to week 12 and was not evaluable for response. There was one instance of Hodgkin's transformation. In TN CLL/SLL, at a median follow-up time of 7.6 months (3.7–11.6 months), the ORR was 100% (16/16) with CRs in 6% (1/16), PRs in 81% (13/16) and PR-Ls in 13% (2/16) of patients. In R/R CLL/SLL, at a median follow-up time of 14.0 months (2.2–26.8 months), the ORR was 92% (46/50) with CRs in 2% (1/50), PRs in 82% (41/50) and PR-Ls in 8% (4/50) of patients. SD was observed in 6% (3/50) patients.

The table below shows the progression-free survival data of CLL/SLL patients treated with zanubrutinib:



Other Lymphomas

On December 9, 2017, we presented additional data from our Phase 1 trial at the 59th American Society of Hematology, or ASH, Annual Meeting in Atlanta, GA. This dataset included 34 patients in an indolent lymphoma cohort, which consisted of 24 patients with FL and 10 patients with MZL, and 65 patients in an aggressive lymphoma cohort, which consisted of 27 patients with diffuse large B-cell lymphoma, or DLBCL, and 38 patients with MCL. The median follow-up time was 5.6 months (0.3—22.3 months) and 5.1 months (0.1—31.9) for indolent and aggressive lymphoma, respectively.

As of the data cutoff of September 15, 2017, the most frequent AEs (occurring in $\geq 15\%$ of patients) of any attribution among 34 patients with indolent lymphoma were petechiae/purpura/contusion (24%), upper respiratory tract infection (21%), nausea (18%) and pyrexia (15%). The most frequently reported grade 3 or greater AEs (occurring in $\geq 5\%$ of patients) of any attribution were anemia (9%), neutropenia (9%), urinary tract infection (6%) and abdominal pain (6%). SAEs were reported in 11 patients (32%). Of those, four patients had SAEs that were considered possibly related to zanubrutinib, including one case each of nausea, urinary tract infection, diarrhea and creatinine increase.

The most frequent AEs (occurring in $\geq 15\%$ of patients) of any attribution among 65 patients with aggressive lymphoma were petechiae/purpura/contusion (25%), diarrhea (23%), constipation (22%), fatigue (18%), upper respiratory tract infection (18%), anemia (17%), cough (15%), pyrexia (15%) and thrombocytopenia (15%). The most frequently reported grade 3 or greater AEs (occurring in $\geq 5\%$ of patients) of any attribution were anemia (11%), neutropenia (9%), thrombocytopenia (9%) and pneumonia (6%). SAEs were reported in 26 patients (40%). Of those, three patients had SAEs that were considered possibly related to zanubrutinib, including one case each of peripheral edema and joint effusion (occurring in the same patient), pneumonia and pneumonitis.

At the time of data cutoff, 26 patients with indolent lymphoma, including 17 patients with FL and nine patients with MZL, were evaluable for efficacy. In patients with FL, the ORR was 41%, with CRs in 18% and PRs in 24% of patients. SD was observed in 41% of patients. Progressive disease was observed in one patient. In patients with MZL, the ORR was 78%, with no CRs and PRs in 78% of patients. SD was observed in 22% of patients. No progressive disease was observed.

58 patients with aggressive lymphoma, including 26 patients with DLBCL and 32 patients with MCL, were evaluable for efficacy. In patients with DLBCL, the ORR was 31%, with CRs in 15% and PRs in 15% of patients. In patients with MCL, the ORR was 88%, with CRs in 25% and PRs in 63% of patients.

Combination with GAZYVA® (obinutuzumab)

We are also evaluating zanubrutinib in combination with GAZYVA® (obinutuzumab), an approved anti-CD20 antibody therapy, in patients with B-cell lymphoma in an open label, multi-center Phase 1b trial in Australia, the United States and South Korea. On December 9, 2017, we presented

updated preliminary clinical data from this trial at the 59th ASH Annual Meeting in Atlanta, GA. As of the data cutoff of September 15, 2017, 45 patients with CLL/SLL and 26 patients with FL were enrolled in the trial. The preliminary Phase 1b data demonstrated that the combination was generally well-tolerated and was highly active in patients with FL and TN or R/R CLL/SLL.

At the time of data cutoff, the most common AEs were grades 1 and 2. The most common AEs in patients with CLL/SLL (occurring in $\geq 20\%$ of patients) of any attribution were petechiae/purpura/contusion (42%), neutropenia (40%), upper respiratory tract infection (36%), fatigue (24%), thrombocytopenia (24%), diarrhea (20%) and pyrexia (20%). The most common AEs in patients with FL (occurring in $\geq 20\%$ of patients) of any attribution were upper respiratory tract infection (38%), petechia/purpura/contusion (35%), rash (27%) and thrombocytopenia (23%). Grade 3 or 4 AEs of any attribution reported in $\geq 5\%$ of the CLL/SLL patients included neutropenia (24%) and thrombocytopenia (7%). Grade 3 or 4 AEs of any attribution reported in $\geq 5\%$ of the FL patients included neutropenia (12%). There were no cases of serious hemorrhage, which is \geq grade 3 hemorrhage or central nervous system hemorrhage of any grade, atrial fibrillation, or grade 3 or above diarrhea. Only one patient with CLL/SLL discontinued treatment due to an AE, a case of squamous cell carcinoma, or SCC, who had a prior history of SCC. This was also the only patient in the study who had a fatal AE.

45 patients with CLL/SLL (20 TN and 25 R/R) and 21 patients with R/R FL were evaluable for efficacy. In TN CLL/SLL patients, after a median follow-up of 11.4 months (6.0–17.3 months), the ORR was 95%, with CRs in 35% and PRs in 60% of patients. In R/R CLL/SLL patients, at a median follow-up time of 12.7 months (7.9–19.5 months), the ORR was 92%, with CRs in 20% and PRs in 72% of patients. In R/R FL patients, at a median follow-up time of 12.1 months (0.8–19.7 months), the ORR was 76%, with CRs in 38% and PRs in 38% of patients.

Combination with Tislelizumab

We are also evaluating zanubrutinib in combination with our investigational anti-PD1 antibody tislelizumab. The open-label, multi-center Phase 1b trial is being conducted in Australia and is currently in a dose-escalation phase to be followed by a dose-expansion phase. On December 11, 2017, we presented initial data from the ongoing Phase 1b trial at the 59th ASH Annual Meeting in Atlanta, GA. The initial dose-escalation data suggested that the combination of zanubrutinib and tislelizumab was generally well-tolerated and exhibited anti-tumor activity in patients with B-cell malignancies. As of September 15, 2017, 25 patients had been enrolled. There were 13 patients with indolent lymphoma, including CLL, FL, MZL and WM, and 12 patients with aggressive lymphoma, including DLBCL, MCL and transformed lymphoma. The median follow-up time was 5.1 months (0.4–14.1 months). Two cases of autoimmune hemolysis occurred in patients with WM in the dose 2 cohort, and one qualified as a dose-limiting toxicity, or DLT. These events were not associated with a positive direct antiglobulin test and were resolved with immunosuppressive therapy, but resulted in the decision to exclude further enrollment of WM patients in the trial. As of the data cutoff date, this autoimmune hemolysis is the only DLT case that was observed.

Among patients with indolent lymphoma, the most common AEs (occurring in $\geq 20\%$ of patients) of any attribution were petechiae/purpura/contusion (31%) and thrombocytopenia (23%). Grade 3 and 4 AEs of any attribution reported in at least two patients included thrombocytopenia, anemia and hemolysis (15% each). In addition to the two cases of autoimmune hemolysis, there was one more immune-related event, a grade 4 autoimmune encephalitis. The patient was treated with aggressive immunosuppressive therapy and gradually improved over time.

Among patients with aggressive lymphoma, the most common AEs (occurring in $\geq 20\%$ of patients) of any attribution were diarrhea, fatigue, pyrexia, upper respiratory tract infection (33% each), cough (25%) and nausea (25%). Grade 3 and 4 AEs of any attribution reported in at least two patients included pyrexia (17%). There was one patient with multiple occurrences of grade 2 and 3 pneumonitis.

In addition, certain IRAEs may be associated with checkpoint inhibition and the combination of checkpoint inhibitors with other drugs.

At the time of data cutoff, the efficacy-evaluable population consisted of 25 patients. Objective responses were observed in 10 patients (40%). By tumor type, two PRs were observed out of five patients with CLL, one CR and one PR were observed out of five patients with FL, one VGPR and one minor response were observed out of two patients with WM, one CR was observed out of five patients with DLBCL, and three PRs were observed out of five patients with transformed lymphoma.

Pooled Analysis of Safety Data from Monotherapy Trials

We presented at the 2018 EHA meeting the pooled safety data from patients with various B-cell lymphomas in four ongoing zanubrutinib monotherapy studies, totaling 476 patients with a median exposure of seven months. Overall, the data suggest that exposure levels of zanubrutinib resulting in complete and sustained BTK inhibition can be achieved and that zanubrutinib was generally well-tolerated. There are infrequent events of interest with BTK inhibitor therapy, such as atrial fibrillation/flutter (2%), major hemorrhage (2%), and grade 3 and above diarrhea (1%). Treatment discontinuation due to zanubrutinib-related AEs was uncommon (3%). The majority of patients (94%) experienced one or more AE of any attribution, primarily grades 1 or 2. The most common grade 3 or higher AEs of any attribution were neutropenia/neutrophil count decreased/febrile neutropenia (14%), anemia (7%) and thrombocytopenia/platelet count decreased (7%). SAEs were reported in 116 patients (24%), with 38 patients (8%) assessed by the investigator as related to zanubrutinib. The most common SAEs were pneumonia/lung infection (6%), pleural effusion (1%), and febrile neutropenia (1%). The only treatment-related SAE reported in greater than 1% of patients was pneumonia/lung infection (2%). No cases of pneumocystis jiroveci pneumonia (PJP) or cytomegalovirus (CMV) reactivation were reported. The most common bleeding events observed included petechiae/purpura/contusion (26%) and hematuria (11%). Major hemorrhage (2%) included gastrointestinal hemorrhage/melena (n=3), intraparenchymal CNS hemorrhage grade 5, hematuria, purpura, hemorrhagic cystitis, renal hematoma, and hemothorax (one each). The median time to first major hemorrhage was 1.2 months. Among patients with emergent atrial fibrillation/flutter (n=8), a majority had known risk factors including hypertension (n=2), pre-existing cardiovascular disease (n=2), and concurrent infection (n=1). The cumulative rates of grade 3 or higher infections were 14 percent at six months, 19% at 12 months and 21% at 18 months. The exposure-adjusted incidence rate was 1.82 per 100 person-months. The most common second primary malignancies included basal cell carcinoma (3%) and squamous cell carcinoma of the skin (1%).

Clinical Development Plan

Based on the clinical data to date, we believe that zanubrutinib has a potentially best-in-class profile, and we are running a broad global pivotal program in multiple indications.

Globally, we have an ongoing monotherapy head-to-head Phase 3 trial versus ibrutinib in WM, which has met the enrollment target. The trial has closed new patient screening and completed enrollment. We are also conducting an ongoing Phase 3 trial compared to bendamustine and rituximab in patients with TN CLL/SLL; and an ongoing Phase 2 trial in combination with GAZYVA® (obinutuzumab) in patients with FL, which is a pivotal trial for accelerated or conditional approval and will require a confirmatory study. We are also planning a Phase 3 trial for head-to-head comparison versus ibrutinib in patients with R/R CLL/SLL, which is expected to be initiated in 2018.

In July 2018, zanubrutinib was granted Fast Track Designation by the FDA for the treatment of patients with WM. Based on our discussions with the FDA, internal review of available data from our global Phase 1 trial of zanubrutinib in patients with WM, and supported by the Fast Track Designation, we are preparing to submit in the first half of 2019 an NDA to pursue an accelerated approval of zanubrutinib for patients with WM based on results from the global Phase 1 study.

In China, we are conducting three separate pivotal Phase 2 trials of zanubrutinib as monotherapy in patients with R/R MCL, R/R CLL/SLL, and WM, respectively. We expect to file for regulatory approvals in China for zanubrutinib in these indications based on the results of these Phase 2 trials. If we receive conditional approval instead of full approval, we will be required to conduct one or more confirmatory studies after such conditional approvals. We have completed enrollment in all three pivotal trials. On June 15, 2018, we announced results from the independent review of response data from the 86-patient single-arm pivotal Phase 2 study of zanubrutinib in Chinese patients with relapsed or refractory MCL. The ORR of 84% (59% complete response rate) met the pre-specified criteria for a positive trial, and the median duration of response has not been reached with 8.3 months median follow-up. The safety profile was consistent with previously reported clinical data for zanubrutinib. Subject to the successful completion and satisfactory results of the trials, we plan to submit an NDA in China for patients with R/R MCL later this year. If approved, we plan to commercialize zanubrutinib shortly after approval. In addition, we are also conducting a Phase 2 trial of zanubrutinib in patients with R/R DLBCL.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ZANUBRUTINIB SUCCESSFULLY.

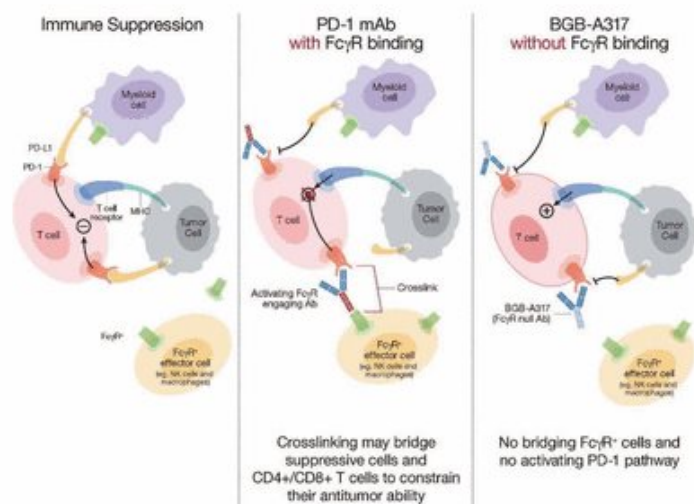
Tislelizumab (BGB-A317), a PD-1 Antibody

Tislelizumab is an investigational humanized monoclonal antibody against the immune checkpoint receptor PD-1 that is currently being evaluated in pivotal clinical trials globally and in China and for which we plan to commence additional pivotal trials as a monotherapy and in combination with standard of care to treat various solid and hematological cancers. Tislelizumab is designed to bind to and block downstream activity of PD-1, a cell surface receptor that plays an important role in downregulating the immune system by preventing the activation of T-cells. Tislelizumab has high affinity and specificity for PD-1. It is differentiated from the currently approved PD-1 antibodies by an engineered Fc region, which we believe may minimize potentially negative interactions with other immune cells based on preclinical data. We have a global strategic collaboration with Celgene for tislelizumab for solid tumors outside of Asia (other than Japan) as further described in “—Collaboration Agreements—Celgene.”

Mechanism of Action

Cells called cytotoxic T-lymphocytes, or CTLs, provide an important self-defense mechanism against cancer, patrolling the body, recognizing cancer cells due to immunogenic features that differ from normal cells, and killing cancer cells by injecting deleterious proteins into them. T-lymphocytes have various mechanisms that prevent them from damaging normal cells, among which is a protein called PD-1 receptor, which is expressed on the surface of T-lymphocytes. PD-L1 is an important signaling protein that can engage PD-1. PD-L1 binding to PD-1 sends an inhibitory signal inside the T-lymphocyte and abrogates its cytotoxic effects. Many types of cancer cells have hijacked the PD-L1 expression system that normally exists in healthy cells. By expressing PD-L1, cancer cells protect themselves from being killed by CTLs. Tislelizumab is a monoclonal antibody designed to specifically bind to PD-1, without activating the receptor, thereby blocking engagement of PD-1 by its ligands PD-L1 and PD-L2. Therefore, we believe tislelizumab has the potential to restore the ability of CTLs to kill cancer cells. In addition, tislelizumab was specifically engineered to minimize binding to FcγR on macrophages, thereby abrogating antibody-dependent phagocytosis, a potential mechanism of T-cell clearance.

Tislelizumab's Lack of FcγR Binding Prevents Macrophage-Mediated T-Cell Clearance



FcγR1=Fc gamma receptor-1, mAb=monoclonal antibody, MHC=major histocompatibility complex, NK=natural killer, PD-1=programmed cell death receptor-1, PD-L1=programmed cell death-ligand.
Arlauckas et al. SciTransl Med. 2017;9(389):eaal3604.

BUSINESS

Market Opportunity and Competition

A number of PD-1 or PD-L1 antibody drugs have been approved by the FDA. These include Merck's KEYTRUDA® (pembrolizumab), Bristol-Myers Squibb's OPDIVO® (nivolumab), Roche's TECENTRIQ® (atezolizumab), AstraZeneca's IMFINZI® (durvalumab) and Pfizer and Merck Sereno's BAVENCIO® (avelumab). In the global setting, several PD-1 or PD-L1 antibody agents are in clinical development besides us, such as Regeneron's cemiplimab, Novartis' PDR-001, Tesaro's TSR042 and Pfizer's PF-06801591. According to the Frost & Sullivan Report, in 2017, global sales of the PD-1 class reached US\$10.1 billion, which make some of these therapies among the best-selling and fastest launched oncology drugs in history.

We believe there is a large commercial opportunity in China for PD-1 or PD-L1 antibody drugs. Currently available clinical data suggest that some of the most prevalent cancers in China, such as lung, gastric, liver and esophageal cancers, are responsive to this class of agents. In 2012, 38%, 45%, 51% and 49% of the worldwide mortalities from lung, gastric, liver and esophageal cancers, respectively, occurred in China, according to the World Health Organization. Collectively, these four tumor types comprised over 2.3 million new cases in 2016 in China alone, according to Chen et al. 2016. In addition, China has a higher proportion of PD-1 responsive tumors in its total annual cancer incidence in comparison to other geographies like the United States and the European Union, or EU. According to Chen et al. 2016, the annual incidence of the top 10 PD-1 responsive tumors in China is estimated to be 3.0 million out of 4.3 million in total annual cancer incidence. In comparison, the estimated annual incidence of the top 10 PD-1 responsive tumors is 0.9 million out of 1.7 million in total annual cancer incidence in the United States, and 0.9 million out of the 1.8 million total in the EU5 countries according to SEER program of the U.S. National Cancer Institute and the World Health Organization.

In China, there is only one approved PD-1 antibody agent, Bristol-Myers Squibb's OPDIVO® (nivolumab) and there are no approved PD-L1 antibody agents yet. The CDE, under the CDA, released guidance in February 2018 on the requirements for NDA submissions of PD-1/L1 agents, specifically for data from single-arm trials on refractory / recurrent advanced cancers without standard-of-care therapies. A pre-NDA meeting is required before NDA submission, and a rolling NDA submission will be accepted for PD-1/L1 therapies. On June 15, 2018, the CDA approved Bristol-Myers Squibb's OPDIVO® (nivolumab) for the treatment of locally advanced or metastatic NSCLC after platinum-based chemotherapy in adult patients without EGFR or ALK genomic tumor aberration. Merck submitted an NDA for pembrolizumab in February 2018. Among domestic Chinese companies, Junshi submitted an NDA for JS001 (trepinzumab) in March 2018, and Innovent submitted an NDA for IBI308 (sintilimab) and Hengrui submitted an NDA for SHR-1210 (camrelizumab) in April 2018. The table below summarizes the China competitive landscape of tislelizumab, according to the Frost & Sullivan Report.

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PD-1/PD-L1 Competitive Landscape in China (Late-Stage)							
Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T-cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Thus, PD-1 or PD-L1 inhibitor antibodies could inhibit this pathway and reactivate the T-cell immune surveillance of tumors.							
Products (generic name)	Products (brand name)	Company	CDA Status	Lead Indication	Reimbursement	U.S. Patent Exclusivity	Generic Versions
nivolumab	OPDIVO®	BMS	Approved in June 2018	2L NSCLC	NA	2027	NA
pembrolizumab	KEYTRUDA®	MSD	NDA review	melanoma	NA	2028	NA
trepinzumab (JS001)	NA	Junshi	NDA review	melanoma	NA	NA	NA
sintilimab (IBI308)	NA	Innovent	NDA review	cHL	NA	NA	NA
camrelizumab (SHR-1210)	NA	Hengrui	NDA review	cHL	NA	NA	NA
tislelizumab (BGB-A317)	NA	BeiGene	NDA submission in 2018 for the treatment of cHL; currently also in other PhIII and pivotal PhII trials	cHL	NA	2033	NA

Abbreviations: cHL = classical Hodgkin's lymphoma

Summary of Clinical Results

As of July 5, 2018, we have enrolled over an aggregate of 1,500 patients in clinical trials of tislelizumab, including combination trials. Preliminary data from our monotherapy Phase 1 trials suggested that tislelizumab was generally well-tolerated and exhibited anti-tumor activity in a variety of tumor types. There is no guarantee that these results will be reproduced in pivotal trials.

A multi-center, open-label Phase 1 trial of tislelizumab as monotherapy in advanced solid tumors is being conducted in Australia, New Zealand, the United States, Taiwan and South Korea and consists of dose escalation, schedule-expansion, fixed-dose expansion, and indication expansion in disease-specific cohorts. On November 11, 2016, we presented updated data from the dose escalation phase of our Phase 1 trial for a total of 103 patients with advanced solid tumors at the Society for Immunotherapy of Cancer, or SITC, 31st Annual Meeting.

A mixed patient population of 27 different tumor types was included in this data analyses, in which patients with melanoma, NSCLC or HNSCC were not enrolled, and patients with renal cell cancer and urothelial carcinoma together represented close to 15% of the enrolled patients. Among 99 patients evaluable for efficacy as of September 30, 2016, anti-tumor activities were observed in 15 patients with a PR and 23 patients with SD. The PRs include three PRs in nine renal cell carcinoma

patients; three in six urothelial cancer patients; two in four gastric cancer patients; two in two Merkel cell carcinoma patients; one in four nasopharyngeal patients; one in one penis squamous cell carcinoma patient; one in one duodenal carcinoma patient; two in two MSI-high patients, one with colorectal cancer among a total of 13 colorectal cancer patients, and one with pancreatic cancer among a total of two pancreatic cancer patients. At the time of the data cutoff for the safety analysis, the most common treatment-related AEs ($\geq 5\%$) were fatigue (19%), diarrhea (13%), rash (11%), pruritus (11%), nausea (8%), hypothyroidism (7%), and infusion related reactions (6%). Treatment-related SAEs included four cases of colitis, two cases of hypotension, and one case each of diarrhea, diabetes mellitus, diabetic ketoacidosis, dyspnea, hypoxia, infusion-related reaction, and pneumonitis. Among these, grade 3 or above treatment-related SAEs included the two cases of hypotension and one case each of colitis, diabetes mellitus, diabetic ketoacidosis, dyspnea, hypoxia, and pneumonitis. Other treatment-related grade 3 or above AEs included two cases each of fatigue and hyperglycemia, and one case each of back pain, elevated alanine aminotransferase, or ALT, and elevated gamma-glutamyl transferase, or GGT.

From 2017 to date, we have presented preliminary data from multiple disease-specific subgroups in the ongoing Phase 1 trial of tislelizumab in advanced solid tumors, including patients with HCC, GC, esophageal cancer, or EC, HNSCC, OC and UC.

Hepatocellular (Liver) Cancer

The data presented on HCC are from 40 patients treated with tislelizumab at a dose of 5 mg/kg every three weeks, or Q3W. The majority of the enrolled patients (34/40 patients) had a hepatitis B virus infection. At the time of the data cutoff on April 28, 2017, the median treatment duration was 64 days (range of 1 to 471 days).

AEs assessed by the investigator to be treatment-related occurred in 21 patients (53%). Of those, rash (20%), pruritus (13%), increased aspartate aminotransferase, or AST (8%), fatigue (5%), hypothyroidism (5%) and decreased appetite (5%) were reported in more than one patient. All of the treatment-related AEs were grades 1 or 2, with the exception of one grade 5 event of acute hepatitis assessed by the investigator to be related to tislelizumab. This patient had widely metastatic disease and died five weeks after receiving his first and only dose of tislelizumab and subsequently developing evidence of disease progression.

At the time of the data cutoff, the efficacy evaluation was early, and 27 patients were evaluable for response, defined as having measurable disease at baseline and at least one post-baseline tumor assessment, or progression or death. Twelve of the evaluable patients remained on treatment and seven of these had only one tumor assessment at the time of the data cutoff. Confirmed and unconfirmed PRs were observed in three patients, all with hepatitis-B-positive HCC. One PR was confirmed before the cutoff date, one was confirmed one day following the cutoff date, and one was unconfirmed and the patient remained on therapy. Nine patients achieved SD, some of whom also had significant reductions in Alpha-fetoprotein levels.

Gastric and Esophageal Cancers

The data presented on GC and EC were from 83 patients, 46 with advanced or metastatic GC and 37 with EC, treated with tislelizumab at 2 mg/kg or 5 mg/kg every two weeks, or Q2W, or Q3W. At the time of the data cutoff on June 8, 2017, median treatment duration was 45 days (range 4—457 days) for patients with GC and 50 days (range 1—246 days) for patients with EC.

AEs assessed by the investigator to be treatment-related occurred in 15 patients with GC (33%). Of those, abdominal pain (9%), decreased appetite (9%), fatigue (7%), nausea (7%) and pruritus (4%) were reported in more than one patient, and all of these cases were grades 1 or 2. AEs assessed to be treatment-related occurred in 15 patients with EC (41%). Of those, fatigue (16%), nausea (8%), decreased appetite (5%), infusion-related reaction (5%) and myalgia (5%) occurred in more than one patient, and all of these cases were grades 1 or 2. Only one patient in each cohort reported a treatment-related AE of grade 3 or higher: grade 3 proteinuria in one patient with GC and grade 3 dermatitis in one patient with EC. SAEs considered treatment-related included one case of diarrhea and one case of pyrexia, each occurring in patients with GC. Eight patients (two with GC, six with EC) had a treatment-emergent AE with a fatal outcome; none of which was assessed as treatment-related.

The efficacy-evaluable population included 34 GC patients and 31 EC patients. Despite the short median follow-up time, four achieved confirmed PRs and three achieved SD among GC patients. Among EC patients, two achieved a confirmed PR and nine achieved SD. Three of the nine patients with EC who achieved SD also achieved an unconfirmed PR, including one who awaits response confirmation. At the time of the data cutoff, 27 patients remained on treatment.

Head and Neck Squamous Cell Cancer

The HNSCC data presented were from 18 patients treated with tislelizumab at 5 mg/kg Q3W. At the time of the data cutoff on June 8, 2017, median treatment duration was 104 days (range 30—339 days).

AEs assessed by the investigator to be treatment-related occurred in seven patients (39%). Of those, only fatigue (11%, all grade 1 or 2) was reported in more than one patient. One case of grade 3 nausea was the only treatment-related AE of grade 3 or higher in severity. No patient discontinued treatment due to a treatment-related AE, and of the nine deaths reported, none were considered to be treatment-related.

The efficacy-evaluable population included 17 HNSCC patients. Despite short median follow-up time, three achieved a confirmed PR and six achieved SD. At the time of the data cutoff, three patients remained on treatment.

Ovarian Cancer

The OC dataset included 51 patients treated with tislelizumab at different dose levels (0.5 to 10 mg/kg Q2W in dose escalation, 2 or 5 mg/kg Q2W or Q3W or 200 mg Q3W in dose expansion, or 5 mg/kg Q3W in indication expansion). At the time of the data cutoff on June 8, 2017, median treatment duration was 71 days (range 29—540 days).

AEs assessed by the investigator to be treatment-related occurred in 28 patients (55%). Of those, fatigue (18%), pruritus (10%), rash (10%), diarrhea (10%), lethargy (6%), nausea (6%), abdominal pain (4%), dry eye (4%), dry skin (4%), onychoclasia (4%) and maculo-papular rash (4%) were reported in more than one patient, and all, except one case of grade 3 diarrhea, were grades 1 or 2. Two additional treatment-related AEs of grade 3 or higher included one case each of grade 3 pyrexia and stomatitis. SAEs considered to be treatment-related occurred in three patients and included one case each of pyrexia, colitis and mucosal inflammation.

The efficacy-evaluable population included 50 OC patients. Two achieved a confirmed PR and 20 achieved SD. At the time of the data cutoff, six patients remained on treatment.

Urothelial Cancer

The UC dataset included 16 patients. Of these, 12 had one or more prior systemic anticancer treatment for metastatic disease and the remaining four had progressed after receiving platinum-based regimen in the neoadjuvant or adjuvant setting. In addition, five patients had prior radiotherapy. At the time of the data cutoff on August 28, 2017, median treatment duration was 4.3 months (range of 0.7 to 18.3 months). A total of six patients remained on treatment.

AEs assessed by the investigator to be treatment-related occurred in 14 patients (88%). Of those, fatigue (31%), rash (19%), infusion-related reactions (13%), nausea (13%), pain in extremity (13%) and proteinuria (13%) occurred in more than one patient. All of the treatment-related AEs were grade 1 or 2 except one case each of fatigue, hyperglycemia and diabetes mellitus. One AE of muscle weakness, which was associated with disease progression and occurred more than one month after the last dose of tislelizumab, had a fatal outcome. This event was considered by the investigator not to be treatment-related.

The efficacy-evaluable population included 15 UC patients. One patient had a confirmed CR, four achieved a confirmed PR, and three achieved SD. Nine evaluable patients had PD-L1 status determined. There was one CR, two PR and one SD among six PD-L1 high patients, and one PR among three PD-L1 low or negative patients.

We expect to complete enrollment of patients in pivotal Phase 2 trial of urothelial cancer in China in 2018.

Hodgkin's Lymphoma

In June 2018, we received preliminary topline results from the independent review of response data from our Phase 2 single-arm pivotal trial of tislelizumab in Chinese patients with R/R cHL. This trial enrolled 70 patients with cHL who either failed autologous stem cell transplantation, or ASCT, or who were ineligible for ASCT. The primary endpoint was overall response rate as defined by the Lugano 2014 criteria. Secondary endpoints included progression-free survival, duration of response, complete response rate, time to response, safety, and tolerability. As of the data cutoff, the median follow-up time was approximately 6.0 months. The overall response rate was 73%, including 50% complete response, and the median duration of response had not been reached. Frequency and severity of adverse events was generally consistent with the previously reported Phase 1 safety and tolerability

data for tislelizumab, or, in the case of certain immune-related events such as hypothyroidism and fever, consistent with previous reports of other PD-1 antibodies for the treatment of cHL. We expect to include these data, along with additional follow-up data from the study, in the NDA that we plan to file with the CDA in China later this year, and we also plan to present full results of the trial at an upcoming medical conference.

Combination with Pamiparib

On June 5, 2017, we presented initial data from the dose-escalation portion of the Phase 1 trial of tislelizumab in combination with our investigational PARP inhibitor, pamiparib, in patients with advanced solid tumors at the 2017 American Society for Clinical Oncology, or ASCO, Annual Meeting. We presented an updated dataset on January 25, 2018 at the 2018 ASCO-SITC Clinical Immuno-Oncology Symposium. The preliminary data suggested that the combination of tislelizumab and pamiparib was generally well-tolerated and showed anti-tumor activity in multiple solid tumor types.

At the data cutoff of July 31, 2017, 49 patients were enrolled in the dose-escalation portion of the trial. Cohorts of six to 13 patients each received treatments at five planned dose levels, or DLs. Tislelizumab was administered at 2 mg/kg Q3W with pamiparib at 20, 40, or 60 mg twice daily, or BID, in DLs 1, 2 and 3, respectively. Tislelizumab was also administered at a fixed dose of 200 mg Q3W with pamiparib at 40 or 60 mg twice daily in DLs 4 and 5, respectively. Duration of treatment was greater than 200 days for 10 patients, and a total of seven patients remained on treatment as of the data cutoff date.

Dose-limiting toxicities occurred in four patients; these included one patient with grade 2 nausea, one patient with grade 3 rash at DL 4, one patient with grade 2 nausea or vomiting and one patient with grade 4 autoimmune hepatitis at DL 5. The trial identified the recommended Phase 2 dose to be tislelizumab at 200 mg fixed dose Q3W and pamiparib at 40 mg BID.

Grade 3 or 4 non-immune AEs assessed by the investigator to be related to the treatment regimen and reported in more than one patient included anemia (12%), nausea (4%) and fatigue (4%). Immune-related AEs of any grade regardless of causality occurred in 23 patients (47%); those reported in at least two patients included elevated alanine aminotransferase, or ALT, elevated AST, hypothyroidism, auto-immune hepatitis / hepatitis, diarrhea, elevated gamma-glutamyl transferase, or GGT, hyperthyroidism and pruritus. Grade 3 and 4 liver-related AEs regardless of causality were reported in nine patients, including five patients with hepatitis and four patients with ALT, AST and/or GGT elevations. Together, liver-related AEs of any grade regardless of causality were observed in 13 patients; all events were manageable and reversible with corticosteroid treatment. The trial protocol was amended to increase real-time hepatic safety monitoring consistent with new European Society for Medical Oncology, or ESMO, guidance for immune-related treatment-emergent AEs. Certain IRAEs may be associated with checkpoint inhibition and the combination of checkpoint inhibitors with other drugs.

At the data cutoff of July 31, 2017, 49 patients were evaluable for efficacy. Best responses included two confirmed CRs, five confirmed PRs, and seven unconfirmed PRs. The clinical benefit rate including CRs, PRs and durable SDs with at least 24 weeks was 31%. With longer follow-up, as

BUSINESS

of January 4, 2018, among the 49 evaluable patients, best responses included two confirmed CRs, eight confirmed PRs, and four unconfirmed PRs. The clinical benefit rate was 39%. As of the July 31, 2017 cutoff, 11 patients remained on treatment, the median duration of response was 168.5 days (range: 64-508 days), and duration of treatment was over 200 days in 10 patients.

The trial is currently planned to further evaluate the combination's activity in expansion cohorts of patients with ovarian, triple-negative breast, castration-resistant prostate, lung, gastric or gastro-esophageal junction, urothelial and pancreatic cancers.

Clinical Development Plan

We are running a broad development program with Celgene including global pivotal trials in Asia-prevalent cancers, such as NSCLC, EC and HCC, which are intended to support regulatory submissions globally and in China. We have initiated Phase 3 trials to evaluate tislelizumab as a potential second- or third-line treatment compared to docetaxel in patients with NSCLC; as a potential first line treatment compared to sorafenib in patients with HCC; and as a potential second-line treatment compared to investigator-chosen chemotherapy in patients with ESCC. We have also recently initiated a global Phase 2 trial in patients with previously treated advanced HCC, as well as a global Phase 2 trial in patients with relapsed or refractory mature T- and NK-cell lymphomas, with the first patient in both trials dosed in April 2018. We and Celgene expect to commence additional pivotal trials in 2018 and 2019, such as a pivotal trial in gastric cancer.

We have two additional China pivotal Phase 2 trials ongoing, in patients with R/R cHL and in patients with PD-L1 positive urothelial cancer, and we are screening patients in preparation of the first dosing of one China Phase 3 trial in combination with chemotherapy in patients with non-squamous NSCLC. We expect to file for regulatory approvals in China for tislelizumab in these indications based on the results of these Phase 2 trials. If we receive conditional approval instead of full approval, we will be required to conduct one or more confirmatory studies after such conditional approvals. We received preliminary topline results from the independent review of the Phase 2 pivotal trial in Chinese patients with R/R cHL. The overall response rate was 73%, including 50% complete response, and the frequency and severity of adverse events was generally consistent with the previously reported data for tislelizumab, or, in the case of certain immune-related events such as hypothyroidism and fever, consistent with previous reports of other PD-1 antibodies for the treatment of cHL. We expect to include these data, along with additional follow-up data from the study, in the NDA that we plan to file with the CDA in China later this year, subject to the successful completion and satisfactory results of the trials.

If approved, we plan to commercialize tislelizumab shortly after approval.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TISLELIZUMAB SUCCESSFULLY.

Pamiparib (BGB-290), a PARP Inhibitor

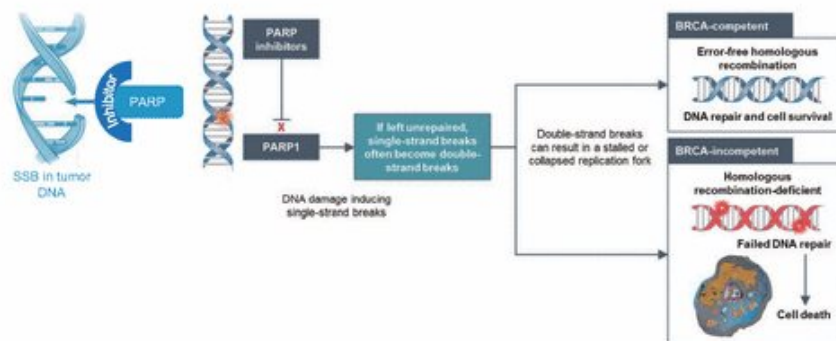
Pamiparib is an investigational small molecule inhibitor of PARP1 and PARP2 that is being evaluated as a potential monotherapy and in combinations for the treatment of various solid tumors. We believe pamiparib has the potential to be differentiated from other PARP inhibitors because of its potential brain penetration, greater selectivity, strong DNA-trapping activity, and good oral bioavailability. Pamiparib has demonstrated pharmacological properties such as brain penetration and PARP—DNA complex trapping in preclinical models.

Mechanism of Action

PARP family members PARP1 and PARP2 play essential roles in cell survival in response to DNA damage. PARP1 and PARP2 are key base-excision-repair proteins that function as DNA damage sensors by binding rapidly to the site of damaged DNA and modulating a variety of proteins in DNA repair processes. Inhibition of PARPs prevents the repair of common single-strand DNA breaks which leads to formation of double-strand breaks during DNA replication. Double-strand DNA breaks in normal cells are repaired by homologous recombination, and normal cells are relatively tolerant of PARP inhibition. On the other hand, cancer cells with mutations in breast cancer susceptibility gene, or BRCA1/2 genes, which are key players in homologous recombination, are highly sensitive to PARP inhibition. This phenomenon is called “synthetic lethality” and is the foundation of the therapeutic utility of PARP inhibitors as a monotherapy for BRCA mutant cancers. In addition to hereditary BRCA1/2 mutations, the synthetic lethality concept has been broadened to include sporadic tumors that display homologous recombination deficiency, or HRD, a gene expression profile that resembles that of a BRCA deficient tumor. HRD can stem from somatic mutation of BRCA1/2, epigenetic silencing of BRCA genes or genetic or epigenetic loss of function of other genes in homologous recombination DNA damage repair pathways. Third-party clinical studies have published results demonstrating that sensitivity to platinum-based chemotherapies confers sensitivity to PARP inhibitors in OC as well. Thus, the application of PARP inhibitors is likely broader than BRCA or HRD mutations, and there is additional possibility to identify and enrich patient populations for PARP inhibition.

Another potential therapeutic utility of PARP inhibitors is combination therapy that has strong scientific rational. PARP proteins are key factors in base-excision-repair, which is critical for the repair of DNA lesions caused by some chemotherapeutic agents and by radiation. PARP inhibitors are hypothesized to potentiate cytotoxicity of DNA-alkylating agents such as platinum compounds, temozolomide and ionizing radiation and may be used in combination with these agents in treating various cancers.

Role of PARP and BRCA in DNA Repair



SSB = single-strand DNA breaks, BRCA=breast cancer gene, PARPi=poly (ADP-ribose) polymerase inhibitor.
McLornan et al. N Engl J Med. 2014;371(18):1725–1735, 2. Høijm akers et al. Nature. 2001;411:366–374.

PARP inhibitors are also considered good potential combination partners with checkpoint inhibitors in part due to increased mutations in tumor cells as a result of the blockade of DNA repair by PARP inhibitors as a higher mutational load of cancers has been shown in clinical studies to correlate with improved response to checkpoint inhibitors. In addition, preclinical data suggest that BRCA mutant tumors which are sensitive to PARP inhibition are likely to be immunogenic and responsive to PD-1 or PD-L1 antibodies.

Market Opportunity and Competition

We believe that the market opportunity for PARP inhibitors is large and expanding in various tumor histologies, settings and patient segments. Many tumor types have been shown to be responsive to PARP inhibitors, including OC, breast cancer, prostate cancer and GC. PARP inhibitors have demonstrated encouraging activities both in relapsed and refractory patients as well as in the maintenance setting. In the United States, each year there are approximately 22,440 new cases of OC, 252,710 new cases of breast cancer, 161,360 new cases of prostate cancer, and 28,000 new cases of GC, according to the U.S. National Cancer Institute. In China, each year there are approximately 52,000 new cases of OC, 272,000 new cases of breast cancer, 60,000 new cases of prostate cancer, and 680,000 new cases of GC according to Chen et al. 2016.

A number of PARP inhibitors have been approved by the FDA. These include AstraZeneca's LYNPARZA® (olaparib), Clovis Oncology's RUBRACA® (rucaparib) and Tesaro's ZEJULA® (niraparib). Several PARP inhibitors are in late-stage clinical development besides pamiparib, including AbbVie's veliparib and Pfizer's talazoparib. In 2017, global sales of the PARP class exceeded US\$461 million according to company reports. In China, there were no approved PARP inhibitors as of July 18, 2018. AstraZeneca has submitted an NDA for olaparib. In addition, Zai Lab obtained the development and commercial rights for niraparib in China, and is currently running a Phase 1 pharmacokinetics study and a Phase 3 pivotal trial as a maintenance treatment after two lines

BUSINESS

of platinum-containing therapy in patients with OC up to the end of May, 2018. There are some other PARP inhibitors being developed by domestic Chinese companies, including pamiparib and fluzoparib from Hengrui and Hansoh. The table below summarizes the China competitive landscape of pamiparib, according to the Frost & Sullivan Report.

PARP Competitive Landscape in China (Late-Stage)							
PARP inhibitors are involved in DNA transcription and repair. PARP can detect and initiate the immediate cellular response to chemical or radiation-induced single-strand DNA breaks by signaling the enzymatic machinery involved in the repair process. Cancer cells with mutations in breast cancer susceptibility gene, or BRCA1/2 genes, are highly sensitive to PARP inhibition. This phenomenon is called "synthetic lethality" and is the foundation of the therapeutic utility of PARP inhibition in cancer therapy.							
Products (generic name)	Products (brand name)	Company	CDA Status	Lead Indications	Reimbursement	U.S. Patent Exclusivity	Generic Versions
olaparib	LYNPARZA®	AstraZeneca	NDA review	Ovarian cancer, Breast cancer	NA	2022	NA
ZL-2306	ZEJULA® (in the US)	Tesaro, Zai Lab	PhIII	Ovarian cancer	NA	2030	NA
Pamiparib (BGB-290)	NA	BeiGene	PhIII	Ovarian cancer	NA	2031	NA

Summary of Clinical Data

As of July 5, 2018, we have enrolled over 350 patients in clinical trials of pamiparib, including combination trials.

A multi-center, open-label Phase 1/2 trial of pamiparib is being conducted in Australia in patients with advanced solid tumors. On September 8, 2017, we presented preliminary clinical data from the ongoing Phase 1/2 trial of pamiparib in patients with advanced solid tumors at the ESMO 2017 Congress. As of June 1, 2017, 68 patients were enrolled in the trial. The median duration of therapy for all patients was 79 days (range 1 to 926 days). At the time of the data cutoff, 20 patients remained on treatment.

The safety analysis suggested that pamiparib was generally well-tolerated in patients with advanced solid tumors. AEs assessed to be treatment-related occurred in 78% of patients and were all grade 3 or lower in severity. The most common treatment-related AEs ($\geq 10\%$ of patients) were nausea (56%), fatigue (40%), anemia (25%), vomiting (21%), diarrhea (21%), decreased appetite (15%), and neutropenia or neutrophil count decrease (12%). SAEs occurred in 46% of patients, and SAEs considered to be treatment-related and occurring in more than one patient included two cases each of nausea and anemia. Four patients reported dose-limiting toxicity, or DLT. Four patients had a treatment-emergent AE with a fatal outcome, none were assessed as being treatment-related and all of which were associated with disease progression.

At the time of the data cutoff, 39 patients with epithelial ovarian cancer, or EOC, or associated tumors such as fallopian tube or primary peritoneal cancers were evaluable for efficacy. Among this group, there were three confirmed CRs, 10 confirmed PRs, and 21 cases of SD. Of the 23 evaluable

patients with EOC or other associated tumors known to be BRCA-mutated, there were three CRs, seven PRs, and 10 cases of SD. Of the 13 evaluable patients whose BRCA gene types are wild type, there were two PRs. Of the three evaluable patients whose BRCA gene types were unknown, there was one PR. Complete and partial responses were observed in patients known to be platinum-resistant as well as patients with platinum-sensitive disease. There is no guarantee that these results will be reproduced in pivotal trials.

On April 16, 2018, we presented the preliminary clinical data from the open-label, multi-center Phase 1 dose-escalation trial of pamiparib in Chinese patients with locally advanced or metastatic high-grade non-mucinous ovarian cancer, or HGOC, including fallopian cancer, or triple-negative breast cancer, or TNBC, who had disease progression following at least one line of chemotherapy at the 2018 American Association for Cancer Research Annual Meeting in Chicago, IL.

Patients were dosed at 20mg, 40mg, or 60mg BID. As of September 25, 2017, 15 female patients were enrolled, nine with HGOC and six with TNBC. Nine patients received four or more prior lines of therapies. All nine patients with HGOC were platinum-resistant (n=8) or refractory (n=1). Seven patients had a confirmed BRCA1/2 mutation (BRCAm), including five patients with HGOC and two patients with TNBC and the remaining patients had BRCA 1/2 wildtype (BRCA-WT). The median duration of treatment was 2.5 months (range: 8-260 days).

The safety analysis suggested that pamiparib was generally well-tolerated. No dose-limiting toxicities were reported across the dose range, with RP2D confirmed as 60mg BID. Asthenia (n=12) and nausea (n=12) were the most commonly reported treatment-emergent AE. Severity of all AEs was grade 3 or less. Overall, three patients experienced a serious AE (grade 2 abdominal infection, n=1; grade 3 pleural effusion, n=1; grade 3 ileus, n=1), none of which were considered related to treatment. Two of the SAEs led to treatment withdrawal (abdominal infection, n=1; pleural effusion, n=1).

As of September 25, 2017, 13 of the 15 patients were evaluable for antitumor activity; five patients remained on treatment. Two of the nine HGOC patients achieved a confirmed PR including one platinum-refractory patient with BRCA wildtype status and one platinum-resistant patient with BRCA1/2 mutation, six HGOC patients had SD (BRCAm, n=4 and BRCA-WT, n=2) and one patient discontinued before the first radiographic assessment. Of the six treated TNBC patients, five (BRCAm, n=1, BRCA-WT, n=4) experienced disease progression and one patient (BRCAm) discontinued before the first radiographic assessment. Four of these evaluable TNBC patients were BRCA-WT and all experienced disease progression during the previous platinum-based chemotherapy.

Clinical Development Plan

In addition to the ongoing Phase 2 trial of pamiparib in combination with tislelizumab, we are currently conducting two other global combination trials: a Phase 1b/2 trial of pamiparib with radiation therapy and/or temozolomide in patients with glioblastoma and a Phase 1b/2 trial of pamiparib with temozolomide in patients with advanced tumors such as OC, TNBC, small cell lung cancer, prostate cancer and GC. In addition, we are screening patients in preparation of the first dosing of a global Phase 3 maintenance trial in patients with platinum-sensitive GC.

In China, we are conducting a Phase 2 pivotal trial in patients with gBRCA-positive OC who have received at least two prior lines of therapy in advanced or metastatic setting and a Phase 3 trial as a maintenance therapy in patients with platinum-sensitive recurrent OC.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PAMIPARIB SUCCESSFULLY.

Lifirafenib (BGB-283), a RAF Dimer Inhibitor

Lifirafenib is an investigational novel small molecule inhibitor with RAF monomer and dimer inhibition activities. Lifirafenib has shown antitumor activities in preclinical models and in cancer patients with tumors harbouring BRAF V600E mutations, non-V600E BRAF mutations or KRAS/NRAS mutations. We have been developing lifirafenib for the treatment of cancers with aberrations in the mitogen-activated protein kinase, or MAPK, pathway, including BRAF gene mutations and KRAS/NRAS gene mutations where first generation BRAF inhibitors are not effective. The MAPK pathway consists of proteins in the cell that transmit a signal from a receptor on the surface of the cell to the DNA in the nucleus of the cell. This pathway plays an essential role in regulating cell proliferation and survival. We believe that lifirafenib as monotherapy or in combination with other agents may have a potential for treating various malignancies, such as melanoma, NSCLC and endometrial cancer.

Roche's ZELBORAF® (vemurafenib) and Novartis' TAFINLAR® (dabrafenib) are two of the currently approved BRAF inhibitors for treating late-stage BRAF V600E/K mutant melanoma. In addition, the combination of dabrafenib and GSK's MEKINIST® (trametinib), an MEK inhibitor, as well as vemurafenib and COTELLIC® (cobimetinib), another MEK inhibitor, are approved in patients with BRAF V600E/K mutation-positive metastatic melanoma. We are aware of several other BRAF inhibitors in clinical development targeting BRAF V600E/K mutated cancers including melanoma, NSCLC, hairy cell leukemia and thyroid cancer. These BRAF inhibitors include Array Biopharma's encorafenib, currently in Phase 3 trials, and Takeda's MLN-2480 (BIIB-024) and TAK-580, Daiichi Sankyo's PLX-8394, Roche's RG-6185, Genentech's HM95573 and Novartis' LXH254 in Phase 1 trials.

Currently approved first-generation BRAF inhibitors, vemurafenib and dabrafenib, are only active against the BRAF monomer. Because lifirafenib is designed to inhibit both the monomer and dimer forms of RAF, we believe lifirafenib has the potential to be a first-in-class RAF dimer inhibitor. Lifirafenib was evaluated in a multicenter, open-label Phase 1 trial conducted in Australia and New Zealand comprised of two parts — dose escalation and dose expansion — in patients with BRAF or KRAS/NRAS mutated solid tumors or patients with pancreatic cancer. Lifirafenib demonstrated antitumor activity in both BRAF and KRAS-mutated tumors in preclinical studies and in the dose-escalation portion of this Phase 1 trial.

We presented data from the dose-expansion portion of the trial at the 2017 American Association for Cancer Research Annual Meeting. The dose-expansion portion of the trial was designed to evaluate the safety and efficacy of lifirafenib at the recommended Phase 2 dose of 30 mg once daily established in the dose-escalation part of the trial. In the dose-expansion portion, lifirafenib was generally well-tolerated at a dose of 30 mg once daily and continued to show antitumor activity in patients with BRAF V600-mutated solid tumors and patients with KRAS-mutated solid tumors. The safety analysis, which included 96 patients as of the September 12, 2016 cutoff, suggested that lifirafenib was generally well-tolerated at 30 mg once daily, with most drug-related AEs being grades 1 or 2 in severity. The most frequent drug-related AEs ($\geq 10\%$) of any grade were fatigue (38.5%), dysphonia (26.0%), decreased appetite (21.9%), palmar-plantar erythrodysesthesia syndrome (21.9%), thrombocytopenia (19.8%), dermatitis acneiform (17.7%), diarrhea (16.7%), rash (16.7%), nausea (15.6%), hypertension (11.5%) and glossodynia (10.4%). The most frequent drug-related grade 3 and 4 AEs ($\geq 2\%$, two patients or more) included fatigue (7.3%), hypertension (6.3%), thrombocytopenia (6.3%), pyrexia (3.1%), hyponatremia (2.1%), anemia (2.1%), neutropenia (2.1%), febrile neutropenia (2.1%), decreased platelet count (2.1%), increased alanine aminotransferase (2.1%), increased GGT (2.1%) and sepsis (2.1%).

The cutoff for the efficacy analysis was September 17, 2016. In seven patients with BRAF V600-mutated melanoma (including one V600K and one V600R) who were naïve to BRAF or MEK inhibitors, there were three PRs and three cases of SD. In three patients with BRAF V600-mutated PTC, there was one PR and two cases of SD. In six patients with KRAS-mutated NSCLC, there was one PR and two cases of SD. In ten patients with solid tumors with BRAF non-V600 mutations or solid tumors with BRAF V600 mutations that are not included in other cohorts, there were two PRs, in one patient with BRAF V600E-mutated melanoma and one with BRAF V600E-mutated OC, and three cases of SD. In two patients with BRAF V600-mutated NSCLC, there was one unconfirmed PR and one case of SD. Additional cases of SD were observed in four of six melanoma patients with BRAF V600-mutated melanoma who had responses to but developed resistance against BRAF or MEK inhibitors, nine of 13 patients with BRAF V600-mutated CRC, five of five patients with KRAS-mutated endometrial cancer, 12 of 20 patients with KRAS/NRAS-mutated CRC, and 10 of 21 patients with other KRAS/NRAS-mutated solid tumors or pancreatic cancer. In the Phase 1a portion of the trial, confirmed objective responses included a CR in a patient with BRAF V600E-mutated melanoma and two PRs, one in a patient with BRAF V600E-mutated thyroid cancer and one in a patient with KRAS-mutated endometrial cancer.

BGB-A333, a PD-L1 Inhibitor

BGB-A333 is an investigational humanized IgG1-variant monoclonal antibody against PD-L1, the ligand of PD-1. We intend to develop BGB-A333 either as a monotherapy or in combination with other cancer therapies, such as tislelizumab, to treat various cancers and potentially other indications. BGB-A333 is currently being evaluated in a Phase 1 clinical trial in Australia to test the safety and anti-tumor effect of BGB-A333 alone and in combination with tislelizumab in patients with advanced solid tumors.

BUSINESS

BGB-A425, a TIM-3 Inhibitor

BGB-A425 is an investigational humanized IgG1-variant monoclonal antibody against T-cell immunoglobulin and mucin-domain containing-3, or TIM-3. We received the investigational new drug clearance in the U.S., and we plan to develop BGB-A425 either as a monotherapy or in combination with other cancer therapies to treat various cancers.

Sitravatinib (MGCD-0516), a Multi-Kinase Inhibitor

In January 2018, we entered into an exclusive license agreement with Mirati for the development, manufacturing and commercialization of Mirati's sitravatinib in Asia (excluding Japan and certain other countries), Australia and New Zealand. Sitravatinib is an investigational spectrum-selective kinase inhibitor which potently inhibits receptor tyrosine kinases, including RET, TAM family receptors (TYRO3, Axl, MER), and split family receptors (VEGFR2, KIT). Sitravatinib is being evaluated by Mirati as a single agent in a dose-expansion trial in patients whose tumors harbor specific genetic alterations in NSCLC and other tumors. Sitravatinib has shown encouraging interim results in an ongoing Phase 2 trial in combination with nivolumab in NSCLC patients who have progressed after prior treatment with a checkpoint inhibitor. We plan to investigate sitravatinib in combination with tislelizumab in China and the licensed territory.

Under the license agreement, Mirati retains exclusive rights for the development, manufacturing and commercialization of sitravatinib outside of the licensed territory. We made an upfront cash payment of US\$10 million to Mirati and agreed to pay up to US\$123 million based upon the achievement of certain development, regulatory and sales milestones, as well as royalties at tiered percentage rates ranging from mid-single digits to twenty percent on annual net sales of sitravatinib in the licensed territory, subject to reduction under specified circumstances.

Avadomide (CC-122), a Cereblon Modulator

Avadomide (CC-122) is an investigational next-generation Cereblon modulator currently in clinical development by Celgene. It is in multiple Phase 1 and Phase 1/2 clinical trials, both as a single agent and in combination, for hematological and solid tumor cancers outside of China. Avadomide (CC-122) has been differentiated from previous compounds (such as thalidomide, lenalidomide and pomalidomide) and has been developed based on the scientific understanding of Cereblon-mediated protein homeostasis.

In August 2017, we entered into a license and supply agreement with Celgene, pursuant to which we were granted a license to develop and commercialize avadomide (CC-122) in China. See “—Collaboration Agreements—Celgene Corporation.”

Our Commercial Products

We commercialize the following cancer drugs in China under an exclusive license from Celgene.

ABRAXANE®

ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension) is a solvent-free chemotherapy product which was developed using Celgene's proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. Globally, ABRAXANE® is approved for uses in breast cancer, NSCLC, pancreatic cancer and GC with geographic differences in labeling. In China, ABRAXANE® is approved for metastatic breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

According to Chen et al. 2016, there were approximately 4.3 million new cancer cases and 2.8 million cancer deaths in China in 2015, with breast cancer as the most common tumor type in Chinese women. It is estimated that in 2015 breast cancer affected 268,600 women and resulted in 69,500 deaths. Targeted therapy, hormone therapy and chemotherapy are three main strategies to treat different types of breast cancer.

Taxane is the backbone chemotherapy to treat triple negative breast cancer, Her2+ or aggressive estrogen-receptor-positive and/or progesterone-receptor-positive breast cancer patients. ABRAXANE® is the only currently approved taxane that does not need pre-medication of dexamethasone to prevent hypersensitivity reactions, and several Phase 3 trials have demonstrated its efficacy and safety compared to solvent-based taxanes in both metastatic breast cancer and neo-adjuvant settings. Unlike other taxanes, ABRAXANE® has demonstrated unique and strong efficacy in pancreatic cancer and has become the backbone of first line standard of care for metastatic pancreatic cancer globally.

The taxanes marketed in China include two branded solvent-based paclitaxel (TAXOL® and ANZATAX), one branded docetaxel (TAXOTERE®), one liposome-paclitaxel (LIPUSU), one albumin-bound paclitaxel (ABRAXANE®) and dozens of generic taxanes. LIPUSU is currently the market leader with approximately one-third of the value share.

In 2017, ABRAXANE® held an estimated 5.4% value share in the taxane market in China. In February 2018, a albumin-bound paclitaxel from CSPC Pharmaceutical Group was approved by the CDA. Another form of albumin-bound paclitaxel from Hengrui is under review by the CDA.

In 2018, we plan to seek to differentiate and defend ABRAXANE® against generic competition in China, expand our sales force footprint and hospital coverage, and improve patient access through critical illness insurance negotiations and provincial reimbursement listings. As of July 18, 2018, ABRAXANE® is listed on provincial reimbursement drug lists of Fujian, Hubei, Ningxia, and Jiangsu, as well as in critical illness insurance program in Zhejiang and Shandong. ABRAXANE® has recently been added to the PRDL in Hunan, effective September 1, 2018.

REVLIMID®

REVLIMID® (lenalidomide) is an oral immunomodulatory drug that was approved by the CDA in China in 2013 for the treatment of multiple myeloma, or MM, in combination with dexamethasone in adult patients who have received at least one prior therapy. On February 2, 2018, REVLIMID® received CDA approval of a new indication for the treatment of MM in combination with dexamethasone in adult patients with previously untreated MM who are not eligible for transplant.

MM is a malignant plasma cell disease whose tumor cells originate in plasma cells in the bone marrow, which are cells in which B-lymphocytes develop to the final functional phase. The current World Health Organization classifies it as a B-cell lymphoma, also known as plasma cell myeloma / plasmacytoma. MM is characterized by abnormal proliferation of bone marrow plasma cells accompanied by overproduction of monoclonal immunoglobulin. MM is often accompanied by multiple osteolytic lesions, hypercalcemia, anemia, and kidney damage. Due to the inhibition of normal immunoglobulin production, patients are prone to a variety of bacterial infections.

At present, MM is one of the most common malignant tumors in the blood system and occurs frequently in the elderly. The actual incidence increases with age, peaking from 60 to 70 years of age. Men suffer slightly more than women. Globally, the incidence was estimated at 2 to 3 per 100,000, with a male-to-female ratio of 1.6:1, and most patients are over 40 years old, according to Siegel et al., 2011 and IMS analysis. It is estimated that the incidence rate of MM is approximately 1-2 per 100,000 people in China, or approximately 18,000 new patients in 2017, out of which 10,000 are in urban populations, according to Lu et al., 2014, IMS analysis, and local market research. With a growing aging population and improving diagnosis, China has seen a steady increase in MM incidence.

Although MM cannot be cured, the progression of the disease can be controlled. The purpose of treatment is to extend patients' survival and improve quality of life. The main treatments for MM in China include VELCADE®, which is a proteasome inhibitor marketed by Johnson and Johnson in China since 2006, generic thalidomide and REVLIMID®. VELCADE® currently dominates the market in first-line MM treatment in China, while VELCADE® and REVLIMID® share the market in the second line. Chinese guidelines recommend lenalidomide as a standard of care for the treatment of R/R and newly diagnosed MM as well as in the maintenance setting. The first lenalidomide generic and first bortezomib generic in China were approved in November 2017. Another new agent for R/R MM, ixazomib, an oral proteasome inhibitor developed by Takeda, is currently under regulatory review in China. In February 2018, generic lenalidomide from Shuanglu Pharmaceutical Company was approved by the CDA.

In 2017, the patient share for REVLIMID® in second-line MM in the top 30 hospitals in China rose from an estimated 36% to 47%. REVLIMID® achieved national reimbursement drug listing through a successful price negotiation with the Ministry of Human Resources and Social Security in June 2017.

VIDAZA*

VIDAZA* (azacitidine for injection) is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA was approved in China in April 2017 for the treatment of intermediate-2 and high-risk myelodysplastic syndromes, or MDS, chronic myelomonocyte leukemia, or CMML, and acute myeloid leukemia, or AML, with 20% to 30% blasts and multi-lineage dysplasia. In January 2018, VIDAZA* became commercially available in China.

MDS are a group of cancers in which immature blood cells in the bone marrow do not mature and therefore do not become healthy blood cells. Approximately seven per 100,000 people are affected with approximately four per 100,000 people newly acquiring the condition each year globally according to Germing et al., 2013. The typical age of onset is 70 years. The higher-risk MDS (intermediate-2 and high-risk MDS) is fatal because the median overall survival rate is only 0.4-1.1 years and nearly 30% of these patients progress to AML, according to the U.S. National Comprehensive Cancer network, or NCCN, MDS guideline 2013 and MDS Foundation. DNA methylation is an important mechanism of epigenetic gene regulation, but aberrant DNA hypermethylation can result in gene silencing. Silencing of tumor suppressor genes promotes cancer development and progression. MDS patients display aberrant DNA methylation of thousands of genes, which increases with advanced disease and is a poor prognostic factor.

In China, the main treatments for intermediate-2 and high-risk MDS are conventional care regimen, or CCR (best supportive care, low-dose cytarabine and intensive chemotherapy), and hypomethylating agents, or HMAs. DACOGEN* (decitabine) marketed by Johnson and Johnson was the first HMA agent approved in China in 2009. In the past several years, at least six decitabine generics have become available. In 2017, decitabine was listed in the NRDL. Nevertheless, there are still over 50% of higher-risk MDS patients treated by CCR and the unmet need remains large.

VIDAZA* is the only approved HMA shown to prolong survival for patients with MDS. Besides reversing the effects of DNA hypermethylation, VIDAZA* inhibits protein synthesis via RNA incorporation. VIDAZA* is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS, according to the U.S. NCCN guideline. It is also a first-line recommended treatment for patients with intermediate-2 and high-risk MDS, according to the Chinese MDS treatment guidelines.

Our Preclinical Programs

We have a proprietary cancer biology platform that has also allowed us to develop our clinical-stage drug candidates and several additional preclinical-stage drug candidates in potentially important areas. These currently consist of targeted therapies and immuno-oncology agents, including an additional RAF dimer inhibitor and a BTK inhibitor for non-oncology indications. We anticipate advancing one or more of our preclinical assets into the clinic in the next 12 months. We believe we have the opportunity to combine tislelizumab with our preclinical candidates to target multiple points in the cancer immunity cycle. We also may seek to develop companion diagnostics that will help identify patients who are most likely to benefit from the use of our drug candidates.

BUSINESS

Collaboration Agreements

Celgene Corporation

Exclusive License and Collaboration Agreement

On July 5, 2017, we entered into an Exclusive License and Collaboration Agreement, as amended and restated, with Celgene and its wholly-owned subsidiary, Celgene Switzerland LLC, or Celgene Switzerland, which became effective on August 31, 2017, pursuant to which we granted the Celgene parties an exclusive right to develop and commercialize tislelizumab in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia, which we refer to as the PD-1 License Agreement.

Pursuant to the terms of the PD-1 License Agreement, the Celgene parties made upfront payments of US\$263 million to us. In addition, pursuant to a share subscription agreement with Celgene Switzerland dated July 5, 2017, or the Share Subscription Agreement, we issued approximately 32.7 million of our ordinary shares on August 31, 2017 for an aggregate purchase price of US\$150 million at \$4.58 per ordinary share, or \$59.55 per ADS, representing a 35% premium to an 11-day volume-weighted average price of our ADSs. We may also receive up to US\$980 million in potential development, regulatory and sales milestone payments and tiered royalties based on percentages of annual net sales, depending on specified terms, in the low double digit to mid-twenties, with customary reductions in specified circumstances. Royalties are payable on a licensed product-by-product and country-by-country basis until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity, or 12 years after the first commercial sale of such licensed product in the country of sale.

Each party has the right to develop and commercialize tislelizumab in its respective field and territory, and has also agreed to collaborate through a joint steering committee comprised of an equal number of representatives from each party on, among other things, the conduct of up to eight global pivotal clinical trials, or the Basket Studies. Each Basket Study will be conducted and funded by either us or Celgene in accordance with a mutually agreed development plan and study design. For any Basket Studies conducted and funded by us, Celgene has the right to opt into such program, at which time it will reimburse us for agreed upon development costs based on a multiple of such costs that varies according to the stage of development at which Celgene opts into the program. Celgene has committed to use commercially reasonable efforts to develop at least one licensed product, to seek specified regulatory approvals and to spend at least US\$100 million on development for the Basket Studies led by Celgene, subject to specified conditions. In addition, we retain the right to develop tislelizumab in combination therapies with our portfolio compounds, and Celgene has a right of first negotiation for tislelizumab in the hematology field and in our territory, subject to specified conditions.

The PD-1 License Agreement contains customary representations, warranties and covenants by us and Celgene. Unless earlier terminated, the agreement will expire on a licensed product-by-product and country-by-country basis upon the expiration of the royalty term in such country for such licensed product. The agreement may be terminated by Celgene upon 30 days' prior written notice, or by either party upon the other party's bankruptcy or uncured material breach.

BUSINESS

Celgene China Agreement

On July 5, 2017, we and a wholly-owned subsidiary of Celgene, Celgene Logistics Sàrl, or Celgene Logistics, entered into a License and Supply Agreement, which we refer to as the China License Agreement and which became effective on August 31, 2017, pursuant to which we were granted the right to exclusively distribute and promote Celgene's approved cancer therapies, ABRAXANE®, REVLIMID® and VIDAZA®, and its investigational agent avadomide (CC-122) in clinical development in China, excluding Hong Kong, Macau and Taiwan. In addition, if Celgene decides to commercialize a new oncology product through a third-party in the licensed territory during the first five years of the term, we have a right of first negotiation to obtain the right to commercialize the product, subject to certain conditions. We paid an aggregate of US\$4.5 million in cash for the license and our acquisition of Celgene Shanghai, as described below. Subsequent to the closing of the arrangements and through the Latest Practicable Date, we had paid Celgene US\$17.5 million in total for inventory purchases.

The term of the China License Agreement is 10 years and may be terminated by either party upon written notice in the event of uncured material breach or bankruptcy of the other party, or if the underlying regulatory approvals for the covered products are revoked. Celgene Logistics also has the right to terminate the agreement with respect to REVLIMID® at any time upon written notice to the Company.

The China License Agreement contains customary representations and warranties and confidentiality and mutual indemnification provisions.

On August 31, 2017, our wholly owned subsidiary, BeiGene (Hong Kong) Co., Ltd., acquired 100% of the equity interests of Celgene Pharmaceutical (Shanghai) Co., Ltd., or Celgene Shanghai, a wholly-owned subsidiary of Celgene Holdings East Corporation established under the laws of China. The purchase price of Celgene Shanghai was determined to be approximately US\$28.1 million from an accounting perspective, and comprised of a cash consideration of US\$4.5 million and non-cash consideration of US\$23.6 million. The amount allocated to non-cash consideration, related to the discount on ordinary shares issued to Celgene in connection with the Share Subscription Agreement and was a result of the increase in fair value of our shares between the fixed price of US\$59.55 per ADS specified in the Share Subscription Agreement and the fair value per ADS on August 31, 2017, the date the transaction closed. This company, which we subsequently renamed BeiGene Pharmaceutical (Shanghai) Co., Ltd., is in the business of, among other things, providing marketing and promotional services for the pharmaceutical products that we license from Celgene. Prior to closing, Celgene separated out certain business functions, including regulatory and drug safety, that continue to support the business acquired by us.

Merck KGaA, Darmstadt Germany

Pamiparib

On October 28, 2013, we entered into license agreements with Merck KGaA, Darmstadt Germany, which we refer to respectively as the Ex-PRC PARP Agreement and the PRC PARP Agreement, pursuant to which (a) we granted to Merck KGaA, Darmstadt Germany an exclusive

BUSINESS

license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA, Darmstadt Germany exercised a continuation option, to commercialize and manufacture pamiparib and any other compound covered by the same existing patent rights with primary activity to inhibit PARP 1, 2 or 3 enzymes, or the Licensed PARP Inhibitors, in the Ex-PRC (worldwide except PRC) territory, and (b) Merck KGaA, Darmstadt Germany granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the Licensed PARP Inhibitors in the People's Republic of China, or the PRC, which we refer to as the PRC Territory.

On October 1, 2015, pursuant to a purchase of rights agreement, we repurchased all of Merck KGaA, Darmstadt Germany's rights under the Ex-PRC PARP Agreement, in consideration for, among other things, a one-time payment of US\$10 million, which payment has been made, and reduction of future milestone payments we were eligible for under the PRC PARP Agreement. In connection with that repurchase, we also agreed to provide Merck KGaA, Darmstadt Germany with global access to our clinical PARP supplies, including pamiparib, for its combination trials, during the option period. The Ex-PRC PARP Agreement was terminated, except for certain provisions that are needed to effectuate the continuation of the PRC PARP Agreement, including those provisions that were required in the event that Merck KGaA, Darmstadt Germany exercised its PRC Commercialization Option (described below). We repurchased all of Merck KGaA, Darmstadt Germany's rights under the Ex-PRC PARP Agreement and terminated the Ex-PRC PARP Agreement in order to reacquire the rights to pursue both monotherapy and combination therapy.

Pursuant to the PRC PARP Agreement, if we failed to achieve national priority project status in the PRC Territory under its 12th or 13th five-year plan with respect to our pamiparib program in the PRC Territory by July 28, 2017, Merck KGaA, Darmstadt Germany has an option to acquire exclusive commercialization rights under the pamiparib program in the PRC Territory, which we refer to as the PRC Commercialization Option. If, however, we achieved national priority by July 28, 2017, Merck KGaA, Darmstadt Germany only has a right of first negotiation to acquire exclusive commercialization rights under the pamiparib program in the PRC Territory in the event we seek to license our intellectual property rights to a third party. We applied for national priority project status for pamiparib to be effective from the beginning of 2017, and our application is in process and we believe that it will be approved. However, there have been unanticipated governmental delays that have impacted the 2017 applicant pool for national project priority status and we expect that we will now receive formal notification in 2018. As such, we intend to discuss with Merck KGaA, Darmstadt Germany the impact of this delay on the PRC Commercialization Option. If Merck KGaA, Darmstadt Germany exercises the PRC Commercialization Option, it is required to pay us a US\$50 million non-refundable payment upon such exercise, and we are eligible for a US\$12.5 million milestone payment upon the successful achievement of a certain additional regulatory event in the PRC Territory.

Under these agreements, we received US\$6 million in non-refundable upfront payments in December 2013 in connection with the signing of the agreements, including US\$5 million under the PRC PARP Agreement and US\$1 million under the Ex-PRC PARP Agreement. We had also received US\$10 million in milestone payments as of March 31, 2018, including US\$1 million under the PRC PARP Agreement upon dosing of the first patient in the first Phase 2 trial in the PRC Territory, and US\$9 million under the Ex-PRC PARP Agreement upon dosing of the fifth patient in the first Phase 1 trial in the Ex-PRC territory. Pursuant to the terms of the agreements, we are eligible to receive an additional US\$7 million and US\$2.5 million, respectively, in payments upon the successful

BUSINESS

achievement of pre-specified clinical and regulatory milestones in the PRC Territory. Also, in consideration for the licenses granted to us, we are required to pay Merck KGaA, Darmstadt Germany a high single-digit royalty on aggregate net sales of Licensed PARP Inhibitors in the PRC Territory.

The PRC PARP Agreement continues unless terminated as permitted by either party. Merck KGaA, Darmstadt Germany has the right to terminate due to our uncured breach or for convenience upon prior written notice. We have the right to terminate these agreements due to Merck KGaA, Darmstadt Germany's uncured breach or for any challenge brought against our licensed patent rights.

Lifirafenib

On May 24, 2013, we entered into license agreements with Merck KGaA, Darmstadt Germany for lifirafenib, which were amended in 2013 and 2015 and which we refer to respectively as the Ex-PRC BRAF Agreement and PRC BRAF Agreement. In March 2017, Merck KGaA, Darmstadt Germany informed us that it would not exercise a continuation option in the ex-PRC territory, and thus, the ex-PRC BRAF Agreement terminated in its entirety, except for certain provisions that survive termination. Under the PRC BRAF Agreement, Merck KGaA, Darmstadt Germany granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the RAF dimer inhibitor in the PRC, which we refer to as the PRC Territory, subject to certain non-compete restrictions. Further, pursuant to the PRC BRAF Agreement, Merck KGaA, Darmstadt Germany has an exclusive right of first negotiation to acquire exclusive commercialization rights under the lifirafenib BRAF program in the PRC Territory on terms to be mutually agreed in the event we seek to license our intellectual property rights to a third party in the territory.

Under these agreements, in December 2013, we received US\$13 million in non-refundable payments, including US\$10 million under the PRC BRAF Agreement and US\$3 million under the Ex-PRC BRAF Agreement. As of March 31, 2018, we had received US\$9 million in milestone payments, including US\$4 million under the PRC BRAF Agreement upon dosing of the fifth patient in the first Phase 1 trial in the PRC Territory, and US\$5 million under the Ex-PRC BRAF Agreement upon dosing of the fifth patient in the first Phase 1 trial in the Ex-PRC territory. We are eligible to receive an additional US\$14 million in payments upon the successful achievement of pre-specified clinical milestones in the PRC Territory. We are required to pay Merck KGaA, Darmstadt Germany a high single-digit royalty on aggregate net sales of the licensed compounds in the PRC Territory.

The term of the PRC BRAF Agreement continues unless terminated as permitted by either party. Under the PRC BRAF Agreement, Merck KGaA has the right to terminate due to our uncured breach or voluntarily upon prior written notice. We have the right to terminate the PRC BRAF Agreement due to Merck KGaA's uncured breach or for any challenge brought against our licensed patent rights.

Intellectual Property

The proprietary nature of, and protection for, our drug candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. We have obtained patents and filed patent applications in the United States and other countries, such as China, relating to certain of our drug candidates, and are pursuing additional patent protection for them and for other of our drug candidates and technologies. We rely on trade secrets

BUSINESS

to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection including our manufacturing processes. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and support our development programs.

As of July 18, 2018, we owned 17 issued U.S. patents, seven issued China patents, nine pending U.S. patent applications, 11 pending China patent applications, and corresponding patents and patent applications internationally. In addition, we owned 12 pending international patent applications under the Patent Cooperation Treaty, or PCT, which we plan to file nationally in the United States and other jurisdictions, as well as additional priority PCT applications. With respect to any issued patents in the United States and Europe, we may be entitled to obtain a patent term extension to extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the United States, we can apply for a patent term extension of up to five years for one of the patents covering a product once the product is approved by the FDA. The exact duration of the extension depends on the time we spend in clinical studies as well as getting an NDA approval from the FDA. Summaries of patents of our Core Product Candidates and marketed products as of July 18, 2018 are set forth below:

Summary of U.S. Patents of Our Core Product Candidates

Product	Scope of patent protection	Patent Expiration	Market commercial rights of BeiGene	Eligibility for patent extension
Zanubrutinib	Directed to zanubrutinib, a small molecule BTK inhibitor, combinations of zanubrutinib with other therapeutic agents, and its use for the treatment of hematological malignancies	2034	All rights in the U.S.	Yes
Tislelizumab	Directed to tislelizumab, a humanized monoclonal antibody against PD-1, and its use for the treatment of cancer	2033	All rights in the field of hematology in the U.S., and rights to combine with our products in all indications	Yes
Pamiparib	Directed to pamiparib, a small molecule PARP1/2 inhibitor, and its use for the treatment of cancer, including glioblastomas and breast cancer	2031	All rights in the U.S.	Yes
Lifirafenib	Directed to lifirafenib, a small molecule BRAF inhibitor, and its use for the treatment of cancer, including BRAF mutated cancers	2031	All rights in the U.S.	Yes

BUSINESS

Summary of China Patents for Our Core Product Candidates and Marketed Products

Product	Scope of patent protection	Patent Expiration	Market commercial rights of BeiGene	Eligibility for patent extension
Zanubrutinib	Directed to zanubrutinib, a small molecule BTK inhibitor, combinations of zanubrutinib with other therapeutic agents, and its use for the treatment of hematological malignancies	2034	All rights in China	N/A
Tislelizumab	Directed to tislelizumab, a humanized monoclonal antibody against PD-1, and its use for the treatment of cancer	2033	All rights in China	N/A
Pamiparib	Directed to pamiparib, a small molecule PARP1/2 inhibitor, and its use for the treatment of cancer, including glioblastomas and breast cancer	2031	All rights in China, subject to Merck KGaA's PRC Commercialization Option	N/A
Lifirafenib	Directed to lifirafenib, a small molecule BRAF inhibitor, and its use for the treatment of cancer, including BRAF mutated cancers	2031	All rights in China, subject to certain rights of Merck KGaA	N/A
ABRAXANE®	Directed to ABRAXANE®, a nanoparticle albumin-bound paclitaxel, covering its composition, liquid formulation, and use for the treatment of cancer	2018, 2021, 2026, 2031, respectively	Marketing and sales in China	N/A
REVLIMID®	Directed to REVLIMID®, covering its use for the treatment of cancer, including MM	2023, 2027, respectively	Marketing and sales in China	N/A
VIDAZA®	N/A	N/A	Marketing and sales in China	N/A

BUSINESS

The patent portfolios for our four lead product candidates as of July 18, 2018 are summarized below:

Zanubrutinib. We own two issued U.S. patents, one pending U.S. patent application, one issued China patent, two pending PCT applications, and corresponding patent applications in other jurisdictions directed to zanubrutinib, a small molecule BTK inhibitor, combinations of zanubrutinib with other therapeutic agents, and its use for the treatment of hematological malignancies. The expected expiration for the issued U.S. patent is 2034, excluding any additional term for patent term extensions. Any patents that may issue from the currently pending U.S. patent applications would be expected to expire in 2034, not including any patent term adjustments. If a U.S. application is filed based on the pending PCT applications, a patent issuing from these applications, if any, would be expected to expire in 2037. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

Tislelizumab. We are the owner of three issued U.S. patents, one pending U.S. application, one pending PCT application, four pending China patent applications, and corresponding pending patent applications in other jurisdictions directed to tislelizumab, a humanized monoclonal antibody against PD-1, and its use for the treatment of cancer. The expected expiration for the issued U.S. patents is 2033, excluding any additional term for patent term extensions. Any patent that may issue from the currently pending U.S. patent application would be expected to expire in 2033, not including any patent term adjustments. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

Pamiparib. We own two issued U.S. patents, two pending U.S. patent applications, three pending PCT applications, one issued China patent, two pending China patent applications, and corresponding pending patent applications in other jurisdictions directed to pamiparib, a small molecule PARP1/2 inhibitor, and its use for the treatment of cancer, including glioblastomas and breast cancer. We also own the corresponding pending patent applications in other jurisdictions. The expected expiration for the issued U.S. patents is 2031, excluding any additional term for patent term extensions. Any patent that may issue from the currently pending U.S. patent applications would be expected to expire in 2031 and 2036, not including any patent term adjustments. If a U.S. application is filed based on the pending PCT applications, patents issuing from these applications, if any, would be expected to expire in 2037 and 2038. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

Lifirafenib. We own two issued U.S. patents, two pending U.S. patent applications, one pending PCT application, two issued China patents, one pending China patent application, and corresponding pending patent applications in other jurisdictions directed to lifirafenib, a small molecule BRAF inhibitor, and its use for the treatment of cancer, including BRAF mutated cancers. We also own pending patent applications in other jurisdictions corresponding to the U.S. patent applications. In addition, we plan to file nationally in the U.S. and other jurisdictions based on the pending PCT application. The expected expiration for the issued U.S. patents are 2031, excluding any additional term for patent term extensions. Any patents that may issue from the currently pending U.S. patent

BUSINESS

applications would be expected to expire in 2031 and 2036, not including any patent term adjustments. If a U.S. application is filed based on the pending PCT application, a patent issuing from this application, if any, would be expected to expire in 2037. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

The patent portfolios for our three in-licensed commercial products in China are summarized below:

ABRAXANE®. We are the exclusive licensor of five issued Chinese patents and four pending Chinese patent applications directed to ABRAXANE®, a nanoparticle albumin—bound paclitaxel, covering its composition, liquid formulation, and use for the treatment of cancer. The expected expirations for the issued Chinese patents are 2018, 2021, 2026 and 2031, respectively, excluding any additional term for patent term extensions. Any patent that may issue from the currently pending Chinese patent applications would be expected to expire in 2023, 2026 or 2034. In February 2018, a generic version of albumin-bound paclitaxel was approved in China and another is currently under regulatory review.

REVLIMID®. We are the exclusive licensor of seven issued Chinese patents directed to REVLIMID®, covering its use for the treatment of cancer, including MM. The expected expirations for the issued Chinese patents are 2023 and 2027 respectively, excluding any additional term for patent term extensions. The first lenalidomide generic in China was approved in November 2017.

VIDAZA®. We do not have any rights in any issued China patent or pending China patent applications directed to VIDAZA®, a chemical analog of cytidine, and its use for the treatment of cancer. We are aware of third parties who are seeking to develop and obtain approval for generic forms of this drug.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords, is limited. As noted above, ABRAXANE®, REVLIMID®, and VIDAZA® face or are expected to face competition from generic medications, and we may face similar competition for any approved drug candidates even if we successfully obtain patent protection once the patent life has expired for the drug. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents in court, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Under our license agreement with Celgene, Celgene retains the responsibility for, but is not obligated, to prosecute, defend and enforce the patents for these in-licensed products. As such, any issued patents may not protect us from generic competition for these drugs.

The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file, including the United States and China, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the

BUSINESS

USPTO in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. However, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval.

In certain foreign jurisdictions similar extensions as compensation for regulatory delays are also available. The actual protection afforded by a patent varies on a claim by claim and country by country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We may rely, in some circumstances, on trade secrets and unpatented know-how to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Additionally, we currently own a number of registered trademarks and pending trademark applications. We currently have registered trademarks for BeiGene and our corporate logo in China, the European Union and other jurisdictions and are seeking trademark protection for BeiGene and our corporate logo in the United States and other countries where available and appropriate.

Research and Development

We are a leader in the research and development of innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer. We have made significant investments identifying, developing and commercializing biologic drug product candidates with significant market potential. Our current research and development activities mainly relate to the clinical advancement of our six internally-developed drug candidates: (1) zanubrutinib, an investigational small molecule inhibitor of BTK; (2) tislelizumab, an investigational humanized monoclonal antibody against PD-1; (3) pamiparib, an investigational small molecule inhibitor of PARP1 and PARP2; (4) lifirafenib, a novel small molecule inhibitor of both the monomer and dimer forms of BRAF; (5) BGB-A333, an investigational humanized monoclonal antibody against PD-L1; and (6) BGB-A425, an investigational humanized monoclonal antibody against TIM-3. In July 2017, we entered into an Exclusive License and Collaboration Agreement, as amended and restated, with Celgene and Celgene Switzerland, pursuant to which we agreed to collaborate to develop and commercialize tislelizumab. For more details see “— Collaboration Agreements — Celgene Corporation — Exclusive License and Collaboration Agreement.”

BUSINESS

We had over 500 clinical development staff and approximately 200 research staff as of July 20, 2018. We designate employees in our business units to our research and development projects based on their credentials, areas of expertise and capacity.

Recruiting and retaining qualified scientific personnel is critical to our success. We have entered into formal employment agreement with each member of our scientific team. The agreements provide for at-will employment and base salary, cash incentives and equity compensation of various amounts depending on the position of the employee. We also enter into non-disclosure and confidentiality agreements with our scientific personnel. An employment agreement can be terminated by us or the employee in accordance with local employment regulations. While we believe we don't rely on any single key scientific personnel, replacing key scientific personnel 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 products. The loss of the services of our key research and development personnel could impede the achievement of our research and development objectives. We have our internal succession plan on each critical position in the research team, which helps ensure the continuity of product development. Therefore, in the event of the departure of any of our scientific personnel, we believe his or her duties and responsibilities can easily be shifted to other scientific personnel in similar positions.

Customers

During the Track Record Period, we derived revenues only from the product distributor in China in connection with our product sales, from Celgene in connection with our strategic collaboration for tislelizumab entered into in 2017 and from Merck KGaA, Darmstadt Germany in connection with our collaboration for pamiparib and lifirafenib. During the year ended December 31, 2017, we had only three customers. We generated 90.0% of our revenues from upfront license fees, reimbursed research and development expenses and milestone payments from our strategic collaboration with Celgene, 9.6% from our product distributor in China in connection with the sales of our drugs licensed from Celgene and 0.4% from Merck KGaA, Darmstadt Germany in connection with our collaboration for pamiparib and lifirafenib. During the year ended December 31, 2016, 100% of our revenues were generated in connection with our collaboration agreements with Merck KGaA, Darmstadt Germany for pamiparib and lifirafenib. See “—Collaboration Agreements” for further details of our collaborations with Celgene and Merck KGaA, Darmstadt Germany.

As of the Latest Practicable Date, none of our Directors or any Shareholder, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest customers.

BUSINESS

Raw Materials and Suppliers

Raw materials

We currently have a facility that may be used as our clinical-scale manufacturing and processing facility. We are also building manufacturing facilities in China. We obtain raw materials for our manufacturing activities from multiple suppliers who we believe have sufficient capacity to meet our demands. We have not yet caused our drug candidates to be manufactured or processed on a commercial scale.

Raw materials/starting materials used in manufacturing at our facilities in Suzhou include active pharmaceutical ingredients custom-made by our CROs and excipients, which are commercially available from well-known vendors that meet the requirements of the relevant regulatory agencies. The core raw material to be used in manufacturing at our Guangzhou facility under construction is expected to be a genetically modified cell line that we co-developed and licensed from Boehringer Ingelheim.

We typically order raw materials on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. We pay for our purchases of raw materials on credit. Credit periods granted to us by our suppliers generally range from 30 to 60 days. Our suppliers are generally not responsible for the defects of our finished products.

CROs

In line with industry practice, we also engaged certain CROs to conduct preclinical and clinical research as well as clinical trials during the two years ended December 31, 2016 and 2017. We select CROs based on various factors, including their quality, reputation and research experience. Our largest five CROs are all leading global or Chinese CROs. They provide drug discovery and development services to pharmaceutical, biotechnology, medical device, government and academic organizations in China or throughout the world. We generally enter into master contract services agreements with the CROs we engage, which include a statement of work specifying the terms of services provided by CROs.

Key terms of an agreement that we typically enter into with a CRO are summarized as follows:

- *Services.* The CRO provides preclinical and clinical research services or clinical trial services as specified in the statement of work.
- *Term.* The CRO is required to provide the services within the prescribed time limit.
- *Payments.* We are required to make payments to the CRO in accordance with the payment schedule set forth in the statement of work.
- *Intellectual property rights.* All intellectual property rights arising from or made in the performance of the services will generally be owned by us.

BUSINESS

- *Audit.* The service provider shall allow us to inspect their facilities.
- *Insurance.* During the term of the agreement and for a period of at least two (2) years after termination or expiration of the agreement, the service provider will maintain certain minimum insurance and name us as an additional insured.

For the years ended December 31, 2016 and 2017, purchases from our five largest suppliers were approximately US\$50.3 million and US\$113.6 million in terms of expenses, accounting for approximately 73% and 62% of our total purchases, respectively. During the same period, purchases from our largest supplier were approximately US\$14.9 million and US\$35.1 million, respectively, in terms of expenses, accounting for approximately 22% and 19% of our total purchases, respectively.

As of the Latest Practicable Date, none of our Directors or any Shareholder, who to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest suppliers.

Production

We have an approximately 11,000 square meter manufacturing facility in Suzhou, China, where we produce small molecule and biologics drug candidates for clinical supply and which we plan to use for commercial supply of our small molecule drug candidates, if approved. This facility consists of one oral-solid-dosage production line for small molecule drug products and one pilot plant for monoclonal antibody drug substances. In January 2018, the facility received a manufacturing license from Jiangsu Food and Drug Administration, which is required for the commercial manufacture of zanubrutinib in China following NDA approval.

In addition, we have formed a joint venture with Guangzhou GET Technology Development Co., Ltd., an affiliate of Guangzhou Development District, to build a 24,000-liter commercial-scale biologics manufacturing facility in Guangzhou, China. Over US\$300 million in funding has been committed for the construction of the 100,000 square meter manufacturing site. We have contracted with General Electric for the purchase of its state-of-the-art KuBio™ prefabricated biomanufacturing equipment and commenced construction in 2017. We expect the first phase of the facility to be completed in 2019.

We also have an approximately 140 square meter manufacturing facility at our research and development facilities in Beijing, China, which produces preclinical and clinical trial materials for some of our small molecule drug candidates.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements governing recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our manufacturing facilities and the contract manufacturing organizations we use to manufacture our drugs and drug candidates operate under cGMP conditions. cGMP are regulatory requirements for the production of pharmaceuticals that will be used in humans.

BUSINESS

CMOs

We outsource to a limited number of external contract manufacturers the production of some drug substances and drug products, and we expect to continue to do so to meet the preclinical, clinical and potential commercial requirements of our drugs and drug candidates. By outsourcing our manufacturing activities, we can increase our focus on core areas of competence such as drug candidate development, commercialization and research. We have adopted procedures to ensure that the production qualifications, facilities and processes of our third-party outsourced suppliers comply with the relevant regulatory requirements and our internal guidelines. We select our third-party suppliers carefully by taking into account a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and terms offered by such third-party outsourced suppliers. As of the Latest Practicable Date, we had engaged approximately 30 outsourced suppliers, who are Independent Third Parties and most of them had established business relationships with us for more than three years.

We have framework agreements with most of our external service providers, under which they generally provide services to us on a short-term and project-by-project basis. For example, we have an agreement with a contract manufacturer for clinical supply of zanubrutinib and expect to enter into a commercial supply agreement for zanubrutinib in the future. In addition, in January 2018, we entered into a commercial supply agreement with Boehringer Ingelheim Biopharmaceuticals (China) Ltd., or Boehringer Ingelheim, for our investigational anti-PD-1 antibody therapy, tislelizumab, which will be manufactured at Boehringer Ingelheim's facility in Shanghai, China as part of a MAH trial project pioneered by us and Boehringer Ingelheim. We believe the MAH status will be maintained after the expiration of the MAH pilot program in November 2018, based on confirmation from the relevant governmental authority, and therefore we believe that the expiration of the MAH pilot program will not impact our drug candidates. Under the terms of the commercial supply agreement, Boehringer Ingelheim will manufacture tislelizumab in China under an exclusive multi-year arrangement, with contract extension possible. In addition, we also obtained certain preferred rights for future capacity expansion by Boehringer Ingelheim in China. For our commercial products licensed from Celgene, we rely on Celgene and its contract manufacturers outside of China for the supply of these drugs.

Agreements with outsourced suppliers generally set out terms, including product quality or service details, technical standards or methods, delivery terms, agreed price and payment, and product inspection and acceptance criteria. We are general allowed to return any products that fail to meet our quality standards. Our outsourced suppliers procure raw materials themselves. Typically, outsourced suppliers request settlement of payment within 30 days from the date of invoice. Either party may terminate the agreements by serving notice to the other party under certain circumstances.

Sales and Marketing

As of the Latest Practicable Date, we had no internally-developed products approved for commercial sale. In connection with our strategic collaboration with Celgene, we were granted an exclusive license in China, excluding Hong Kong, Macau and Taiwan, to commercialize Celgene's approved cancer therapies, ABRAXANE®, REVLIMID® and VIDAZA®, and Celgene's investigational

BUSINESS

agent avadomide (CC-122) in clinical development. We rely on an independent third-party distributor to sell these drugs. As of the Latest Practicable Date, we had sold our products to one distributor in China. See “Risk Factors—If we fail to maintain an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected.”

We selected our distributor based on its business qualifications and marketing capabilities, such as distribution network coverage, quality, number of personnel, cash flow conditions, creditworthiness, logistics, compliance standard and past performance, and its capacities in customer management. As of the Latest Practicable Date, we were not aware of any potential abuses or improper use of our name by our distributor which could adversely affect our reputation, business operation or financial condition.

We have entered into a written distribution agreement with our distributor. The principal terms are as follows:

Duration	The distribution agreement will remain effective unless terminated by either party upon six months' prior written notice.
Geographic or other exclusivity	<p>Our distributor shall not sell or otherwise distribute the products outside the PRC, unless otherwise agreed by us in writing.</p> <p>We grant our distributor a non-sublicensable, non-transferable and non-assignable:</p> <ul style="list-style-type: none">• non-exclusive limited right to use the know-how and other confidential information in the PRC.• exclusive right to sell the commercial pack in the PRC.
The rights and obligations of parties involved	<p>We offer rebates to our distributor, consistent with pharmaceutical industry practice.</p> <p>We retain no ownership control over the products sold to our distributor, and all significant risks and rewards associated with the products are generally transferred to the distributor upon delivery to and acceptance by the distributor.</p>
Sales and pricing policies	Our distributor retains the discretion to determine the retail prices with reference to local market conditions, competition and customer demand in the regions where it operates, whether greater or lesser than any prices listed, referred or charged by us.
Obsolete stock arrangements	There is no obsolete stock arrangements condition.
Goods return arrangements	There is no goods return arrangements condition.

BUSINESS

Sales and expansion targets	Based on sale forecasts we provide, our distributor shall provide its required amounts of the products to us.
Sales and inventory reports and estimates	<p>Our distributor shall provide to us daily and monthly reports containing full details about the inventory, forecasts, shipping and, returns of the products.</p> <p>Our distributor shall also provide to us daily and monthly reports containing full details about the local sales of the products.</p>
Any minimum purchase amounts	There is no binding minimum purchase condition.
Payment and credit terms	Credit term is generally 90 days following the invoice date.
Conditions for terminating and renewing the agreements	Either party has the right to terminate the agreement on a product-by-product basis with immediate effect upon written notice, if the other party breaches any of the material provisions in the agreement applicable to it and fails to rectify such breach within 30 days of written notice from the other party.
Use of the trademark	Our distributor shall have a non-sublicensable, non-transferable, non-assignable and non-exclusive right to use our trademark for selling our products in the PRC. The use of trademark shall be subject to our prior written approval. Our distributor shall not use the trademark within the PRC for any other product and shall use the trademark only for the purpose of selling our products in the PRC under the agreement.

We rely on our internal sales team for the sales and marketing of our products. As of July 20, 2018, our commercial team consisted of 285 sales and marketing personnel. In anticipation of our business expansion and as our internally-developed drugs become available for sale, if approved, we plan to further expand our sales and marketing force in the next few years.

We also actively attend trade shows, symposia, conventions, seminars and other notable events to promote our brand at the forefront of the industry. We frequently conduct technical seminars at well-recognized academic institutes and pharmaceutical companies to promote our products.

In China, prices of pharmaceutical products are regulated by the government to ensure that drugs are offered at affordable prices. In June 2015, the Chinese government abolished the 15-year-old government-led pricing system for drugs, and lifted the maximum retail price requirement for most drugs, including drugs reimbursed by government medical insurance funds, patented drugs, and some other drugs. The government regulates prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening regulation of medical and pricing practices. See the section titled “Regulations—PRC Regulation—PRC Drug Regulation—Post-Marketing Surveillance—Government price controls” for further details on pricing regulations.

BUSINESS

Our commercial products need to go through the centralized procurement process in the form of public tenders operated by provincial-level government agencies, in order to be commercially available at public medical institutions owned by the government or owned by state-owned or controlled enterprises. Assessment of the bids takes a number of factors into consideration, including but not limited to bid price, product quality, clinical effectiveness, product safety, level of technology, qualifications and reputation of the manufacturer, after-sale services and innovation. As a result, the prices of our commercial products are affected by the bidding process. In addition, in order for our commercial products to be included in the NDRL and critical illness insurance reimbursement listings, we are subject to price negotiation with the Ministry of Human Resources and Social Security and the relevant authorities at provincial level. As of July 18, 2018, REVLIMID® is included in the NDRL and ABRAXANE® is included in various provincial drug or critical illness insurance reimbursement listings.

Employees

As of July 20, 2018, we had a total of 1,335 full-time employees, which increased from 321 full-time employees as of December 31, 2016. Approximately 1,000 of our employees are based in China, and approximately 300 employees are based in the United States. The remaining employees are based in Australia and Switzerland.

The following table sets out the breakdown of our full-time employees by function as of July 20, 2018:

Function	Number of employees
Clinical development.....	533
Manufacturing	115
Others	203
Research	199
Commercial.....	285
Total	<u>1,335</u>

We primarily recruit our employees through recruitment agencies, on-campus job fairs and online channels including our corporate website and social networking platforms, as well as industry referrals. We have adopted a training policy, pursuant to which management, technology and other training are regularly provided to our employees by internally sourced speakers or externally hired consultants. Our employees may also attend external trainings upon their supervisors' approvals.

As required under PRC regulations, we participate in housing fund and various employee social security plans that are organized by applicable local municipal and provincial governments, including housing, pension, medical, work-related injury and unemployment benefit plans, under which we make contributions at specified percentages of the salaries of our employees. We also purchase

BUSINESS

commercial health and accidental insurance for our employees. We have granted performance-based cash bonuses to our executive officers. In addition, we have granted and plan to continue to grant share-based incentive awards to our employees in the future to incentivize their contributions to our growth and development.

None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages, and we consider our relations with our employees to be good.

Insurance

We maintain property damage and business interruption insurance coverage on our corporate, development, research and manufacturing facilities in amounts we believe are reasonable. We hold product liability coverage for our internally-developed drugs as well as public liability, and products and completed operations liability coverage for our commercial products. In addition, we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials. We do not maintain key-man life insurance, or insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous. We believe the coverage of the insurance obtained by us is adequate and consistent with market practice in China and in the United States for our business and operations.

During the Track Record Period, we did not make any material insurance claims in relation to our business. See "Risk Factors — Risks Related to Our Industry, Business and Operations — Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses."

Properties

As of the Latest Practicable Date, through BeiGene Guangzhou Manufacturing, which is a wholly owned subsidiary of our joint venture with Guangzhou Development District and its affiliate, GET, we jointly owned one property in Guangzhou. The property is being used for the construction of a 24,000 liter commercial-scale biologics manufacturing facility with a total of gross floor area of approximately 100,000 square meters.

As of the Latest Practicable Date, we operated our businesses through 12 leased properties in Beijing, Shanghai, Guangzhou and Suzhou, China, and in Emeryville and San Mateo, California, Cambridge, Massachusetts, Fort Lee and Ridgefield, New Jersey and Basel, Switzerland. These properties are used for non-property activities as defined under Rule 5.01(2) of the Listing Rules and are principally used as office and manufacturing premises and for our business operations. We believe that there is sufficient supply of properties in China. Furthermore, even if we experience temporary interruption to our usage of any of our leased office, laboratory or manufacturing space, we believe that our employees can continue to perform the material aspects of their duties remotely given that our offices in other locations can adequately support the functioning of our business operations in areas where we experience temporary office space interruptions. Therefore, we do not rely on the existing leases for our business operations, and we do not believe a contingency relocation plan is required.

BUSINESS

As of the Latest Practicable Date, our leased properties have a total gross floor area of approximately 44,639 square meters, and each leased property ranges from a gross floor area of approximately 73 square meters to 11,290 square meters. The relevant lease agreements have lease expiration dates ranging from August 21, 2018 to January 31, 2024.

As of the Latest Practicable Date, the lessor of two of our leased properties in China had not provided us with valid title certificate, valid title certificate for commercial purpose or relevant authorization documents evidencing its rights to lease the property to us. As a result, this lease may not be valid, and there are risks that we may not be able to continue to use such property.

Pursuant to the applicable PRC laws and regulations, property lease contracts must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, except for one lease that is (located in Room 1506, Tower A, NO. 33, Zhongshan No.3 Road, Yuexiu District, Guangzhou) renewing the lease registration, we had not obtained any lease registration for the rest of the properties we leased in China, primarily due to the difficulty of procuring our lessors' cooperation to register such leases. The registration of such leases will require the cooperation of our lessors. We will take all practicable and reasonable steps to ensure that the unregistered leases are registered. Our PRC Legal Advisor has advised us that the lack of registration of the lease contracts will not affect the validity of the lease agreements under PRC laws.

Health, Safety and Environmental Matters

We and third parties, such as our CROs and CMOs, 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 involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any fines or other penalties due to material non-compliance with health, safety or environmental regulations.

Legal Proceedings and Compliance

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. As of the Latest Practicable Date, we were not aware of any current, pending or threatened material litigation arbitration proceedings or administrative proceedings against us that could have a material adverse effect on our business, results of operations, financial condition or cash flows.

On June 8, 2017, Nasdaq notified us that the resignation from our Board of Ke Tang, one of our audit committee members caused us to no longer comply with Nasdaq's audit committee requirements in Nasdaq listing rule 5605, which require that audit committees have at least three members. Ke Tang had served as a member of the Board since October 2014, and his resignation was due to his decision not to stand for re-election to the Board when his term expired at our annual general meeting of

BUSINESS

shareholders held in June 2017. This decision not to stand for re-election did not involve any disagreement with us on any matter relating to our operations, policies or practices. Under the Nasdaq rules, we had a cure period in order to regain compliance with this rule until the earlier of our next annual general shareholders' meeting or June 1, 2018.

Effective April 1, 2018, our Board appointed Mr. Timothy Chen, one of our existing independent directors, to serve as a member of the audit committee, resulting in us regaining compliance with the Nasdaq's audit committee requirements in the Nasdaq listing rule 5605.

Risk Management and Internal Control

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies and procedures that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems.

We have adopted and implemented comprehensive risk management policies in various aspects.

Financial Reporting Risk Management

As a public company in the United States, we are subject to the Sarbanes-Oxley Act, together with rules implemented by the U.S. Securities and Exchange Commission, or the SEC, and applicable market regulators. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control for financial reporting and disclosure controls and procedures. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Management is responsible for establishing and maintaining adequate internal control over our financial reporting process, and the audit committee oversees our financial reporting process on behalf of the Board. We perform system and process evaluations and testing of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, in order to allow management to report on the effectiveness of our internal control over financial reporting and describe any material weakness in internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The effectiveness of our internal control over financial reporting is also tested by our independent registered public accounting firm on an annual basis.

Information System Risk Management

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. We have implemented

BUSINESS

relevant internal procedures and controls to ensure that such sensitive data is protected and that leakage and loss of such data is avoided. During the Track Record Period and up to the Latest Practicable Date, we do not believe that we have experienced any material information leakage or loss of sensitive data.

Human Resources Risk Management

We provide regular and specialized training tailored to the needs of our employees in different departments. We regularly organize internal training sessions conducted by senior employees or outside consultants on topics of interest. The human resources team, run by senior leaders and experienced human resource professionals, create, schedule and deliver the training. The long term goal is to further increase the number of trainings available to all employees as well as measure the success of the trainings.

In China, we have in place an employee handbook approved by our management and distributed to all our employees, which contains internal rules and guidelines regarding best commercial practice, work ethics, fraud prevention mechanism, negligence and corruption. A similar handbook for the U.S. employee base is in production.

We also have in place an FCPA Policy to safeguard against any corruption within our company. The policy explains potential corruption conducts and our anti-corruption measures. We make our internal reporting channel open and available for our staff to report any corruption acts, and our staff can also make anonymous reports to our internal audit department. Our internal audit department is responsible for investigating the reported incidents and taking appropriate measures.

Investment Risk Management and Treasury Policy

With our surplus cash on hand, we make short-term investments comprised primarily of U.S. treasury securities, U.S. agency securities and time deposits with original maturities between three and twelve months. The primary objective of short-term investments is to preserve principle, provide liquidity and maximize income without significant increasing risk. Our investment decisions are made on a case-by-case basis and after due and carefully consideration of a number of factors, including but not limited to the market conditions, the anticipated investment conditions, the investment costs, the duration of the investment and expected benefit and potential loss of the investment.

Our finance department, under the supervision of our Chief Financial Officer, is responsible for managing our short-term investment activities. Before making a proposal to invest in wealth management products, our financial department must assess our cash flow and operational needs and capital expenditures. We operate under a Board approved investment policy which governs the investment of our funds. The investment policy is reviewed annually by the Board and is circulated to the investment advisors to ensure compliance of investments. Our investments to date have been limited to U.S. Treasury securities, U.S. agency securities, and time deposits at reputable banks. Any deviations from the investment policy, would require consent by the Board. There have been no cases of deviation from our investment policy to date.

BUSINESS

In assessing a proposal to invest in wealth management products, a number of criteria must be met, including but not limited to:

- investments in high risk products being prohibited;
- the primary objectives of investment activities are safety, liquidity and reasonable yield;
- the proposed investment must not interfere with our business operation or capital expenditures; and
- the wealth management products should be issued by a reputable bank.

We believe that our internal policies regarding investment in wealth management products and the related risk management mechanism are adequate. We may make investments in wealth management products that meet the above criteria, after consultation and approval by our Board, as part of our treasury management where we believe it is prudent to do so after the [REDACTED].

Audit Committee Experience and Qualification and Board Oversight

We have established an audit committee to review the adequacy of our internal control over financial reporting to ensure that our internal control system is effective in identifying, managing and mitigating risks involved in our business operations. The audit committee consists of three members, namely Thomas Malley, Qingqing Yi and Timothy Chen. Each of our audit committee members is an independent non-executive director. Thomas Malley is the chairman of the audit committee. For the professional qualifications and experiences of the members of our audit committee, see “Directors and Senior Management” in this [REDACTED]. We also maintain an internal audit department which is responsible for reviewing the effectiveness of internal control and reporting to the audit committee on any issues identified.

Ongoing Measures to Monitor the Implementation of Risk Management Policies

Our audit committee, internal audit department and management together monitor the implementation of our risk management policies on an ongoing basis to ensure our policies and implementation are effective and sufficient.

Licenses and Permits

As of the Latest Practicable Date, we believe that we have obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations.

The following table sets out a list of material licenses and permits currently held by us:

No.	Entity	Name of the License	Expiry Date
1.	BeiGene (Suzhou) Co., Ltd.	Drug Production License	2020/12/31

BUSINESS

Awards and Recognition

We have received recognition for our research and development achievements and our global collaborations. Some of the significant awards and recognition we have received are set forth below.

Award/Recognition	Award Year	Awarding Institution/Authority
Deal of the Year: BeiGene/Celgene collaboration.....	2017	The BayHelix Group
Leading Innovative Enterprise - Beijing Bio-pharmaceutical Industry Leaping Development Project (G20 Project)	2016	Beijing Municipal Science and Technology Commission
Alliance of the Year: BeiGene Ltd./Merck KGaA, for a global licensing, co-development and commercialization agreement for BeiGene-283, a second-generation BRAF inhibitor for the treatment of cancer.	2013	The BayHelix Group and Elsevier Business Intelligence

RISK FACTORS

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

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

Risks Related to Clinical Development of Our Drug Candidates

We depend substantially on the success of our drug candidates, which are in clinical development. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates for the treatment of patients with cancer, which are still in clinical development, and other drug candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates. The success of our drug candidates will depend on several factors, including:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by contract research organizations, or CROs, or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;

RISK FACTORS

- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- successfully launching our drug candidates, if and when approved;
- obtaining favorable reimbursement from third-party payors for drugs, if and when approved;
- competition with other products;
- continued acceptable safety profile following regulatory approval; and
- obtaining sufficient supplies of any competitor drug products that may be necessary for use in clinical trials for evaluation of our drug candidates.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to obtain approval for and/or to successfully commercialize our drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol.

Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

RISK FACTORS

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

Also, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set for the protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from early trials due to differences in the number of patients, clinical trial sites, countries and regions and populations involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Even if our future clinical trial results show favorable efficacy and impressive durability of antitumor responses, not all patients may benefit. For certain drugs, including checkpoint inhibitors, and in certain indications, it is likely that the majority of patients may not respond to the agents at all, some responders may relapse after a period of response and certain tumor types may appear particularly resistant.

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

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

RISK FACTORS

authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; manufacturing issues, including problems with manufacturing, supply quality, compliance with China's drug Good Manufacturing Practice, or GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate; our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including noncompliance with regulatory requirements; the cost of clinical trials of our drug candidates may be greater than we anticipate; and the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, 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 they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

RISK FACTORS

Risks Related to Extensive Government Regulation

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

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of the United States, China and other Asian countries, and the European Union. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes—some minor, some significant—that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in each of these regions.

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

The regulatory approval processes of the U.S. Food and Drug Administration, China Drug Administration, European Medicines Agency and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the CDA, the European Medicines Agency, or EMA, and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

Our drug candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or that a biologic candidate is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;

RISK FACTORS

- disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The FDA, CDA, EMA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

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

We believe that our drug candidates' designation in China as Category 1 products should confer certain regulatory advantages on us. These advantages may not result in commercial benefits to us as we expect, and they might be changed in the future in a manner adverse to us.

In China, prior to seeking approval from the CDA, a pharmaceutical company needs to determine the drug's registration category, which will determine the requirements for its clinical trial and marketing application. These categories range from Category 1, for drugs incorporating a new chemical entity that has not previously been marketed anywhere in the world, to Category 2, for drugs with new indications, dosage forms or routes of administration and the like, to Categories 3 and 4, for certain generic drugs, to Category 5, for "originator" (what would be known elsewhere as innovative)

RISK FACTORS

or generic drugs previously marketed abroad but not yet approved for marketing in China. Therapeutic biologics follow a similar classification system. All of our internally developed drug candidates are classified as Category 1 based on the respective clinical trial approval from the CDA, which is a favored category for regulatory review and approval.

The CDA has adopted several mechanisms for expedited review and approval for drug candidates that apply to Category 1 drug candidates. While we believe that the Category 1 designation of our internally developed clinical stage drug candidates should provide us with a significant regulatory, and therefore commercial, advantage over non-Chinese companies seeking to market products in China, we cannot be sure that this will be the case. The pharmaceutical regulatory environment is evolving quickly, and changes in laws, regulations, enforcement and internal policies could result in the “favored” status of Category 1 products changing, or being eliminated altogether or our products classification in Category 1 changing. We cannot be certain that the advantages we believe will be conferred by our Category 1 classifications will be realized or result in any material development or commercial advantage.

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

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

In China, however, there is no currently effective law or regulation providing patent term extension, patent linkage, or data exclusivity (referred to as regulatory data protection). Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. To be implemented, this framework will require adoption of regulations. To date, CDA has issued several draft implementing

RISK FACTORS

regulations in this regard for public comment but no regulations have been formally issued. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States until the relevant implementing regulations for extension, patent linkage, or data exclusivity are put into effect officially in China.

Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA inspections, which may result in a longer and costlier current good manufacturing practice inspection and approval process by the FDA for our Chinese manufacturing processes.

To obtain FDA approval for our products in the United States, we will need to undergo strict pre-approval inspections of our manufacturing facilities, which we have located in China. Historically, manufacturing facilities in China have had difficulty meeting the FDA's standards. When inspecting our Chinese manufacturing facilities, the FDA might cite current good manufacturing practice, or cGMP, deficiencies, both minor and significant, which we may not be required to disclose. Remediating deficiencies can be laborious and costly and consume significant periods of time. Moreover, if the FDA notes deficiencies as a result of this inspection, it will generally reinspect the facility to determine if the deficiency was remediated to its satisfaction. The FDA may note further deficiencies as a result of its reinspection, either related to the previously identified deficiency or otherwise. If we cannot satisfy the FDA as to our compliance with cGMP in a timely basis, FDA marketing approval for our products could be seriously delayed, which in turn would delay commercialization of our drug candidates.

Undesirable adverse events caused by our drugs and drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events, or AEs, caused by our drugs drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CDA, EMA or other comparable regulatory authority, or could result in limitations or withdrawal following approvals. If results of our trials reveal a high and unacceptable severity or prevalence of AEs, our trials could be suspended or terminated and the FDA, CDA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates.

Numerous drug-related AEs and serious AEs, or SAEs, have been reported in our clinical trials. Some of these events have led to patient death. Drug-related AEs or SAEs could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In this [REDACTED] and from time to time we disclose clinical results for our drug candidates, including the occurrence of AEs and SAEs. Each such document speaks only as of the date of the data cutoff used in such document, and we undertake no duty to update such information unless required by applicable law. Also, a number of immune-related adverse events, or IRAEs, have been associated with treatment with checkpoint inhibitors, including

RISK FACTORS

immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and renal dysfunction, skin adverse reactions, and encephalitis. These IRAEs may be more common in certain patient populations (potentially including elderly patients) and may be exacerbated when checkpoint inhibitors are combined with other therapies.

Additionally, undesirable side effects caused by our drugs and drug candidates, or caused by our drugs and drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including:

- regulatory authorities could delay or halt pending clinical trials;
- we may suspend, delay or alter development of the drug candidate or marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a Risk Evaluation Mitigation Strategy, or REMS, for the drug, as is the case with REVLIMID®, or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies; and
- we could be sued and held liable for harm caused to subjects or patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug or drug candidate, and could significantly harm our business, results of operations and prospects.

Our drugs and any future approved drug candidates will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

Our drugs and any additional drug candidates that are approved are and will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable regulatory authorities in China and other countries.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, CDA, EMA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers are and will be subject to continual review and inspections to assess

RISK FACTORS

compliance with cGMP and adherence to commitments made in any NDA or Biologics License Application, or BLA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The regulatory approvals for our drugs and any approvals that we receive for our drug candidates are and may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug or drug candidate. The FDA or comparable regulatory authorities may also require a REMS program as a condition of approval of our drug candidates or following approval, as is the case with REVLIMID[®]. In addition, if the FDA, CDA, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and Good Clinical Practice, or GCP, for any clinical trials that we conduct post-approval.

The FDA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if compliance with regulatory requirements is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drugs or drug candidates or with our drug's manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our drugs, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our drugs and drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, CDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses

RISK FACTORS

may be subject to significant liability. The policies of the FDA, CDA, EMA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, particularly in China, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of any of our drug candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and may also require post-marketing safety studies. Other comparable regulatory authorities outside the United States, such as the CDA or EMA, may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

If safety, efficacy or other issues arise with any medical product that is used in combination with our drugs, we may be unable to market such drug 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. If the FDA, CDA, EMA or another comparable regulatory agency revokes its approval of 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 component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline or at all.

Reimbursement may not be available for our drug candidates. Even if we are able to commercialize our drugs and any approved drug candidates, the drugs may become subject to unfavorable pricing regulations or third-party reimbursement practices, which could harm our business.

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

RISK FACTORS

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our genetically modified drugs. Patients are unlikely to use our drugs and any approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drug. Because some of our drugs and drug candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that our drugs and any approved drug candidates will be included in the NRDL. Products included in the NRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance, although this has been changing in recent years.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug which we commercialize. Obtaining or maintaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we in-license or successfully develop.

RISK FACTORS

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

We intend to seek approval to market our drug candidates in the United States, China, Europe and in other jurisdictions. In some non-U.S. countries, particularly those in the European Union, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of our drugs will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs and may be affected by existing and future health care reform measures.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States, China, the European Union and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drugs and any drug candidates for which we obtain regulatory approval. We expect that healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our drug candidates, if any, may be.

RISK FACTORS

In recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies, including modification, repeal, or replacement of all, or certain provisions of, the Affordable Care Act, or ACA. The implications of the ACA, its possible repeal, any legislation that may be proposed to replace the ACA, modifications to the implementation of the ACA, and the political uncertainty surrounding any repeal or replacement legislation for our business and financial condition, if any, are not yet clear.

Risks Related to Commercialization of Our Drugs and Drug Candidates

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the drug candidate is safe and effective, or the biologic drug candidate is safe, pure and potent, for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA or BLA must include significant information regarding the chemistry, manufacturing and controls for the drug candidate. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA or BLA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

We have not yet demonstrated an ability to file for or receive regulatory approval for our drug candidates. For example, we do not have experience in preparing the required materials for regulatory submission or navigating the regulatory approval process. As a result, our ability to successfully submit an NDA or BLA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

Regulatory authorities outside of the United States, such as the CDA and EMA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. 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. Seeking non-U.S. regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time consuming. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the United States and China, and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from the regulatory

RISK FACTORS

authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the FDA, CDA and EMA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

Our drugs and any future approved drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Our drugs and any future approved drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drugs and drug candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our drugs and drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drugs and drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drugs and drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drugs and drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drugs and drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drugs and drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;

RISK FACTORS

- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any drugs that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

We have limited experience in marketing third-party drugs and no experience in launching an internally-developed drug candidate. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates and third-party drugs, we may not be able to generate product sales revenue.

In connection with our strategic collaboration with Celgene, we were granted an exclusive license in China, excluding Hong Kong, Macau and Taiwan, to commercialize Celgene's approved cancer therapies, ABRIXANE[®], REVLIMID[®] and VIDAZA[®], and Celgene's investigational agent avadomide (CC-122) in clinical development, and acquired Celgene's commercial operations in China, excluding certain functions. We started marketing Celgene's approved drugs in September 2017. We continue to build our salesforce in China to market these drugs and our drug candidates, in the event they receive commercial approval, and any additional drugs or drug candidates that we may in-license, which will require significant capital expenditures, management resources and time.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. For example, we do not have experience in building a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our internally-developed drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer and cost more than it would if we were a company with experience launching drug candidates.

We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drugs, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drugs ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drugs.

RISK FACTORS

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

We face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of cancer for which we are commercializing our drugs or developing 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.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we commercialize or may develop. Our competitors also may obtain approval from the FDA, CDA, EMA or other comparable regulatory authorities 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 and or slow our regulatory approval.

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, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The market opportunities for our drugs and drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

In markets with approved therapies, we expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second line or first line therapy.

RISK FACTORS

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates and may prove to be inaccurate or based on imprecise data. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our drugs and drug candidates may be limited or may not be amenable to treatment with our drugs and drug candidates. Even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy.

We may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the United States and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or other voluntary industry codes of conduct. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Neither the U.S. government nor the U.S. courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with

RISK FACTORS

applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We may explore the licensing of commercialization rights or other forms of collaboration worldwide, which will expose us to additional risks of conducting business in additional international markets.

Non-U.S. markets are an important component of our growth strategy. For example, in connection with the Celgene transactions, we retained exclusive rights for the development and commercialization of tislelizumab for hematological cancers globally and for solid tumors in China and the rest of Asia, other than Japan. We initially intend to focus on opportunities in China, in particular. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potential third-party patent rights or potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation;

RISK FACTORS

- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

The illegal distribution and sale by third parties of counterfeit versions of our drugs or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our drugs, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a commercial-stage biopharmaceutical company formed in October 2010. Our operations to date have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, conducting preclinical studies and clinical trials of our drug candidates and the commercialization of our drugs. We have not yet completed large-scale, pivotal or registrational clinical trials, obtained regulatory approvals, or manufactured or had manufactured a commercial scale drug. We have no internally-developed products approved for commercial sale and have not generated any revenue from internally-developed product sales. Since September 2017, we have generated revenues from the sale of drugs in China licensed from Celgene. Our limited operating history, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

RISK FACTORS

We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never become profitable.

Investment in pharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we have incurred losses in each period since our inception, except in the third quarter of 2017, when we were profitable due to revenue recognized from an up-front license fee from Celgene. As of December 31, 2017 and March 31, 2018, we had an accumulated deficit of US\$333.4 million and US\$438.0 million, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative expenses associated with our operations.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue and expand our development of, and seek regulatory approvals for, our drug candidates, and continue to commercialize the drugs that we have licensed from Celgene in China and any other drugs that we may successfully develop or license. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company in the United States and will start incurring costs associated with being a public company in Hong Kong after the [REDACTED]. We will also incur costs in support of our growth as a commercial-stage global biopharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with arrangements with third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. 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.

We will need to obtain additional financing to fund our operations, and if we are unable to obtain that financing, we may be unable to complete the development and commercialization of our primary drug candidates.

Our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. Our operating activities provided US\$12.8 million and used US\$89.5 million of net cash during the years ended December 31, 2017 and 2016, and used US\$104.5 million and US\$35.7 million of net cash during the three months ended March 31, 2018 and 2017, respectively. We recorded negative net cash flows from operating activities in 2016 primarily due to our net loss of US\$119.2 million. Although we recorded positive net cash flows from operating activities in 2017, we cannot assure you that we will be able to generate positive cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows, and we cannot

RISK FACTORS

assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise finance by issuing further equity securities your interest in our company may be diluted. If we have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, commercializing our drugs and launching and commercializing any drug candidates for which we receive regulatory approval, including building our own commercial organization to address China and other markets. While we have generated product revenue in China since September 2017 from sales of our drugs licensed from Celgene, these revenues are not sufficient to support our operations. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that we have sufficient cash, cash equivalents and short-term investments to meet our projected operating requirements for at least the next 12 months. However, we believe that our existing cash, cash equivalents and short-term investments will not be sufficient to enable us to complete all global development or commercially launch all of our current drug candidates for the currently anticipated indications and to invest in additional programs. Accordingly, we will require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the number and characteristics of drug candidates that we may in-license and develop;
- the amount and timing of the milestone and royalty payments we receive from our collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our drugs in China and any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

RISK FACTORS

- cash requirements of any future acquisitions and/or the development of other drug candidates;
- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities; and
- our headcount growth and associated costs.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our ordinary shares and/or 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 and/or ordinary shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party 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.

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially reduce the value of your [REDACTED].

We incur portions of our expenses, and derive revenues, in currencies other than the U.S. dollar or Hong Kong dollar, in particular, the RMB and Australian dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

RISK FACTORS

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy proposed or adopted by the PRC, Australia and other non-U.S. governments. It is difficult to predict how market forces or PRC, Australia, other non-U.S. governments and U.S. government policies may impact the exchange rate of RMB and the U.S. dollar or any other currencies in the future. There remains significant international pressure on the PRC government to adopt a more flexible currency policy, including from the U.S. government, which has threatened to label China as a “currency manipulator,” which could result in greater fluctuation of the RMB against the U.S. dollar.

Substantially all of our revenues are denominated in U.S. dollars and RMB, and our costs are denominated in U.S. dollars, Australian dollars and RMB, and a large portion of our financial assets and a significant portion of our debt is denominated in U.S. dollars and RMB. Any significant revaluation of the RMB may materially reduce any dividends payable on our ordinary shares and/or ADSs in U.S. dollars. To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our 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 amount we would receive.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the RMB against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the RMB may adversely affect the value of, and any dividends payable on, our ordinary shares and/or ADSs in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to obtain the SAFE's approval before converting significant sums of foreign currencies into RMB. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our ordinary shares and/or ADSs in foreign currency terms.

Our business, profitability and liquidity may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers, and an impairment in the carrying value of our short-term investments could negatively affect our consolidated results of operations.

We are exposed to the risk that our distributors and customers may default on their obligations to us as a result of bankruptcy, lack of liquidity, operational failure or other reasons. As we continue to expand our business, the amount and duration of our credit exposure will be expected to increase over the next few years, as will the breadth of the entities to which we have credit exposure. Although we regularly review our credit exposure to specific distributors and customers that we believe may present credit concerns, default risks may arise from events or circumstances that are difficult to detect or foresee.

Also, the carrying amounts of cash and cash equivalents, restricted cash and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of US\$490.6 million, US\$239.6 million and US\$87.5 million, restricted cash of US\$17.5

RISK FACTORS

million, nil and nil and short-term investments of US\$973.4 million, US\$597.9 million and US\$280.7 million at March 31, 2018, December 31, 2017 and 2016, respectively, most of which are deposited in financial institutions outside of China. Although our cash and cash equivalents in China are deposited with various major reputable financial institutions, the deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. As of March 31, 2018 and December 31, 2017, our short-term investments consisted primarily of U.S. Treasury securities, U.S. agency securities and time deposits. Although we believe that the U.S. Treasury securities, U.S. agency securities and time deposits are of high credit quality and continually monitor the credit worthiness of these institutions, concerns about, or a default by, one institution in the U.S. market, could lead to significant liquidity problems, losses or defaults by other institutions, which in turn could adversely affect us.

Risks Related to Our 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 large part on our ability to protect our proprietary technology and 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 patent applications in the United States, the PRC and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent 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. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs 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 were the first

RISK FACTORS

to make the inventions claimed in our patents or pending patent applications or that we 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.

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 United States, PRC and other countries. We 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 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 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 invention or other features of patentability of our 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 patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords, is limited. For example, the approved cancer therapies we have licensed from Celgene in China, ABRAXANE[®], REVLIMID[®] and VIDAZA[®], face or are expected to face competition from

RISK FACTORS

generic medications, and we may face similar competition for any approved drug candidates even if we successfully obtain patent protection once the patent life has expired for the drug. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents in court, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in “Business—Intellectual Property” of this [REDACTED]. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

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 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.

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

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength than do those in the United States. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as U.S. federal and state laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drugs made using our inventions in and into the United States or non-U.S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the United States. These drugs may compete with our drugs and drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely

RISK FACTORS

affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights.

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

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable non-U.S. authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability

RISK FACTORS

is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further

RISK FACTORS

develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

We are aware of U.S. patents with claims covering certain antibodies that are relevant to tislelizumab for which patents are expected to expire in 2023 or 2024; complexes of irreversible BTK inhibitors that are relevant to zanubrutinib for which the patent is expected to expire in 2027; and the use of PARP inhibitors to treat certain cancers that are relevant to pamiparib for which patents are expected to expire between 2027 and 2031. We are also aware of issued patents in Europe and China relevant to pamiparib. Although we believe that the relevant claims of these patents would likely be held invalid, we can provide no assurance that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims of one or more of these patents were to be upheld upon a validity challenge, and our related drug candidate was to be approved for sale in the United States before the expiration of the relevant patents, we would need a license to commercialize the drug candidate in the United States before the expiration of the relevant patents. In addition, depending upon the circumstances, we may need licenses for jurisdictions outside of the United States where we wish to commercialize a particular drug candidate before the expiration of corresponding patents covering that drug candidate. In such cases, we can provide no assurance that we would be able to obtain a license or licenses on commercially reasonable terms or at all, which could materially and adversely affect our business.

Even if litigation or other proceedings are resolved in our favor, 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 market price of the ordinary shares and/or ADSs. 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 adequately conduct such litigation or proceedings. 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. 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.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant

RISK FACTORS

jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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 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 clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. 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 beyond the new pilot program, and implementation of the pilot program may not occur quickly. As a result, the patents we have in the PRC are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. 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.

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

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

RISK FACTORS

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

RISK FACTORS

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

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications. These license agreements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials and we must work effectively with collaborators to develop our drug candidates. 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 our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs

RISK FACTORS

does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, CDA, EMA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, CDA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, 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 ongoing clinical and nonclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our 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.

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. 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 effect on our business, financial condition and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition, cash flows and results of operations.

RISK FACTORS

We expect to rely on third parties to manufacture at least a portion of our clinical and commercial drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we currently have a facility that may be used as our clinical-scale manufacturing and processing facility and are building manufacturing facilities in China, we intend to at least partially rely on outside vendors to manufacture supplies and process our drugs and drug candidates. For example, we have entered into a commercial supply agreement for tislelizumab with Boehringer Ingelheim Biopharmaceuticals (China) Ltd. In addition, we rely on Celgene and its third-party manufacturers for supply of ABRAXANE[®], REVLIMID[®] and VIDAZA[®] in China. We have not yet caused our drug candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our drug candidates. We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

Although we intend to further develop our own manufacturing facilities, we also intend to use third parties as part of our manufacturing process and for the clinical and commercial supply of our drugs and drug candidates. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, CDA, EMA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by FDA, CDA, EMA or other comparable regulatory authorities;
- our manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drugs and drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with cGMPs and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates and drugs;

RISK FACTORS

- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our drugs. In addition, we will rely on third parties to perform certain specification tests on our drugs and drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

Currently, the raw materials for our manufacturing activities are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in our supply of our drugs and drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drugs for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before a third party can begin commercial manufacture of our drugs and drug candidates, contract manufacturers are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture drug and biological products and our drug candidates, any potential third-party manufacturer may be unable to

RISK FACTORS

initially pass federal, state or international regulatory inspections in a cost-effective manner in order for us to obtain regulatory approval of our drug candidates. If our contract manufacturers do not pass their inspections by the relevant regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates or disruption in sales. In addition, drug and biological manufacturing facilities are continuously subject to inspection by regulatory authorities, before and after drug approval, and must comply with cGMPs. Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, could require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. This review may be costly and time consuming and could delay or prevent the launch of a product. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

We have entered into collaborations, such as with Celgene and Merck KGaA, Darmstadt Germany, and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

For example, we entered into license agreements with Merck KGaA, Darmstadt Germany, pursuant to which Merck KGaA, Darmstadt Germany has an option to acquire exclusive commercialization rights under our pamiparib PARP program in the PRC if pamiparib does not receive national priority project status in China under its 12th or 13th five-year plan by July 28, 2017. We applied for national priority project status for pamiparib to be effective from the beginning of 2017,

RISK FACTORS

and our application is in process and we believe it will be approved. However, there have been unanticipated governmental delays that have impacted the 2017 applicant pool for national project priority status and we expect that we will now receive formal notification in 2018. As such, we intend to discuss with Merck KGaA, Darmstadt Germany the impact of this delay on the PRC PARP license agreement.

Our strategic collaboration with Celgene involves numerous risks. There can be no assurance that we will be able to successfully manage and integrate Celgene's commercial operations in China and its personnel into our business, which could disrupt our business and harm our financial results. Moreover, we may not achieve the revenue and cost synergies expected from the transaction and our management's attention may be diverted from our drug discovery and development business. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with Celgene may be offset by costs incurred in integrating Celgene's commercial operations in China, increases in other expenses, operating losses or problems in the business unrelated to our collaboration with Celgene. As a result, there can be no assurance that these synergies will be achieved.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drugs or drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than us, and any agreement that we do enter may result in the anticipated benefits.

Further, collaborations involving our drugs and drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;

RISK FACTORS

- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships or the license of our third-party drugs if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

RISK FACTORS

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

We rely on a third-party distributor to distribute Celgene's approved cancer therapies, ABRAXANE®, REVLIMID® and VIDAZA®. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributor, who may fail to distribute our products in the manner we contemplate. While we have long-standing business relationship with our distributor, the agreement we entered into with our distributor can be terminated by both parties upon six months' written notice. If PRC price controls or other factors substantially reduce the margins our distributor can obtain through the resale of our products to hospitals, medical institutions and sub-distributors, it may terminate its relationship with us. As of the Latest Practicable Date, we rely on one distributor to distribute our products. While we believe alternative distributors are readily available in China, there is a risk that, if the distribution of our drugs is interrupted, our sales volumes and business prospects could be adversely affected.

We may be restricted from transferring our scientific data abroad

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Risks Related to Our Industry, Business and Operations

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

We are highly dependent on Xiaodong Wang, Ph.D., our Co-Founder, Chairman of our scientific advisory board, which may from time to time provide us assistance upon our request, and director; John V. Oyler, our Co-Founder, Chief Executive Officer and Chairman of the Board; and the other

RISK FACTORS

principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided share option, restricted share unit and restricted share grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the ADS and/or ordinary share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants 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, key employees or consultants 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 products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants 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. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We have significantly increased the size and capabilities of our organization, and we may experience difficulties in managing our growth.

At the beginning of 2017, we had over 320 employees, and we ended the year with approximately 900 employees. As of July 20, 2018, our total employee number reached over 1,300. Most of our employees are full-time. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

RISK FACTORS

- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drugs and drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

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

We incur significant costs as a result of operating as a public company in the United States, and our management is required to devote substantial time to compliance requirements, including establishing and maintaining internal controls over financial reporting. We may be exposed to potential risks if we are unable to comply with these requirements.

As a public company in the United States, we are subject to the periodic reporting requirements of the U.S. Exchange Act and incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, together with rules implemented by the SEC and applicable market regulators. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We have limited experience complying with Section 404, and such compliance may require that we incur substantial accounting expenses and expend significant management efforts. Our testing may reveal deficiencies in our internal controls over financial

RISK FACTORS

reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, the market price of our ordinary shares and/or ADSs could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC or other applicable regulatory authorities and our business could be harmed.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

RISK FACTORS

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, and other 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 (《中華人民共和國反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the Prior Notification Rules issued by the State Council, 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 SAMR when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《實施外國投資者併購境內企業安全審查制度的規定》), or the Security Review Rules, issued by the MOFCOM 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 SAMR, 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.

If we fail to comply with the U.S. Foreign Corrupt Practices Act or other anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the Foreign Corrupt Practices Act, or 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 has expanded, the applicability of the FCPA and other anti-bribery laws to our operations has increased.

RISK FACTORS

We do not fully control the interactions our employees, distributors and third-party promoters have with hospitals, medical institutions and doctors, and they may try to increase sales volumes of our products through means that constitute violations of the PRC anti-corruption and other related laws. If our employees, distributors or third-party promoters engage in corrupt or other improper conduct that results in violation of applicable anti-corruption laws in the PRC or other jurisdictions, our reputation could be harmed. Furthermore, we could be held liable for actions taken by our employees, distributors or third-party promoters, which could expose us to regulatory investigations and penalties.

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.

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

We and third parties, such as our CROs or CMOs, 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. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health and safety have been completed. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

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

RISK FACTORS

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

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

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems,

RISK FACTORS

controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

If we or parties on whom we rely fail to maintain the necessary licenses for the development, production, sales and distribution of our products, our ability to conduct our business could be materially impaired.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Third parties, such as distributors, third party promoters and third-party manufacturers, on whom we may rely to develop, produce, promote, sell and distribute our products may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

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

Our operations, and those of our third-party research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We partially rely on third-party manufacturers to produce and process our drugs and drug candidates. Our ability to obtain supplies of our drugs and drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure,

RISK FACTORS

unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

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

We face an inherent risk of product liability as a result of the commercialization of our drugs in China and the clinical testing and any future commercialization of our drug candidates globally. For example, we may be sued if our drugs or drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drugs and drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drugs; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any drug candidate; and a decline in the ADS or ordinary share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our drugs and drug candidates. Although we currently hold US\$10 million in product liability coverage in the aggregate, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We are subject to the risks of doing business globally.

Because we operate in China and other countries outside of the United States, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain

RISK FACTORS

countries; enforcement of anti-corruption and anti-bribery laws, such as the FCPA; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable local tax regimes and potentially adverse tax consequences; and significant adverse changes in local currency exchange rates.

We manufacture and intend to continue to manufacture ourselves at least a portion of our drug candidates and our drugs, if approved. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

We currently have manufacturing facilities in Beijing and Suzhou, China and are building a biologics manufacturing facility in Guangzhou, China. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation and/or approval of our new facility is delayed, we may not be able to manufacture sufficient quantities of our drug candidates and our drugs, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources.

In addition to the similar manufacturing risks described in “—Risks Related to Our Reliance on Third Parties,” our manufacturing facilities will be subject to ongoing, periodic inspection by the FDA, CDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, CDA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, CDA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could harm our business.

RISK FACTORS

Developing advanced manufacturing techniques and process controls is required to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete.

To produce our drugs in the quantities that we believe will be required to meet anticipated market demand of our drug candidates if approved, we will need to increase, or “scale up,” the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our drugs in a sufficient quantity to meet future demand.

In addition to the similar manufacturing risks described in “—Risks Related to Our Reliance on Third Parties,” if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates or drugs in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates and drugs if there were a catastrophic event or failure of our manufacturing facilities or processes.

Risks Related to Our Doing Business in the PRC

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

A large portion of our business is conducted in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates or drugs in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and

RISK FACTORS

regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the Chinese government's policies, but we cannot ensure that our strategy and approach will continue to be aligned.

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

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC. 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 four decades, growth has been uneven across different regions and among various economic sectors of the PRC. 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 the PRC, which may adversely affect our business and results of operation. More generally, if the business environment in the PRC deteriorates from the perspective of domestic or international investment, our business in the PRC may also be adversely affected.

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

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

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature of such decisions, the interpretation and enforcement of these laws, rules and

RISK FACTORS

regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

A draft of the proposed Foreign Investment Law (《外國投資法(徵求意見稿)》) is being considered and there are substantial uncertainties with respect to the enactment timetable and the final content of the Foreign Investment Law. If enacted as proposed, the Foreign Investment Law may materially impact our current corporate governance practices and business operations in many aspects and may increase our compliance costs. For instance, the proposed Foreign Investment Law would impose stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable foreign invested entities. Depending on the seriousness of the circumstances, non-compliance with the information reporting obligations, concealment of information or providing misleading or false information could result in monetary fines or criminal charges.

Additionally, the CDA'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 the PRC may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Any failure to comply with PRC regulations regarding our employee equity incentive plans and investments in offshore companies by PRC residents may subject the PRC plan participants and PRC-resident beneficial owners or us to fines and other legal or administrative sanctions.

We and our Directors, executive officers and other employees who are PRC residents have participated in our employee equity incentive plans. We are an overseas listed company, and therefore, we and our Directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted share units, restricted shares, options or other forms of equity incentives are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plan of Overseas Publicly Listed Company (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in the PRC for a continuous period of not less than one year, subject to limited 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 other procedures. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our Directors and employees under PRC law.

RISK FACTORS

Some of our existing shareholders, each of whom owns our ordinary shares as a result of exercising share options, are PRC residents under the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or SAFE Circular 37. These shareholders have undertaken to (i) apply to register with local SAFE branch or its delegated commercial bank as soon as possible after exercising their options, and (ii) indemnify and hold harmless us and our subsidiaries against any loss suffered arising from their failure to complete the registration. We do not have control over such shareholders and our other beneficial owners and cannot assure you that all of our PRC-resident beneficial owners have complied with, and will in the future comply with, SAFE Circular 37 and subsequent implementation rules.

If we or our Directors, executive officers or other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted equity awards fail to register the employee equity incentive plans or their exercise of options, or such PRC-resident beneficial owners fail to register or amend their SAFE registrations in a timely manner pursuant to SAFE Circular 37, we, such employees and PRC-resident beneficial owners may be subject to (i) legal or administrative sanctions imposed by the SAFE or other PRC authorities, including fines; (ii) restrictions on our cross-border investment activities; (iii) limits on the ability of our wholly owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us; and (iv) prohibitions on our ability to inject 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.

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 incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their 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. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each operating subsidiary. As of December 31, 2017 and March 31, 2018, these restricted assets totaled US\$39.9 million and US\$37.0 million, respectively.

RISK FACTORS

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

In response to the persistent capital outflow in the PRC and RMB's depreciation against U.S. dollar, in the fourth quarter of 2016, People's Bank of China, or PBOC, and the SAFE promulgated a series of capital control measures, 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 the 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.

The Enterprise Income Tax Law (《企業所得稅法》), or the EIT Law, and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor's jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to PRC withholding tax at a rate of 10%.

Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), or the Hong Kong Tax Treaty, BeiGene HK, the shareholder of some of our PRC subsidiaries, may be subject to a withholding tax at a rate of 5% on dividends received from our PRC operating subsidiaries as a Hong Kong tax resident. Pursuant to the Hong Kong Tax Treaty, subject to certain conditions, this reduced withholding tax rate will be available for dividends from PRC entities provided that the recipient can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. BeiGene HK currently does not hold a Hong Kong tax resident certificate from the Inland Revenue Department of Hong Kong and there is no assurance that the reduced withholding tax rate will be available.

We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and we may therefore be subject to PRC income tax on our worldwide taxable income. Dividends payable to foreign investors and gains on the sale of our ADSs or ordinary shares by our foreign investors may become subject to PRC tax.

Under the EIT Law an enterprise established outside the PRC with “de facto management bodies” within the PRC is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for PRC enterprise income tax, or EIT, purposes. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition, the Notice Regarding the Determination of

RISK FACTORS

Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》), or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders' meetings; and (iv) half or more of senior management or directors having voting rights. The State Administration of Taxation, or the SAT, has subsequently provided further guidance on the implementation of Circular 82.

Although BeiGene, Ltd. does not have a PRC enterprise or enterprise group as its primary controlling shareholder and is therefore not a Chinese-controlled offshore incorporated enterprise within the meaning of Circular 82, in the absence of guidance specifically applicable to us, we have applied the guidance set forth in Circular 82 to evaluate the tax residence status of BeiGene, Ltd. and its subsidiaries organized outside of the PRC. We are not aware of any offshore holding company with a corporate structure similar to ours that has been deemed a PRC "resident enterprise" by the PRC tax authorities. Accordingly, we do not believe that our company or any of our overseas subsidiaries should be treated as a PRC resident enterprise.

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 our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow and we may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. If we are deemed a PRC resident enterprise, dividends paid on our ordinary shares or ADSs, and any gain realized from the transfer of our ordinary shares or ADSs, may be treated as income derived from sources within the PRC. As a result, dividends paid to non-PRC resident enterprise ADS holders or shareholders may be subject to PRC withholding tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprises ADS holders or shareholders from the transfer of our ordinary shares or ADSs may be subject to PRC tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders).

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company, or other assets attributable to a PRC establishment of a non-PRC company.

Pursuant to the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), or Bulletin 7, which was amended by the Announcement on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises issued by SAT (《關於非居民企業所得稅源泉扣繳有關問題的公告》), or Announcement 37, an "indirect transfer" of "PRC taxable assets," including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial

RISK FACTORS

purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a “reasonable commercial purpose” of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in the PRC or if its income mainly derives from the PRC; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be reported on with the enterprise income tax filing of the PRC establishment or place of business being transferred, and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC enterprise income tax at the rate of 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC enterprise income tax pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. As such, the sale of the ADSs or ordinary shares on a public stock exchange will not be subject to PRC enterprise income tax pursuant to Bulletin 7. However, the sale of our ordinary shares or ADSs by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Bulletin 7.

There are uncertainties as to the application of Bulletin 7. Bulletin 7 may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with Bulletin 7 or to establish that we and our non-resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Announcement 37 or Bulletin 7, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

RISK FACTORS

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of the PRC. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our ordinary shares and the ADSs. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities or designated banks. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

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

In the past, local governments in the PRC granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The 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. Government grant and subsidies recognized in the income statement for the years ended December 31, 2016 and 2017, and the three month periods ended March 31, 2018 and 2017 was US\$1,363,000, US\$20,957,000, US\$154,000 and US\$776,000, respectively.

RISK FACTORS

The audit report included in our annual report on Form 10-K filed with the SEC is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, investors are deprived of the benefits of such inspection.

As an auditor of companies that are publicly traded in the United States and a firm registered with the PCAOB, Ernst & Young Hua Ming LLP is required under the laws of the United States to undergo regular inspections by the PCAOB. However, because we have substantial operations within the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our auditor and its audit work is not currently inspected fully by the PCAOB.

Inspections of other auditors conducted by the PCAOB outside the PRC have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in the PRC prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections, and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

Proceedings instituted by the SEC against five PRC-based accounting firms, including our independent registered public accounting firm, could result in our financial statements being determined to not be in compliance with the requirements of the U.S. Exchange Act.

In December 2012, the SEC brought administrative proceedings against five accounting firms in China, including our independent registered public accounting firm, alleging that they had refused to produce audit work papers and other documents related to certain other PRC-based companies under investigation by the SEC. On January 22, 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. The decision is neither final nor legally effective unless and until reviewed and approved by the SEC. On February 12, 2014, four of these PRC-based accounting firms appealed to the SEC against this decision. In February 2015, each of the four PRC-based accounting firms agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC. These firms' ability to continue to serve all their respective clients is not affected by the settlement. The settlement requires these firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC. If these firms do not follow these procedures, the SEC could impose penalties such as suspensions, or it could restart the administrative proceedings. The settlement did not require these firms to admit to any violation of law and preserves these firms' legal defenses in the event the administrative proceeding is restarted. In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the U.S. Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, U.S.-listed companies and the market price of the ADSs and/or ordinary shares may be adversely affected.

RISK FACTORS

If our independent registered public accounting firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the U.S. Exchange Act. Such a determination could ultimately lead to deregistration from the SEC, which would substantially reduce or effectively terminate the trading of the ADSs in the United States. Moreover, any negative news about the proceedings against these audit firms may adversely affect investor confidence in companies with substantial mainland China-based operations listed in the United States. All these would materially and adversely affect the market price of the ADSs and substantially reduce or effectively terminate the trading of the ADSs in the United States, and the market price of the ordinary shares may be adversely affected.

Risks Related to the [REDACTED] and the [REDACTED]

An active trading market for the ordinary shares on the Stock Exchange might not develop or be sustained, their trading prices might fluctuate significantly and the effectiveness of the liquidity arrangements might be limited.

Following the completion of the [REDACTED], we cannot assure you that an active trading market for the ordinary shares on the Stock Exchange will develop or be sustained. In particular, the Stock Exchange has only recently implanted changes to the Listing Rules to facilitate the [REDACTED] of biotech companies and [REDACTED] in Hong Kong listed securities may not be as familiar with [REDACTED] in biotech companies as [REDACTED] in other markets. If an active trading market of the ordinary shares on the Stock Exchange does not develop or is not sustained after the [REDACTED], the market price and liquidity of the ordinary shares could be materially and adversely affected. As a result, the market price for our ordinary shares in Hong Kong following the completion of the [REDACTED] might not be indicative of our ADSs on the Nasdaq, even allowing for currency differences.

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

The trading price of our ordinary shares and/or ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in the PRC that have listed their securities in Hong Kong or the United States may affect the volatility in the price of and trading volumes for our ordinary shares and/or ADSs. Some of these companies have experienced significant volatility. The trading performances of these PRC companies' securities may affect the overall investor sentiment towards other PRC companies listed in Hong Kong or the United States and consequently may impact the trading performance of our ordinary shares and/or ADSs.

In addition to market and industry factors, the price and trading volume for our ordinary shares and/or ADSs may be highly volatile for specific business reasons, including: announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process; announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors; adverse actions taken by regulatory agencies with respect to our clinical

RISK FACTORS

trials, manufacturing supply chain or sales and marketing activities; any adverse changes to our relationship with manufacturers or suppliers; the results of our testing and clinical trials; the results of our efforts to acquire or license additional drug candidates; variations in the level of expenses related to our existing drugs and drug candidates or preclinical, clinical development and commercialization programs; any intellectual property infringement actions in which we may become involved; announcements concerning our competitors or the pharmaceutical industry in general; fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages; variations in our results of operations; announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations; publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts; changes in financial estimates by securities research analysts; media reports, whether or not true, about our business; additions to or departures of our management; fluctuations of exchange rates between the RMB, the U.S. dollar and Hong Kong dollar; release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; sales or perceived potential sales of additional ordinary shares or ADSs by us, our executive officers and Directors or our shareholders; general economic and market conditions and overall fluctuations in the U.S. or Hong Kong equity markets; changes in accounting principles; and changes or developments in the PRC or global regulatory environment.

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

The characteristics of the U.S. capital markets and the Hong Kong capital markets are different.

The Nasdaq and the Stock Exchange have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our ordinary shares and the ADSs representing them might not be the same, even allowing for currency differences. Fluctuations in the price of our ADSs due to circumstances peculiar to its home capital market could materially and adversely affect the price of the ordinary shares. Because of the different characteristics of the U.S. and Hong Kong equity markets, the historic market prices of our ADSs may not be indicative of the performance of our securities (including the ordinary shares) after the [REDACTED].

We may be subject to securities litigation, which is expensive and could divert management attention.

Companies that have experienced volatility in the volume and market price of their shares have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, and, if adversely determined, could have a material adverse effect on our business, financial condition and results of operations.

RISK FACTORS

Future sales of our ordinary shares and/or the ADSs in the public market could cause the ordinary share and/or ADS price to fall.

Our ordinary share and/or ADS price could decline as a result of sales of a large number of ordinary shares and/or the ADSs or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of May 4, 2018, we had 698,883,853 ordinary shares outstanding, of which 495,841,346 ordinary shares were held in the form of 38,141,642 ADSs. Of this amount, 32,746,416 ordinary shares issued to Celgene are subject to a lock-up until September 1, 2018. We have also granted certain registration rights with respect to the shares issued to Celgene in the event that they are not eligible for sale under Rule 144.

In connection with the [REDACTED], our Directors and executive officers, certain trusts and parties affiliated with such Directors and officers and certain holders of our shares [have signed] lock-up agreements. See "[REDACTED]" Upon completion of the [REDACTED], assuming the [REDACTED] do not exercise their [REDACTED], approximately [REDACTED]% of our outstanding ordinary shares immediately after the [REDACTED] will not be subject to lock-up agreements and sold to the public after the [REDACTED] from time to time.

We filed a registration statement with the SEC on behalf of certain shareholders, registering 299,279,370 ordinary shares in the form of 23,021,490 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. Furthermore, we have registered or plan to register the offer and sale of all securities that we have issued and may issue in the future under our equity compensation plans, including upon the exercise of share options and vesting of restricted share units. If these additional securities are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares and/or ADSs could decline.

In addition, in the future, we may issue additional ordinary shares, ADSs or other equity or debt securities convertible into ordinary shares or ADSs in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the ordinary share and/or ADS price to decline.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares and/or ADSs for return on your [REDACTED].

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

RISK FACTORS

Our Board has significant discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual and regulatory restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [REDACTED] in the ordinary shares and/or ADSs will likely depend entirely upon any future price appreciation of the ordinary shares and/or ADSs. There is no guarantee that the ordinary shares and/or ADSs will appreciate in value or even maintain the price at which you purchased the ordinary shares and/or ADSs. You may not realize a return on your [REDACTED] in the ordinary shares and/or ADSs and you may even lose your entire [REDACTED] in the ordinary shares and/or ADSs.

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

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

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

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our Articles of Association (as may be further amended from time to time), the Companies Law (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against the Directors, actions by minority shareholders and the fiduciary responsibilities of our Directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our Directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in Hong Kong and the United States. In particular, the Cayman Islands has a less developed body of securities law than the Hong Kong or United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

RISK FACTORS

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

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

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

Your voting rights as a holder of the ADSs are limited by the terms of the deposit agreement. The depositary for the 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.

You may exercise your voting rights with respect to the ordinary shares underlying your ADSs only in accordance with the provisions of the deposit agreement. Upon receipt of voting instructions from you in the manner set forth in the deposit agreement, the depositary for the ADSs will endeavor to vote your underlying ordinary shares in accordance with these instructions. Under our Articles of Association, the minimum notice period required for convening a general meeting is seven calendar days. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw your ordinary shares to allow you to cast your vote with respect to any specific matter at the meeting. In addition, the depositary and its agents may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make all

RISK FACTORS

reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but you may not receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. Furthermore, the depositary and its agents will not be responsible 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 result, you may not be able to exercise your right to vote and you may lack recourse if your ordinary shares are not voted as you requested.

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

- we have failed to timely provide the depositary with our notice of meeting and related voting materials;
- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

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

Anti-takeover provisions in our constitutional documents may discourage our acquisition by a third party, which could limit our shareholders' opportunity to sell their shares at a premium.

Our Articles of Association include provisions that could limit the ability of others to acquire control of our company, could modify our structure or could cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control in a tender offer or similar transaction.

For example, our Board has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix the powers and rights of these shares, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares. Preferred shares could thus be issued quickly with terms calculated to delay or prevent a change in control or make removal of management more difficult. In addition, if our Board authorizes the issuance of preferred shares, the market price of our ordinary shares and/or ADSs may fall and the voting and other rights of the holders of our ordinary shares and/or ADSs may be materially and adversely affected.

RISK FACTORS

Furthermore, the Articles of Association permit the Directors to vary all or any of the rights attaching to any class of shares in issue without the consent of the shareholder but only if such variation is considered by the Directors not to have a material adverse effect upon such holder. The Directors cannot vary the rights of shares if such variation would have a material adverse effect on the holder. The Articles of Association provide that the holders must consent to any such material adverse changes in the manner set out therein.

Because our Directors are divided into three classes with staggered terms of three years each, shareholders can only elect or remove a limited number of our Directors in any given year. The length of these terms could present an obstacle to certain actions, such as a merger or other change of control, which could be in the interest of our shareholders.

Our Articles of Association provide that any shareholder bringing an unsuccessful action against us may be obligated to reimburse us for any costs we have incurred in connection with such unsuccessful action.

Our Articles of Association provide that under certain circumstances the fees, costs and expenses that we incur in connection with actions or proceedings brought by any person or entity, which we refer to as claiming parties, may be shifted to such person or entity. If a claiming party asserts any claim; initiates any proceeding; or joins, offers substantial assistance to, or has a direct financial interest in any claim or proceeding against us, and such claiming party is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails, then such claiming party may be obligated to reimburse us for all fees, costs and expenses, including but not limited to all reasonable attorneys' fees and other litigation expenses, that we may incur in connection with such claim or proceeding.

Fee-shifting articles are relatively new and untested in the Cayman Islands, the United States and Hong Kong. The case law and potential legislative action on fee-shifting articles are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such articles. The application of our fee-shifting article in connection with claims under the Cayman Islands, United States or Hong Kong securities laws, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting article in any particular dispute. Consistent with our Directors' fiduciary duties to act in the best interests of the Company, the Directors may in their sole discretion from time to time decide whether or not to enforce this article. In addition, given the unsettled state of the law related to fee-shifting articles, such as ours, we may incur significant additional costs associated with resolving disputes with respect to such articles, which could adversely affect our business and financial condition.

If a Shareholder that brings any such claim or proceeding is unable to obtain the judgment sought, the attorneys' fees and other litigation expenses that might be shifted to a claiming party are potentially significant. This fee-shifting article, therefore, may dissuade or discourage current or former Shareholders (and their attorneys) from initiating lawsuits or claims against us. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our Shareholders or otherwise discourage plaintiffs' attorneys from representing our Shareholders at all. As a result, this article may limit the ability of shareholders to affect the management and direction of our company, particularly through litigation or the threat of litigation.

RISK FACTORS

Holders of the ADSs may be subject to limitations on transfer of their ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, as amended, or for any other reason, subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares.

In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

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

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

Holders of ADSs may not receive distributions on our ordinary shares or any value for them if it is illegal or impractical to make them available to you.

The depositary of the ADSs has agreed to pay you the cash dividends or other distributions it or the custodian for the ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares that your ADSs represent. However, the depositary is not responsible for making such payments or distributions if 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 that require registration under the Securities Act, but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by the depositary. We have no obligation to take any other action to permit the distribution of the ADSs.

RISK FACTORS

ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the 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 materially reduce the value of your ADSs.

Holders of the ADSs may not be able to participate in rights offerings and may experience dilution of their holdings.

From time to time, we may distribute rights to our shareholders, including rights to acquire securities. Under the deposit agreement, the depositary will not distribute rights to holders of ADSs unless the distribution and sale of rights and the securities to which these rights relate are either exempt from registration under the U.S. Securities Act with respect to all holders of ADSs or are registered under the U.S. Securities Act. The depositary may, but is not required to, attempt to sell these undistributed rights to third parties and may allow the rights to lapse. We may be unable to establish an exemption from registration under the U.S. Securities Act, and we are under no obligation to file a registration statement with respect to these rights or underlying securities or to try to have a registration statement declared effective. Accordingly, holders of ADSs may be unable to participate in our rights offerings and may experience dilution of their holdings as a result.

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

Our Directors, executive officers and principal shareholders beneficially owned approximately 60.8% of our outstanding ordinary shares as of April 20, 2018. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and reducing the price of our ordinary shares and/or ADSs. These actions may be taken even if they are opposed by our other shareholders. In addition, these persons could divert business opportunities away from us to themselves or others.

As the [REDACTED] is substantially higher than our net tangible book value per ordinary share, you will incur immediate and substantial dilution.

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

RISK FACTORS

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

This [REDACTED], particularly the sections headed “Business” and “Industry Overview,” contains information and statistics relating to the global and China oncology drug markets. Such information and statistics have been derived from a third-party report commissioned by us and publicly available sources. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, we cannot guarantee the quality or reliability of such source materials. The information has not been independently verified by us, the Joint Sponsors, [REDACTED], or any other party involved in the [REDACTED], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics included in this [REDACTED] being inaccurate or not comparable to statistics produced for other economies. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. You should consider carefully the importance placed on such information or statistics.

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

Possible setting of the [REDACTED] after making a [REDACTED]

We have the flexibility to make a [REDACTED] to set the final [REDACTED] at up to 10% below the bottom end of the indicative [REDACTED]. It is therefore possible that the final [REDACTED] will be set at [REDACTED] per [REDACTED] upon the making of a full [REDACTED]. In such a situation, the [REDACTED] will proceed and the [REDACTED] will not apply.

If the final [REDACTED] is set at [REDACTED], the estimated net [REDACTED] we will receive from the [REDACTED] will be reduced to HK\$[●] million.