

BeiGene, Ltd.  
Form 424B4  
November 18, 2016

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[TABLE OF CONTENTS](#)

[Table of Contents](#)

File Pursuant to Rule 424(b)(4)  
Registration Nos. 333-214540  
and 333-214692

*6,250,000 American Depositary Shares*  
*Representing 81,250,000 Ordinary Shares*

*BeiGene, Ltd.*

*We are offering 5,781,250 American Depositary Shares, or ADSs, in this offering at a public offering price of \$32.00 per ADS. The selling shareholders identified in this prospectus are offering 468,750 ADSs. Each ADS represents 13 ordinary shares, par value \$0.0001 per share. We will not receive any proceeds from the sale of ADSs by the selling shareholders.*

*The ADSs are listed on the NASDAQ under the symbol "BGNE." The last reported sale price of the ADSs on the NASDAQ on November 17, 2016 was \$32.70 per ADS.*

*We are an "emerging growth company" as that term is used in the U.S. Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.*

*Investing in the ADSs involves a high degree of risk. See "Risk Factors" on page 22 to read about factors you should consider before buying the ADSs.*

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

	<i>Per ADS</i>	<i>Total</i>
<i>Public offering price</i>	<i>\$32.00</i>	<i>\$200,000,000</i>
<i>Underwriting discounts<sup>(1)</sup></i>	<i>\$1.92</i>	<i>\$12,000,000</i>
<i>Proceeds, before expenses, to us</i>	<i>\$30.08</i>	<i>\$173,900,000</i>
<i>Proceeds, before expenses, to the selling shareholders</i>	<i>\$30.08</i>	<i>\$14,100,000</i>

(1) We refer you to "Underwriting" beginning on page 151 for additional information regarding total underwriting compensation.

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*To the extent the underwriters sell more than 6,250,000 ADSs, the underwriters have the option to purchase up to an additional 937,500 ADSs from us at the public offering price less the underwriting discounts.*

*Two of our existing affiliates, including investors affiliated with Baker Bros. Advisors and Hillhouse Capital Management, Ltd., have agreed to purchase an aggregate of approximately \$77.6 million of our ADSs in this offering on the same terms as other investors. See "Prospectus Summary The Offering."*

*The underwriters expect to deliver the ADSs against payment in New York, New York on November 23, 2016.*

*Morgan  
Stanley*

*Goldman,  
Sachs & Co.*

*Cowen and  
Company*

*Baird*

*William Blair*

*November 17, 2016*

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Table of Contents

TABLE OF CONTENTS

	Page
<u>PROSPECTUS SUMMARY</u>	<u>1</u>
<u>RISK FACTORS</u>	<u>22</u>
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>95</u>
<u>USE OF PROCEEDS</u>	<u>97</u>
<u>PRICE RANGE OF THE ADSs</u>	<u>99</u>
<u>DIVIDEND POLICY</u>	<u>100</u>
<u>CAPITALIZATION</u>	<u>101</u>
<u>DILUTION</u>	<u>103</u>
<u>ENFORCEMENT OF CIVIL LIABILITIES</u>	<u>105</u>
<u>MANAGEMENT</u>	<u>107</u>
<u>CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS</u>	<u>108</u>
<u>PRINCIPAL AND SELLING SHAREHOLDERS</u>	<u>113</u>
<u>DESCRIPTION OF SHARE CAPITAL</u>	<u>116</u>
<u>DESCRIPTION OF AMERICAN DEPOSITARY SHARES</u>	<u>129</u>
<u>SHARES AND AMERICAN DEPOSITARY SHARES ELIGIBLE FOR FUTURE SALE</u>	<u>140</u>
<u>TAXATION</u>	<u>142</u>
<u>UNDERWRITING</u>	<u>151</u>
<u>LEGAL MATTERS</u>	<u>157</u>
<u>EXPERTS</u>	<u>157</u>
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	<u>157</u>
<u>INCORPORATION BY REFERENCE OF CERTAIN DOCUMENTS</u>	<u>158</u>
<u>GLOSSARY OF SCIENTIFIC TERMS</u>	<u>159</u>

We have not, and the underwriters have not, authorized any person to provide you with information different from that contained in this prospectus or any related free-writing prospectus that we authorize to be distributed to you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby.

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

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, you are cautioned not to give undue weight to this information.

All references in this prospectus to "\$," "US\$," "U.S.," "U.S. dollars," "dollars" and "USD" mean U.S. dollars and all references to "¥" and "RMB," mean Renminbi, unless otherwise noted. All references to "PRC" or "China" in this prospectus refer to the People's Republic of China. Please see the Glossary of Scientific Terms on page 159 for definitions of scientific terms.

Table of Contents

**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in the ADSs, you should carefully read the entire prospectus, including the information in our filings with the U.S. Securities and Exchange Commission, or SEC, incorporated by reference in this prospectus. You should also consider, among other things, the matters described under "Risk Factors" beginning on page 22 of this prospectus and those identified in our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, or our September 2016 Quarterly Report, and the matters discussed under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2015, or our 2015 Annual Report, and our September 2016 Quarterly Report, each of which is incorporated by reference herein. Unless otherwise stated, all references to "us," "our," "BeiGene," "we," the "company" and similar designations refer to BeiGene, Ltd. and its consolidated subsidiaries, as a whole.*

**Overview**

We are a globally focused biopharmaceutical company dedicated to becoming a leader in the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. We believe the next generation of cancer treatment will utilize therapeutics both as monotherapies and in combination to attack multiple underlying mechanisms of cancer cell growth and survival. We further believe that discovery of next-generation cancer therapies requires new research tools. To that end, we have developed a proprietary cancer biology platform that addresses the importance of tumor-immune system interactions and the value of primary biopsies in developing new models to support our drug discovery effort.

Our strategy is to advance a pipeline of drug candidates with the potential to be best-in-class monotherapies and also important components of multiple-agent combination regimens. Over the last six years, using our cancer biology platform, we have developed clinical-stage drug candidates that inhibit the important oncology targets Bruton's tyrosine kinase, or BTK, RAF dimer protein complex and PARP family of proteins, and an immuno-oncology agent that inhibits the immune checkpoint protein receptor PD-1. Our drug candidates targeting BTK, PD-1, PARP and RAF dimer have demonstrated early activity and favorable safety profiles in the dose-escalation phases of clinical trials conducted in Australia and New Zealand, and all four of our drug candidates are currently in the dose-expansion phases of their respective clinical trials. As of November 7, 2016, our four clinical-stage drug candidates, as monotherapies and in combination, have been dosed in a total of 803 patients and healthy subjects. We have Investigational New Drug Applications in effect for our BTK, PD-1 and PARP inhibitors with the U.S. Food and Drug Administration, or FDA. We have also received approval of our Clinical Trial Applications, or CTAs, for each of our four clinical-stage drug candidates from the China Food and Drug Administration, or CFDA. We believe that each of our clinical-stage drug candidates is the first in their respective classes being developed in China under the Category 1.1 domestic regulatory pathway to enter the clinic and to present clinical data.

Our research operations are in China, which we believe confers several advantages including access to a deep scientific talent pool and proximity to extensive preclinical study and clinical trial resources through collaborations with leading cancer hospitals in China. Beyond the substantial market opportunities we expect to have in the United States, Europe and Japan, we believe our location in China provides us the opportunity to bring best-in-class monotherapies and combination therapeutics to our home market where many global standard-of-care therapies are not currently approved or available. We have assembled a team of 318 employees and consultants in China, the United States, Australia, and Taiwan with deep scientific talent and extensive global pharmaceutical experience who are deeply committed to advancing our mission to become a leader in next-generation cancer therapies.

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Table of Contents

We believe that oncology treatment has entered an era of revolutionary change in which cancer drugs will be used both as monotherapy and in combination to attack multiple underlying mechanisms of cancer cell growth and survival. Due to breakthroughs in gene sequencing and methods of tumor characterization, cancer is rapidly being redefined from a paradigm of classification based on tissue of origin to one of specific molecular characteristics. As a result, many more specific disease subpopulations can be targeted with more effective treatment than has been possible in the past. This ability to better classify cancers has allowed the development of molecularly targeted drugs that address specific cancer subpopulations and provide high response rates in tumors with particular mutations. In addition, the development of immuno-oncology agents such as antibodies targeting the CTLA-4 and PD-1 protein receptors and the PD-L1 protein has demonstrated the importance of the human immune system in cancer therapy and the potential for high rates of more durable responses from agents that activate the immune system to identify and eliminate tumors. We believe that the future of cancer therapy will involve combinations of molecularly targeted and immuno-oncology drugs tailored to particular tumor sub-groups and have directed our research efforts at both types of drugs.

Our belief that this fundamental shift was about to occur in cancer research led us early in our history to develop a cancer biology platform that addresses the importance of tumor-immune system interactions and the value of primary tumor biopsies in developing new models. Our proximity to leading cancer treatment centers in Beijing and our close relationships with clinicians who treat patients and perform biopsies and surgeries at those centers have allowed us to develop an extensive collection of *in vivo*, *ex vivo* and *in vitro* cancer models. Given our belief that the human immune system can play an important role in combating cancer and that future treatments will involve combination therapies, we have introduced elements of a functional immune system into these models. Our proprietary models allow our research team to better select targets and to screen and evaluate therapeutic agents that we believe have significant potential alone or in combination for treating a variety of cancers. Our models are a key component in the screening cascade we follow in our drug discovery effort and permit us to evaluate potential drug candidates in conditions that much better approximate a patient's cancer at the time of treatment. This is particularly significant when drug discovery requires evaluation not only of monotherapies but also multiple combinations and regimens targeting specific mutations while simultaneously immobilizing the defenses cancer cells mount against the human immune system.

**Our Clinical Stage Drug Candidates**

We have used our cancer biology platform to develop four clinical-stage drug candidates that we believe have the potential to be best-in-class or first-in-class. In addition, we believe that each has the potential to be an important component of a drug combination addressing major unmet medical needs.

Table of Contents

The following table summarizes our monotherapy clinical pipeline:

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- 1 Limited collaboration with Merck KGaA
- 2 Partnered with Merck KGaA outside China

The following table summarizes our combination therapy pipeline:

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**BGB-3111** is a potent and highly selective small molecule BTK inhibitor. We are currently developing BGB-3111 as a monotherapy and in combination with other therapies for the treatment of a variety of lymphomas. BGB-3111 has demonstrated higher selectivity against BTK than ibrutinib, the only BTK inhibitor currently approved by the FDA and the European Medicines Agency, or EMA, based on biochemical assays and higher exposure than ibrutinib based on their respective Phase I experience.

Table of Contents

In addition, we believe BGB-3111 is the only BTK inhibitor that has demonstrated sustained target inhibition in disease originating tissues. Our preclinical data of ibrutinib show that target inhibition at disease originating tissues, such as bone marrow and spleen, in mice and rats was not sustained over a 24-hour period. Published clinical data on ibrutinib show that ibrutinib's target inhibition in the blood is borderline at the approved dose of 420 mg once a day, with BTK occupancy in a significant portion of patients below 80%.

We have completed the 25-patient dose-escalation phase of our clinical trial, and we are currently conducting the dose-expansion phase in patients with different subtypes of B-cell malignancies, including chronic lymphocytic leukemia, diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma, Waldenström's Macroglobulinemia and hairy cell leukemia in Australia, New Zealand, the United States and South Korea. We have dosed 291 patients and healthy subjects as of November 7, 2016 in monotherapy and in combination trials.

As of June 10, 2016, the cutoff date for the most recent data analysis of the Phase I trial, the preliminary data suggest that BGB-3111 is well-tolerated. Proof-of-concept has been established for BGB-3111 with clinical data indicating that BGB-3111 is a potent BTK inhibitor with objective anti-tumor activity observed in multiple types of lymphomas starting at the lowest dose tested, 40 mg once daily, or QD.

The chart below shows the pharmacokinetic profile of BGB-3111 from this Phase I trial, in comparison to historical data with ibrutinib and acalabrutinib.

**BGB-3111: Drug Exposure in Humans, Half-life, and In Vitro Potency Comparison to Historical Data on Ibrutinib and Acalabrutinib<sup>^</sup>**

Note: C<sub>max</sub> = maximum plasma concentration; AUC = area under the concentration-time curve as a standard measurement of drug exposure; Free drug exposure = unbound AUC as a measurement of unbound drug exposure.

<sup>^</sup> Cross-trial comparisons



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<sup>1</sup> Tam *et al.*, ASH, 2015; <sup>2</sup> Byrd *et al.*, NEJM, 2015; <sup>3</sup> Lannutti *et al.*, AACR, 2015; <sup>4</sup> BeiGene data on file

Table of Contents

In addition, sustained BTK occupancy was achieved both in the blood (peripheral blood mononuclear cells, or PBMC) starting at the lowest dose of 40 mg QD, and in the lymph node, with 160 mg twice daily, or BID, in particular, as shown below.

**BGB-3111: Complete and Sustained BTK Inhibition in PBMC and Lymph Node**

On October 7, 2016, we presented data from our Phase I trial for a total of 24 Waldenström's Macroglobulinemia patients at the 9th International Workshop on Waldenström's Macroglobulinemia and Symposium on Advances in Multiple Myeloma. 41 patients with Waldenström's Macroglobulinemia were enrolled in the Phase I trial as of September 9, 2016, of which 24 patients were evaluable for response at the cutoff date of June 10, 2016. These 24 patients were from the dose-escalation phase receiving doses ranging from 40 mg to 320 mg QD or 160 mg BID, and the ongoing dose-expansion phase receiving 160 mg BID or 320 mg QD. Responses were determined according to the modified Sixth International Workshop on Waldenström's Macroglobulinemia, or IWWM, criteria.

Table of Contents

Adverse events were generally mild in severity and self-limited, as shown in the table below.

**BGB-3111 Phase I Trial in WM: Adverse Events Independent of Causality**

In the most recent data analysis, which had a cutoff date of June 10, 2016, the most frequent adverse events ( $\geq 20\%$ ) of any attribution were upper respiratory infection (25%); diarrhea (25%); petechiae, contusion, and bruising (21%); and nausea (21%), all grade 1 or 2 in severity. One patient developed grade 2 atrial fibrillation. Grade 3 or higher adverse events included two cases of anemia and one each of foot fracture, renal artery thrombosis, bronchiectasis, thrombocytopenia, hypertension, cryptococcal meningitis, and neutropenia. There were two serious adverse events assessed as possibly related to BGB-3111 by investigators, grade 2 atrial fibrillation and grade 3 cryptococcal meningitis; in both cases, BGB-3111 was temporarily held but safely resumed. No serious hemorrhage ( $\geq$  grade 3 or CNS hemorrhage of any grade) was reported.

After a median follow-up of eight months (range: 3.3–21 months), 24 patients were evaluable for response and the rate of overall response including complete response, or CR, very good partial response, or VGPR, partial response, or PR, and minor response, or MR, was 92% (22 out of 24 patients). The major response rate (CR plus VGPR plus PR) was 83% (20 out of 24 patients), with VGPRs ( $\geq 90\%$  reduction in IgM and reduction in extramedullary disease) observed in 33% (eight out of 24 patients) and PRs ( $\geq 50\%$ – $90\%$  reduction in IgM and reduction in extramedullary disease) observed in 50% (12 out of 24 patients) of patients.

Table of Contents

**BGB-3111 Phase I Trial in WM: Efficacy Summary**

IgM decreased from a median of 29.9g/l at baseline to 3.0g/l, and hemoglobin increased from a median of 10.1g/dl at baseline to 13.5g/dl. Only one patient discontinued BGB-3111, due to exacerbation of pre-existing bronchiectasis while in VGPR. There have been no cases of disease progression. The remainder of patients remain on study treatment.

Table of Contents

**Comparison of Response Rates of BGB-3111 to Historical Data on Ibrutinib with Comparable Follow-Up Time^**

Table of Contents

**BGB-3111 Phase I Trial in WM: Post-Treatment IgM (vs. Baseline)**

Though MYD88 and CXCR4 sequencing was not included in the original protocol, samples were requested with additional consents, and MYD88 mutational analysis results were available for 15 of the patients who were evaluable for response at the data cutoff of June 10, 2016. Preliminary sequencing data suggest a high VGPR rate seen in six out of 12 evaluable patients with the MYD88<sup>L265P</sup> genotype that included five additional patients with PR and one patient with stable disease, or SD, as well as response in MYD88<sup>WT</sup> patients with one PR, one MR, and one SD observed among three evaluable patients.

**BGB-3111 Phase I Trial in WM: Response Rate by MYD88 Mutation Status Preliminary Results**



Table of Contents

An updated analysis is currently being conducted for presentation at the American Society of Hematology meeting in December 2016 based on a data cutoff date of October 3, 2016 and includes an additional eight patients (all with less than six months follow-up, median 3.8 months). Based on a provisional analysis, which is subject to ongoing data validation, the major response rate is 78% (25 out of 32 patients), with 34% (11 out of 32 patients) of patients achieving VGPR. Compared to the data presented at the IWWM conference, no additional patients have discontinued study treatment for adverse event or progressive disease, and, based on serious adverse event reporting, no new safety signals have been identified.

Based on these findings, we plan to initiate a Phase III study in the United States, the European Union, and Australia in late 2016 or early 2017 comparing BGB-3111 and ibrutinib in patients with Waldenström's Macroglobulinemia.

In addition to data in Waldenström's Macroglobulinemia patients, updated data on BGB-3111 in patients with chronic lymphocytic leukemia from the dose-escalation and dose-expansion phases of the Phase I trial has been accepted for presentation at the American Society for Hematology annual conference. An abstract for this presentation was released on November 3, 2016. 29 patients were included in the most recent data analysis with cutoff date of June 10, 2016, from the dose-escalation and dose-expansion phases of the Phase I trial of BGB-3111 as monotherapy.

BGB-3111 was well-tolerated in 69% of patients with no drug-related adverse events >grade 1 in severity within the first 12 weeks of therapy. The most frequent adverse events of any attribution were petechiae and bruising (38%), upper respiratory tract infection (31%, all grade 1 and 2), diarrhea (28%, all grade 1 and 2), fatigue (24%, all grade 1 and 2), and cough (21%, all grade 1 and 2). Three serious adverse events were assessed as possibly related to BGB-3111 by investigators, including one each of grade 2 cardiac failure and pleural effusion, and one grade 3 purpura, the only major bleeding event reported. One patient developed grade 2 atrial fibrillation. Three patients had temporary dose interruptions and one patient discontinued from the study due to adverse events.

After a median follow-up of 7.5 months (range: 2.9-17.3 months), 29 patients were evaluable and the response rate was 90% (26 out of 29 patients) with PR in 79% of patients (23 out of 29 patients) and partial response with lymphocytosis in 10% of patients (three out of 29 patients). SD were observed in 7% of patients (two out of 29 patients), and one patient had a non-evaluable response due to discontinuation of treatment prior to week 12, the time of first evaluation of tumor response. No instances of disease progression or Richter's transformation have occurred.

An updated analysis is currently being conducted for presentation at the American Society of Hematology meeting in December 2016 based on data cutoff date of October 3, 2016 and includes an additional 17 patients (all with less than six months follow-up). Based on a provisional analysis, which is subject to ongoing data validation, the objective response rate is 93% (43 out of 46 patients). Compared to the analysis for ASH abstract publication, no additional patients have discontinued study treatment for adverse event or progressive disease, and, based on serious adverse event reporting, no new safety signals have been identified.

We initiated a monotherapy Phase I clinical trial of BGB-3111 in China in July 2016, and we believe BGB-3111 is the first BTK inhibitor being developed in China under the Category 1.1 domestic regulatory pathway to enter the clinic and to present clinical data. In addition, we have seen favorable preclinical data for and initiated combination studies of BGB-3111 with obinutuzumab, a CD20 antibody, in January 2016. We have also initiated combination studies of BGB-3111 with BGB-A317, our PD-1 antibody, on June 30, 2016, based on encouraging synergistic effects observed in our preclinical models. In our primary diffuse large B-cell lymphoma tumor models, we observed enhancement of anti-tumor activity of BGB-A317, our PD-1 antibody, by BGB-3111 in both PD-L1-positive and especially in PD-L1-negative diffuse large B-cell lymphoma tumor models, thus supporting our combination strategy.



Table of Contents

**BGB-A317** is an investigational humanized monoclonal antibody against the immune checkpoint receptor PD-1. We are developing BGB-A317 as a monotherapy and as a combination agent for various solid-organ and blood-borne cancers. PD-1 is a cell surface receptor that plays an important role in down-regulating the immune system by preventing the activation of certain types of white blood cells called T-cells. PD-1 inhibitors remove the blockade of immune activation by cancer cells. We believe BGB-A317 is differentiated from the currently approved PD-1 antibodies with the ability to bind Fc gamma receptor I specifically engineered out, and we believe this could potentially result in improved activities. In addition, BGB-A317 has a unique binding signature to PD-1 with high affinity and superior target specificity.

We have dosed a total of 299 patients with BGB-A317 in either monotherapy or combination trials as of November 7, 2016. In April 2016, we completed the enrollment of the ongoing dose-escalation phase and, in May 2016, we initiated the dose-expansion phase of our clinical trial in relapsed or refractory solid tumor patients in Australia and New Zealand. As of September 30, 2016, the cutoff date for the most recent data analysis, the preliminary clinical data show that BGB-A317 is well-tolerated with adverse events in keeping with the class effect. Among 103 patients evaluable for safety at the time of the data cutoff for the current safety analysis, the most common treatment-related adverse events ( $\geq 5\%$ ) were fatigue (19%), diarrhea (13%), rash (11%), pruritus (11%), nausea (8%), hypothyroidism (7%), and infusion related reaction (6%). Treatment-related serious adverse events 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,  $\geq$  grade 3 treatment-related serious adverse events included the two cases of hypotension and one case each of colitis, diabetes mellitus, diabetic ketoacidosis, dyspnea, hypoxia, and pneumonitis. Other treatment-related grade  $\geq 3$  adverse events included two cases each of fatigue and hyperglycemia, and one case each of back pain, elevated alanine aminotransferase and elevated gamma-glutamyl transferase. 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 a 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; one in one evaluable patient of two patients with microsatellite instability high, or MSI-h, colorectal cancer, among 13 colorectal cancer patients; one in one pancreatic cancer patient with MSI-h status, among two pancreatic cancer patients. A mixed patient population of 27 different tumor types was included in this data analyses, in which patients with melanoma, non-small cell lung cancer or head and neck cancer were not enrolled, and patients with renal cell cancer and urothelial carcinoma together represented close to 15% of the enrolled patients.

To date, we have two internal combination trials ongoing BGB-A317 with BGB-290 in patients with advanced solid tumors and BGB-A317 with BGB-3111 in patients with various hematologic malignancies, respectively.

**BGB-290** is a molecularly targeted, orally available, potent and highly selective inhibitor of PARP1 and PARP2. We are currently developing BGB-290 as a monotherapy and in combination with other therapies for the treatment of homologous recombination deficient cancers, which are cancers that contain abnormalities in their DNA molecule repair mechanisms, making these cancers particularly sensitive to PARP inhibitors. We believe BGB-290 has the potential to be differentiated from other PARP inhibitors, including olaparib, the only PARP inhibitor currently approved by the FDA and the EMA, in terms of selectivity, DNA-trapping activity, oral bioavailability, and brain penetration. We have a limited collaboration with Merck KGaA on BGB-290.

We have dosed a total of 88 patients with BGB-290 in either monotherapy or combination trials as of November 7, 2016. We have completed the dose-escalation phase, and we are evaluating BGB-290 in the ongoing dose-expansion phase of our clinical trial in Australia.

Table of Contents

At the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, we presented clinical data from our Phase I clinical trial. 29 relapsed or refractory solid tumor patients were enrolled in seven cohorts receiving monotherapy BGB-290 in doses ranging from 2.5 mg BID to 80 mg BID, as of June 30, 2015. Initial analysis of data from this trial suggests that BGB-290 is well-tolerated. Few adverse events of myelosuppression, no liver toxicity signal, and few drug-related grade 3/4 adverse events were observed in the dose-escalation phase. The most common drug-related adverse events were grade 1 and 2 nausea (38%) and fatigue (28%). Drug-related grade 3/4 adverse events include one each (3%) of neutropenia, anaemia, hypophosphatemia and hypokalemia, all grade 3. As of January 19, 2016, drug-related serious adverse events reported by investigators were three cases of grade 3 anemia and one case of shortness of breath.

Proof-of-concept was established, with significant anti-tumor activity seen in ovarian cancer patients starting at the lowest tested dose and data suggestive of a wide therapeutic window. Among 14 evaluable patients with ovarian cancer as of June 30, 2015, seven had an objective response (six PRs and one CR). Of the ten ovarian cancer patients with germ-line breast cancer susceptibility gene, or BRCA, mutation, five had an objective response (four PRs and one CR), and of the three ovarian cancer patients with germ-line BRCA wild-type, two had an objective response (two PRs). The remaining one patient had unknown BRCA status and progressive disease, or PD. When assessed by underlying mutations, of six evaluable patients with the BRAF V600E, there was one CR, one PR and four SDs.

On February 2, 2016, we initiated a trial with BGB-290 in combination with BGB-A317 for the treatment of cancers with BRCA mutations or deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal and pancreatic cancers, as well as platinum-sensitive ovarian cancer.

**BGB-283** is a small molecule inhibitor of both the monomer and dimer forms of the RAF kinase. We are currently developing BGB-283 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 is a chain of proteins in the cell that communicates 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 and is described in more detail in the section of our 2015 Annual Report, incorporated by reference herein, titled "Item 1 Business Product Pipeline BGB-283, RAF Dimer Inhibitor Mechanism of Action." We intend to develop BGB-283 to treat various malignancies, including colorectal cancer, non-small cell lung carcinoma, endometrial cancer, ovarian cancer, pancreatic cancer and papillary thyroid carcinoma. Currently approved first-generation BRAF inhibitors, vemurafenib and dabrafenib, are only active against the BRAF monomer. BGB-283 inhibits not only the monomer but also the dimer forms of BRAF. We believe BGB-283 has the potential to be a first-in-class RAF dimer inhibitor globally.

We have completed the 37-patient dose-escalation phase of our Phase I clinical trial, and we have completed the enrollment in April 2016 of the dose-expansion phase of our clinical trial in Australia and New Zealand in a broad range of patient populations, including BRAF mutated melanoma, thyroid cancer, colorectal cancer, non-small cell lung cancer and other non-BRAF mutated tumors as well as KRAS/NRAS mutated endometrial cancer, colorectal cancer, non-small cell lung cancer and other KRAS/NRAS mutation bearing cancers, where first-generation BRAF inhibitors have not been effective. We have also initiated a dose-escalation trial in China. We have dosed 168 patients in Australia, New Zealand and China as of November 7, 2016.

Initial analysis of data from these trials suggests that BGB-283 is well-tolerated with a favorable safety profile. We presented initial clinical data from our Phase I clinical trial of BGB-283 in patients with BRAF or KRAS/NRAS-mutated cancers at the 2016 American Association for Cancer Research annual conference. As of January 31, 2016, the data cutoff date, among 31 advanced solid tumor patients, the most frequent treatment-related adverse events were fatigue (52%), thrombocytopenia (39%), decreased

Table of Contents

appetite (39%), hand-foot syndrome (35%), dermatitis acneiform (32%) and hypertension (32%). The most frequent treatment-related grade 3-4 adverse events included thrombocytopenia (13%), fatigue (10%) and liver enzyme elevation (10%).

We have achieved proof-of-concept in a range of cancers including those with KRAS and BRAF mutations. At the time of the data cutoff, among 29 patients enrolled in the dose-escalation phase of the trial evaluable for efficacy, one melanoma patient with BRAF V600E mutation had a CR, one endometrial cancer patient with KRAS mutation and one thyroid cancer patient with BRAF V600E mutation had a PR, and 15 patients had an SD, including one non-small cell lung cancer patient with KRAS mutation with a transient PR or durable SD. 15 patients had remained on treatment for over six months, and the patient with CR had ongoing treatment for 342 days, and the two patients with PR had received treatment for 455 days and 574+ days (ongoing), respectively, as of January 31, 2016. When assessed by underlying mutations, of six evaluable patients with the BRAF V600E mutation, there was one CR, one PR and four SDs. Of three evaluable patients with BRAF non-V600E mutation, there were two SDs. Of 20 evaluable patients with KRAS/NRAS mutations, there was one confirmed PR and nine SDs.

We have granted exclusive licenses for the rights to develop and commercialize BGB-283 to Merck KGaA worldwide (outside China). We are currently conducting all clinical development and will continue to do so until Merck KGaA exercises its Continuation Option as further described in the section of our 2015 Annual Report, incorporated by reference herein, titled "Item 1 Business Collaboration with Merck KGaA."

**Our Preclinical Programs.** Our proprietary cancer biology platform has also allowed us to develop several preclinical-stage drug candidates in potentially important targeted areas. These currently consist of targeted therapies and immuno-oncology agents including a PD-L1 monoclonal antibody, an additional RAF dimer inhibitor, a TIM-3 cell surface protein monoclonal antibody, 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 our PD-1 monoclonal antibody with other clinical-stage and preclinical candidates in our pipeline portfolio to target multiple points in the cancer immunity cycle.

Our research operations are in China, which we believe confers clinical, commercial and regulatory advantages. Our location provides us with access to a deep scientific talent pool and proximity to extensive clinical trial resources through collaborations with leading cancer hospitals in China. In addition, China accounts for approximately 20-25% of the world's cancer population and is experiencing rapid growth in the market for cancer therapeutics. According to CFDA Southern Medicine Economic Research Institute, targeted oncology therapies achieved significant revenues last year in China, maintaining rapid growth. Despite currently requiring out-of-pocket payment by patients, three EGFR targeted therapies (Iressa, Conmana and Tarceva) combined had a revenue of \$462 million in 2015, exemplifying a large cancer therapeutics market.

Currently, many global standard-of-care therapies are not approved or available in China, resulting in a significant need for innovative drugs with strong efficacy and safety profiles for patients who are naive to such treatments. While we plan to seek worldwide regulatory approval for our drug candidates, we also plan to seek expedited approval from the CFDA for our drug candidates as locally developed (Category 1) drugs. In August 2015, the Chinese State Council issued a statement, *Opinions on reforming the review and approval process for pharmaceutical products and medical devices*. In November 2015, the CFDA issued the *Circular Concerning Several Policies on Drug Registration Review and Approval*. In February 2016, the CFDA released the *Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog*. The foregoing developments aimed to accelerate and improve the drug clinical development process in China. The CFDA is soliciting public opinions on detailed policies regarding the circular, however, how and when the clinical trial approval and drug registration pathway will be changed is still subject to further policies to be issued by the CFDA. We believe these announcements on regulatory developments could

Table of Contents

significantly accelerate development of innovative oncology agents. Expedited approval of our drug candidates in China will address the current unmet need in China and further our understanding and characterization of these drugs for approval in other markets.

As of September 30, 2016, we had a global team of 318 employees and consultants, including a global research and development team of 214 scientists, clinicians, and staff. Our team shares the vision of improving the lives of cancer patients globally and has built a scientifically-driven and collaborative culture fostering both nimble and rational decision-making. Our management team and world-renowned scientific advisory board have deep experience and capabilities in biology, chemistry, drug discovery, clinical development, manufacturing and commercialization. Our scientific advisory board is chaired by our co-founder Xiaodong Wang, Ph.D., a highly respected cancer scientist, 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. Our scientific advisory board also includes Ronald Levy, M.D., Ph.D.; Neal Rosen, M.D., Ph.D.; Charles Sawyers, M.D.; David Schenkein, M.D.; Jedd Wolchok, M.D., Ph.D.; and Steve Young, Ph.D.

**Our Mission and Strategy**

Our mission is to become a global leader in the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. To achieve our mission, we intend to pursue the following strategies:

**Rapidly advance our pipeline programs through global development.** In the next 12 months, we plan to make significant advances within our clinical-stage pipeline. We have moved all four of our drug candidates into the dose-expansion phases of their respective clinical trials as monotherapies, and we will continue to enroll multiple expansion cohorts and significantly increase the number of sites globally participating in these trials. We plan to present data from these trials at medical conferences in late 2016 and 2017. We plan to advance BGB-3111 into late-stage development in late 2016 or early 2017 with the initiation of the global Phase III trial for BGB-3111 in Waldenström's Macroglobulinemia. We also have a robust pipeline of preclinical programs and are planning to advance one or more of these programs into the clinic in the next 12 months.

**Pursue global development of combination therapies.** We believe our ownership of both molecularly targeted and immuno-oncology drugs puts us in an advantageous position to develop potentially best-in-combination or first-in-combination therapies that could produce high rates of more durable responses in patients. We have four clinical-stage, independently discovered drug candidates in important and combinable molecularly targeted and immuno-oncology drug classes including BTK inhibitor, PD-1 inhibitor, PARP inhibitor and RAF dimer inhibitor. We believe that we are one of only two companies today to wholly own both a clinical-stage BTK inhibitor for cancer treatment and PD-1 inhibitor and one of the few companies to have discovered, and advanced to clinical stage, a PARP inhibitor and PD-1 inhibitor or a BRAF inhibitor and PD-1 inhibitor for use as combination therapies. In addition to monotherapy trials, we have initiated and are planning combination trials using wholly-owned drug candidates as well as third-party agents. For BGB-3111, in January 2016 we initiated a combination trial with the anti-CD20 antibody, obinutuzumab, and the trial is currently in the dose-expansion phase. On June 30, 2016, we initiated a combination trial with BGB-A317 for the treatment of various B-cell malignancies. For BGB-290, we initiated a combination trial with BGB-A317 on February 2, 2016. We plan to present data from these combination trials at medical conferences in 2017.

**Continue to use our cancer biology platform to discover additional candidates with best-in-class characteristics and potential for use in rational combinations.** We plan to use our cancer biology platform to discover additional drug candidates with the potential to be best-in-class monotherapies and also important components of multiple-agent combination regimens. In the last six years, we

Table of Contents

have been successful in discovering four clinical stage and numerous promising preclinical drug candidates. By further investing in and improving our cancer biology platform, we expect that the platform will continue to help us select relevant drug targets, identify potential best-in-class drug candidates and develop regimens for rational drug combinations.

**Bring transformative oncology therapeutics to our home market in China.** We are committed to addressing the needs of cancer patients in our home market. China is one of the largest and fastest growing markets for cancer drugs worldwide, representing approximately 20-25% of the world's cancer population and an even greater proportion in lung, liver, and gastric cancers. Because many global standard-of-care therapies are not currently approved and available in China, there is a significant unmet need for innovative cancer drugs for patients who are naive to such treatments. In addition, focusing on cancer types of high prevalence in China will aid our global development efforts in these indications. We have received approval of CTAs in China for each of our four clinical-stage drug candidates from the CFDA to develop our drug candidates through the locally developed, Category 1 registration pathway. We plan to pursue accelerated development, single-arm registration studies and brief dose-escalation studies in China. We also strive to have our drug candidates selected and listed as national priorities. The ability to launch our cancer drugs in our home market, which has a large patient population, will also help us establish broad safety and efficacy profiles for each drug, enabling us to build a full portfolio for future drug combinations.

**Maintain our culture as we grow our business globally.** We believe our science-driven, cooperative and non-hierarchical culture is a key strength of our organization and will continue to be instrumental to our success. As an innovative biotechnology company with research facilities in China, we have been able to attract an internationally trained research team. Many members of our team moved back to China from other countries to join us because they share our goals of advancing the discovery and development of drugs in China and of working with Chinese clinicians to treat their patients with innovative and effective drugs not currently available to them. We intend to maintain our patient-focused and research-driven culture as we discover and develop new drugs for China and the rest of the world.

**Retain the value of our pipeline in our core focus area of oncology.** We currently collaborate with Merck KGaA on our BGB-283 program, but retain exclusive development and commercial rights in China, subject to certain non-compete restrictions. Additionally, we currently retain all worldwide development and commercial rights for our other clinical and preclinical therapeutics. We also have a limited collaboration with Merck KGaA on our BGB-290 program. We intend to protect our ability to direct global preclinical studies and clinical trials for our drug candidates as monotherapies and combination therapies and to maintain exclusive rights in our home market. However, we may opportunistically evaluate additional collaboration opportunities that could increase the value of our programs by accessing the expertise or infrastructure of strategic collaborators or by developing drug candidates with potential applications outside of our strategic focus on cancer.

**Risks Associated with Our Business**

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

We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

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

Table of Contents

We depend substantially on the success of our drug candidates, particularly BGB-3111, BGB-A317, BGB-290, and BGB-283, which are in clinical development as monotherapies and in combination. Clinical trials of our drug candidates may not be successful. If we are unable to commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.

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.

Even if any of our drug candidates receives regulatory approval, they 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.

If we are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have entered into collaborations 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.

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

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

**Company and Other Information**

We are an exempted company incorporated in the Cayman Islands with limited liability on October 28, 2010. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The principal executive office of our research and development operations is located at No. 30 Science Park Road, Zhong-Guan-Cun Life Science Park, Changping District, Beijing 102206, People's Republic of China. Our telephone number at this address is +86 10 58958000. Our current registered office in the Cayman Islands is located at the offices of Mourant Ozannes Corporate Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY1-1108, Cayman Islands. Our website address is [www.beigene.com](http://www.beigene.com). We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

We own various applications and unregistered trademarks and servicemarks, including BeiGene, and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Table of Contents

**Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;

the ability to include only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management's discussion and analysis of financial condition and results of operations in the registration statement for this offering of which this prospectus forms a part;

reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and

exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions for up to five years from our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of (1) the last day of the fiscal year in which we have more than \$1.0 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; (3) the issuance, in any three-year period, by our company of more than \$1.0 billion in non-convertible debt securities; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. We may choose to take advantage of some but not all of these exemptions. For example, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this extended transition period. However, we have taken advantage of other reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

Table of Contents

**The Offering**

ADSs offered by us	5,781,250 ADSs
ADSs offered by the selling shareholders	468,750 ADSs
Ordinary shares outstanding immediately after this offering	503,675,281 shares (515,862,781 shares if the underwriters exercise their option to purchase additional ADSs in full)
Underwriters' option to purchase additional ADSs	We have granted a 30-day option to the underwriters to purchase up to an aggregate of 937,500 additional ADSs.
American Depositary Shares	Each ADS represents 13 ordinary shares. You will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and all holders and beneficial owners of ADSs issued thereunder. To better understand the terms of the ADSs, you should carefully read the section in this prospectus titled "Description of American Depositary Shares." We also encourage you to read the deposit agreement, as amended, which is filed as an exhibit to the registration statement that includes this prospectus.
Depository	Citibank, N.A.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately \$173.4 million, or \$201.6 million, if the underwriters exercise their option to purchase additional ADSs in full, based upon a public offering price of \$32.00 per ADS after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering to develop our drug candidates and for working capital and other general corporate purposes. We will not receive any proceeds from the sale of ADSs by the selling shareholders. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read "Risk Factors" in this prospectus, our 2015 Annual Report, and our September 2016 Quarterly Report, each of which is incorporated by reference herein, for a discussion of factors that you should consider before deciding to invest in the ADSs.
NASDAQ trading symbol	"BGNE."
Indications of Interest	Two of our existing affiliates, including investors affiliated with Baker Bros. Advisors and Hillhouse Capital Management, Ltd., have agreed to purchase an aggregate of approximately \$77.6 million of our ADSs in this offering on the same terms as other investors. The underwriters will receive the same underwriting discount on any ADSs purchased by these shareholders as they will on any other ADSs sold to the public in this offering.



Table of Contents

The number of ordinary shares to be outstanding after this offering is based on 428,519,031 ordinary shares outstanding as of September 30, 2016, including 1,075,000 issued but unvested restricted shares, and excludes:

27,656,012 shares issuable upon the exercise of options outstanding as of September 30, 2016 pursuant to our 2011 Option Plan, as amended, or the 2011 Plan, at a weighted-average exercise price of \$0.36 per share;

25,492,593 shares issuable upon the exercise of options outstanding as of September 30, 2016 pursuant to our 2016 Share Option and Incentive Plan, or the 2016 Plan, at a weighted-average exercise price of \$2.21 per share;

43,959,589 shares reserved for future issuance under our 2016 Plan as of September 30, 2016; and

15,200,667 shares issuable upon the exercise of options granted outside our 2011 Plan or 2016 Plan as of September 30, 2016, at an exercise price of \$0.50 per share.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

no issuance or exercise of share options on or after September 30, 2016; and

no exercise by the underwriters of their option to purchase additional ADSs in this offering.

Table of Contents

**SUMMARY FINANCIAL DATA**

The following summary financial data for the years ended December 31, 2013, 2014 and 2015 are derived from our audited consolidated financial statements incorporated by reference in this prospectus from our 2015 Annual Report. The summary financial data as of September 30, 2016 and for the nine months ended September 30, 2015 and 2016 have been derived from our unaudited consolidated financial statements incorporated by reference in this prospectus from our September 2016 Quarterly Report. These unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and, in our opinion, contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. You should read this data together with our audited consolidated financial statements and related notes included elsewhere in this prospectus and the information under the captions "Selected Consolidated Financial Data" appearing in our 2015 Annual Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in our 2015 Annual Report and September 2016 Quarterly Report, each of which is incorporated by reference herein. Our historical results are not necessarily indicative of our future results, and our operating results for the nine-month period ended September 30, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016 or any other interim periods or any future year or period. Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP.

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Table of Contents

	Years Ended December 31,			Nine Months Ended September 30,	
	2013	2014	2015	2015	2016
	(in thousands, except share and per share data)				
<b>Statements of Operations Data:</b>					
Revenue	\$ 11,148	\$ 13,035	\$ 8,816	\$ 4,139	\$ 1,070
Operating expenses					
Research and development	(13,463)	(21,862)	(58,250)	(30,147)	(69,100)
General and administrative	(3,143)	(6,930)	(7,311)	(4,361)	(11,760)
Total operating expenses	(16,606)	(28,792)	(65,561)	(34,508)	(80,860)
Loss from operations	(5,458)	(15,757)	(56,745)	(30,369)	(79,790)
Interest income	2	40	1,788	1,286	965
Interest expense	(3,155)	(3,552)	(1,229)	(840)	(629)
Changes in fair value of financial instruments	133	(2,760)	(1,826)	(502)	(1,514)
Gain on debt extinguishment		2,883			
Disposal loss on available-for-sale securities			(314)	(298)	(1,077)
Other income	694	806	1,309	996	1,261
Other expense	(110)	(206)	(85)	(125)	(529)
Income tax expense					(306)
Net loss	(7,894)	(18,546)	(57,102)	(29,852)	(81,619)
Less: net loss attributable to non-controlling interests	(400)	(268)			
Net loss attributable to ordinary shareholders	\$ (7,494)	\$ (18,278)	\$ (57,102)	\$ (29,852)	\$ (81,619)
Loss per ordinary share attributable to ordinary shareholders, basic and diluted <sup>(1)</sup>	\$ (0.08)	\$ (0.18)	\$ (0.52)	\$ (0.28)	\$ (0.21)
Weighted-average ordinary shares outstanding, basic and diluted	91,484,521	99,857,623	110,597,263	107,015,707	383,472,372
Comprehensive loss	\$ (7,718)	\$ (18,761)	\$ (59,011)	\$ (31,085)	\$ (80,775)

	As of December 31,			As of September 30,
	2013	2014	2015	2016
	(in thousands)			
	(unaudited)			
<b>Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 3,926	\$ 13,898	\$ 17,869	\$ 85,532
Short-term investments		30,497	82,617	118,086

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Working capital	(27,300)	33,817	71,097	180,637
Total assets	11,798	53,621	116,764	235,425
Long-term bank loan			6,188	18,030
Total liabilities	48,757	27,853	42,445	47,593
Preferred shares		78,809	176,084	
Non-controlling interests	1,767			
Total shareholders' (deficit) equity	(38,726)	(53,041)	(101,765)	187,832

For pro forma adjusted information of this offering, please see the section of this prospectus titled "Dilution."

Table of Contents

**RISK FACTORS**

*Investing in the ADSs involves a high degree of risk. You should carefully consider the following risks and all other information contained in this prospectus, or incorporated by reference, including our consolidated financial statements and the related notes and the risks and uncertainties discussed under "Risk Factors" in our 2015 Annual Report and September 2016 Quarterly Report, each of which is incorporated by reference herein in its entirety, before making an investment decision regarding our securities. The risks and uncertainties described below are those significant risk factors, currently known and specific to us, that we believe are relevant to an investment in our securities. If any of these risks materialize, our business, financial condition or results of operations could suffer, the price of the ADSs could decline and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

**Risks Related to Our Financial Position and Need for Additional Capital**

*We are a globally focused biopharmaceutical company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.*

We are a globally focused 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 and conducting preclinical studies and clinical trials of our current drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283. We have not yet demonstrated an ability to initiate or successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. We have not yet obtained regulatory approval for, or demonstrated an ability to commercialize, any of our drug candidates. We have no products approved for commercial sale and have not generated any revenue from product sales. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

We are focused on the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancers. Our limited operating history, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and predict our future performance. Our short history makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

*We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.*

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2010. We reported a net loss of \$14.0 million and \$29.9 million, respectively, for the three and nine months ended September 30, 2015, and \$35.5 million and \$81.6 million, respectively, for the three and nine months ended September 30, 2016. As of September 30, 2016, we had a deficit accumulated of \$199.8 million. Substantially all of our operating losses have resulted from costs

Table of Contents

incurred in connection with our research and development programs and from general and administrative costs 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 our development of, and seek regulatory approvals for, our drug candidates, and begin to commercialize approved drugs, if any. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, our ability to generate revenues and the timing and amount of milestones and other required payments to third parties in connection with our potential future 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 prior losses and expected future losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our cancer biology platform and our ongoing and planned clinical trials for our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283. Furthermore, if we obtain regulatory approval for our drug candidates, we expect to incur increased sales and marketing expenses. In addition, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our shareholders' deficit, financial position, cash flows and working capital.

***We currently do not generate revenue from product sales and may never become profitable.***

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283, as we do not currently have any drugs that are available for commercial sale. We expect to continue to incur substantial and increasing losses through the projected commercialization of our drug candidates. None of our drug candidates have been approved for marketing in the United States, the European Union, the People's Republic of China, or PRC, or any other jurisdiction and may never receive such approval. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our drug candidates, obtain necessary regulatory approvals, and have our drugs manufactured and successfully marketed.

Even if we receive regulatory approval of our drug candidates for commercial sale, we do not know when they will generate revenue, if at all. Our ability to generate product sales revenue depends on a number of factors, including our ability to continue:

completing research regarding, and non-clinical and clinical development of, our drug candidates;

obtaining regulatory approvals and marketing authorizations for drug candidates for which we complete clinical trials;

obtaining adequate reimbursement from third-party payors, including government payors;

developing a sustainable and scalable manufacturing process for our drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;

launching and commercializing drug candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;

obtaining market acceptance of our drug candidates as viable treatment options;

Table of Contents

identifying, assessing, acquiring and/or developing new drug candidates;

addressing any competing technological and market developments;

negotiating and maintaining favorable terms in any collaboration, licensing or other arrangements into which we may enter, such as our collaboration arrangements with Merck KGaA;

maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

attracting, hiring and retaining qualified personnel.

In addition, because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA; the China Food and Drug Administration, or CFDA; the European Medicines Agency, or EMA; or other comparable regulatory authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these drugs.

Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenues from the sale of our potential drugs, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. Failure to become and remain profitable may adversely affect the market price of the ADSs and our ability to raise capital and continue operations.

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

We have financed our operations with a combination of equity and debt offerings, contracts, and private and public grants. Through September 30, 2016, we raised approximately \$170 million in private equity financing and \$10 million in non-convertible debt financings. To date, we have received a total of \$37 million in upfront payments and milestone payments through our collaboration arrangements with Merck KGaA for BGB-283 and BGB-290. On February 8, 2016, we completed our initial public offering of the ADSs and received net proceeds of \$166.2 million, after deducting underwriting discount and offering expenses. Our drug candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any product sales revenue.

Our operations have consumed substantial amounts of cash since inception. Our operating activities used \$23.1 million and \$63.4 million of net cash during the nine months ended September 30, 2015 and 2016, respectively. We expect to continue to spend substantial amounts on drug discovery advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our primary drug candidates: BGB-3111, BGB-A317, BGB-290 and BGB-283. We will need to obtain additional financing to conduct additional clinical trials for the approval of our drug candidates if requested by regulatory bodies, and completing the development of any additional drug candidates we might discover. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

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### Table of Contents

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 utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

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 by the FDA, CFDA, EMA and comparable regulatory authorities, including the potential that the FDA, CFDA, EMA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;

the number and characteristics of drug candidates that we may in-license and develop;

our ability to successfully commercialize our drug candidates;

the amount of sales and other revenues from drug candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party reimbursement;

the amount and timing of the milestone and royalty payments we receive from our collaborators under our licensing arrangements, such as our collaboration with Merck KGaA;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

selling and marketing costs associated with our potential products, 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;

cash requirements of any future acquisitions and/or the development of other drug candidates;

the costs of operating as a public company;

the cost and timing of completion of commercial-scale outsourced manufacturing activities;

the time and cost necessary to respond to technological and market developments; and

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of the ADSs may not



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support capital raising transactions such as an additional public or private offering of the ADSs or other securities. In addition, our ability to raise additional capital may be dependent upon the ADSs being quoted on the NASDAQ or upon obtaining shareholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on the NASDAQ or that we will be able to obtain shareholder approval if it is necessary. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In

Table of Contents

addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or drug candidates or to grant licenses on terms that may not be favorable to us.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to enable us to complete all necessary global development or commercially launch our current drug candidates. Accordingly, we will require further funding through other public or private offerings, debt financing, collaboration and licensing arrangements or other sources. 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 the ADSs or our ordinary shares. 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 the ADSs 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 investment.***

We incur portions of our expenses, and may in the future derive revenues, in currencies other than the U.S. dollar, in particular, the RMB and Australian dollars. 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. For example, a significant portion of our clinical trial activities are conducted outside of the United States, and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in 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.

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 adopted by the PRC, Australia and other non-U.S. governments. Specifically in the PRC, on July 21, 2005, the PRC government changed its policy of pegging the value of the RMB to the U.S. dollar. Following the removal of the U.S. dollar peg, the RMB appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted and the exchange rate between the

Table of Contents

RMB and the U.S. dollar remained within a narrow band. Since June 2010, the PRC government has allowed the RMB to appreciate slowly against the U.S. dollar again, and it has appreciated more than 10% since June 2010. In April 2012, the PRC government announced that it would allow more RMB exchange rate fluctuation. On August 11, 2015, China's central bank executed a 2% devaluation in the RMB. Over the following two days, Chinese currency fell 3.5% against the dollar. However, it remains unclear what further fluctuations may occur or what impact this will have on the currency.

It is difficult to predict how market forces or PRC, Australian, U.S. or other government policies may impact the exchange rate between the Australian dollar, RMB, U.S. dollar and other currencies in the future. There remains significant international pressure on the PRC government to adopt a more flexible currency policy, 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 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. Any significant revaluation of the RMB may materially reduce any dividends payable on the ADSs in U.S. dollars. To the extent that we need to convert U.S. dollars we received from this offering 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 our RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount we would receive.

***Our investments are subject to risks that could result in losses.***

We had cash and cash equivalents of \$17.9 million and \$85.5 million and short-term investments of \$82.6 million and \$118.1 million at December 31, 2015 and September 30, 2016, respectively. At September 30, 2016, our short-term investments mainly consisted of high credit quality corporate fixed income bonds and U.S. Treasury securities. On February 8, 2016, we completed our initial public offering of the ADSs and received net proceeds of \$166.2 million, after deducting underwriting discount and offering expenses. We may invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper and money market instruments, which may not yield a favorable return to our shareholders. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. Our primary exposure to market risk relates to fluctuations in the interest rates of the PRC and the United States. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

**Risks Related to Clinical Development of Our Drug Candidates**

***We depend substantially on the success of our drug candidates, particularly BGB-3111, BGB-A317, BGB-290 and BGB-283, which are in clinical development. Clinical trials of our drug candidates may not be successful. If we are unable to commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.***

Our business and the ability to generate revenue related to product sales, if ever, will depend on the successful development, regulatory approval and commercialization of our drug candidates for the treatment of patients with cancer, particularly BGB-3111, BGB-A317, BGB-290 and BGB-283, which are still in development, and other drugs we may develop. We have invested a significant portion of our efforts

Table of Contents

and financial resources in the development of our existing drug candidates. The success of our drug candidates, including BGB-3111, BGB-A317, BGB-290 and BGB-283, will depend on several factors, including:

successful enrollment in, and completion of, preclinical studies and clinical trials;

receipt of regulatory approvals from the FDA, CFDA, EMA and other comparable regulatory authorities for our drug candidates, including our companion diagnostics;

establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;

relying on third parties to conduct our clinical trials safely and efficiently;

obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;

protecting our rights in our intellectual property;

ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;

launching commercial sales of our drug candidates, if and when approved;

obtaining reimbursement from third-party payors for drug candidates, if and when approved;

competition with other drug candidates and drugs;

continued acceptable safety profile for our drug candidates following regulatory approval, if and when received; 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 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.

***We may not be successful in our efforts to identify or discover additional drug candidates. Due to our limited resources and access to capital, we must and have in the past decided to prioritize development of certain drug candidates; these decisions may prove to have been wrong and may adversely affect our business.***

Although we intend to explore other therapeutic opportunities with our cancer biology platform in addition to the drug candidates that we are currently developing, we may fail to identify other drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Specifically, we have focused on developing our cancer biology platform, which enables us to test a large panel of tumor models for sensitivity to the drug candidates we generated, identify targets to pursue, identify drug-resistance mechanisms, explore combination strategies and regimens, and improve our

understanding of the contributions of tumor micro, or macro-environment in cancer treatments. If our cancer biology platform fails to identify potential drug candidates, our business could be materially harmed.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise

Table of Contents

in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

the research methodology used may not be successful in identifying potential indications and/or drug candidates;

potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or

it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

***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;

the patient eligibility criteria defined in the protocol;

the size of the study population required for analysis of the trial's primary endpoints;

the proximity of patients to trial sites;

the design of the trial;

our ability to recruit clinical trial investigators with the appropriate competencies and experience;

competing clinical trials for similar therapies or other new therapeutics;

clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

our ability to obtain and maintain patient consents;

the risk that patients enrolled in clinical trials will not complete a clinical trial; and

the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283, and this competition will reduce the number and types of patients available to us, because some patients

Table of Contents

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 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.

***Some of our drug candidates represent a novel approach to cancer treatment that could result in delays in clinical development, heightened regulatory scrutiny, or delays in our ability to achieve regulatory approval or commercialization of our drug candidates.***

Some of our drug candidates represent a departure from more commonly used methods for cancer treatment, and therefore represent a novel approach that carries inherent development risks. The need to further develop or modify in any way the protocols related to our drug candidates to demonstrate safety or efficacy may delay the clinical program, regulatory approval or commercialization, if approved. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than enroll patients in any future clinical trial. This may have a material impact on our ability to generate revenues from our drug candidates. Further, given the novelty of our drug candidates, the end users and medical personnel may require a substantial amount of education and training.

***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. 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 protocols 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.

***If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, CFDA, EMA or other comparable 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, such as BGB-3111, BGB-A317, BGB-290 and BGB-283, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and successful interim results of a clinical trial do not necessarily predict successful final results.



Table of Contents

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:

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

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 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 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 for various reasons, including noncompliance with regulatory requirements;

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

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; and

our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

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.

Delays in testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Table of Contents

Significant clinical trial delays also 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 and impair our ability to commercialize our drug candidates and may harm our business and results of operations.

**Risks Related to Obtaining Regulatory Approval for Our Drug Candidates**

*The regulatory approval processes of the FDA, CFDA, EMA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and 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, CFDA, EMA and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug candidate, and it is possible that none of our existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval from the FDA, CFDA, EMA or a comparable regulatory authority for many reasons, including:

disagreement with the design or implementation of our clinical trials;

failure to demonstrate that a drug candidate is safe and effective or that a biologic drug 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;

failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;

disagreement with our interpretation of data from preclinical studies or clinical trials;

the insufficiency of data collected from clinical trials of our drug candidates to support the submission and filing of a new drug application, or NDA; biologics license application, or BLA; or other submission or to obtain regulatory approval;

the FDA, CFDA, EMA or comparable regulatory authority's finding of deficiencies related to the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and

changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA, CFDA, 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. If we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that is not desirable for the successful commercialization of that drug candidate. In addition, if our drug candidate produces undesirable side effects or safety issues, the FDA may require the establishment of a Risk Evaluation Mitigation Strategy, or REMS, or the CFDA, EMA or a comparable regulatory authority may require the establishment of a similar strategy, that may, for instance, restrict distribution of our drugs and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial

prospects of our drug candidates.

Table of Contents

***Regulatory approval may be substantially delayed or may not be obtained for one or all of our drug candidates if regulatory authorities require additional time or studies to assess the safety and efficacy of our drug candidates.***

We may be unable to initiate or complete development of our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283, on schedule, if at all. The timing for the completion of the studies for our drug candidates will require funding beyond the proceeds of this offering. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of our drug candidates, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our drug candidates. Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our drug candidates are time consuming and expensive and together take several years or more to complete. Delays in clinical trials, regulatory approvals or rejections of applications for regulatory approval in the United States, Australia, New Zealand, the PRC, Europe or other markets may result from many factors, including:

our inability to obtain sufficient funds required for a clinical trial;

regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;

regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;

clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;

failure to reach agreement with the FDA, CFDA, EMA or other regulators regarding the scope or design of our clinical trials;

delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

our inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in a clinical trial;

our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;

clinical sites and investigators deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;

failure of our third-party clinical research organizations to satisfy their contractual duties or meet expected deadlines;

delay or failure in adding new clinical trial sites;

ambiguous or negative interim results, or results that are inconsistent with earlier results;

unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;

Table of Contents

feedback from the FDA, CFDA, EMA, an IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol;

unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;

decision by the FDA, CFDA, EMA, an IRB, comparable entities, or us, or recommendation by a data safety monitoring board or comparable regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

failure to demonstrate a benefit from using a drug or biologic;

lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;

our inability to reach agreements on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;

manufacturing issues, including problems with manufacturing or timely obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; and

difficulty in maintaining contact with patients after treatment, resulting in incomplete data.

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 our drug candidates 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 revenues. 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.

If we are required to conduct additional clinical trials or other studies with respect to any of our drug candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for that drug candidate, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. Our drug development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process. Significant clinical trial delays could allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drugs, if and when approved. If any of this occurs, our business will be materially harmed.

***Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.***

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the drug candidates we are developing. In collaboration with partners, we plan to develop

companion diagnostics to help us to more



Table of Contents

accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our drug candidates. Companion diagnostics are subject to regulation by the FDA, CFDA, EMA and other comparable regulatory authorities and require separate regulatory approval or clearance prior to commercialization. We do not develop companion diagnostics internally, and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval or clearance for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval or clearance of the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval or clearance of the companion diagnostics could delay or prevent approval of our drug candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. A failure of such companion diagnostics to gain market acceptance would have an adverse effect on our ability to derive revenues from sales of our drugs. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the diagnostic we anticipate using in connection with development and commercialization of our drug candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our drug candidates.

***Our drug candidates may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.***

Undesirable adverse events caused by our 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, CFDA, EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our trials could be suspended or terminated and the FDA, CFDA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Undesirable adverse events caused by BGB-3111 may include, but are not limited to, neutropenia, petechiae, purpura (subcutaneous bleeding), bruising, rash, peripheral neuropathy, and fatigue. Undesirable adverse events caused by BGB-290 may include, but are not limited to, nausea, vomiting, diarrhea, lethargy, neutropenia, anemia, thrombocytopenia, hypophosphataemia, and hot flush. Undesirable adverse events caused by BGB-283 may include, but are not limited to, thrombocytopenia, fatigue, rash, hand-foot syndrome, hypertension, and anorexia. Drug-related adverse events 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.

Additionally if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

we may suspend marketing of the drug;

regulatory authorities may withdraw approvals or revoke licenses of the drug;

regulatory authorities may require additional warnings on the label;

we may be required to develop an REMS for the drug or, if an 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;

Table of Contents

we may be required to conduct post-market studies;

we could be sued and held liable for harm caused to subjects or patients; and

our reputation may suffer.

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

Further, combination therapy, such as using our wholly-owned drug candidates as well as third-party agents, involves unique adverse events that could be exacerbated compared to adverse events from monotherapies. These types of adverse events could be caused by our drug candidates and could also 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, CFDA, EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events.

***A Fast Track Designation by the FDA, even if granted for any of our drug candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our drug candidates will receive regulatory approval.***

We do not currently have Fast Track Designation for any of our drug candidates but may seek such designation in the future. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for that condition, the drug sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw a Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain approval from the FDA.

***A Breakthrough Therapy Designation by the FDA, even if granted for any of our drug candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our drug candidates will receive regulatory approval.***

We do not currently have Breakthrough Therapy Designation for any of our drug candidates but may seek it in the future. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our drug candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead decide not to grant that designation. In any event, the receipt of a Breakthrough Therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as Breakthrough Therapies, the FDA may later decide that such drug candidates no longer meet the conditions for qualification.

Table of Contents

***We may seek orphan drug exclusivity for some of our drug candidates, and we may be unsuccessful.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the product for the indication can be recovered by sales of the product in the United States. BGB-3111 received orphan drug designation from the FDA for chronic lymphocytic leukemia, mantle cell lymphoma and Waldenström's macroglobulinemia in 2016.

Generally, if a drug with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EMA, from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the drug candidate from competition because different drugs can be approved for the same condition and the same drugs can be approved for a different condition but used off-label for any orphan indication we may obtain. Even after an orphan drug is approved, the FDA can subsequently approve a drug that is otherwise the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***Even if we receive regulatory approval for our drug candidates, we 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.***

If our drug candidates are approved, they 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.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, CFDA, EMA and comparable regulatory authority, requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practice, or cGMP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or BLA, other marketing application, and previous responses to 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.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS program as a

Table of Contents

condition of approval of our drug candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, CFDA, 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 may seek to impose a consent decree or withdraw marketing approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drug candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or 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 to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

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

injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates 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, CFDA, 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 may be subject to significant liability. The policies of the FDA, CFDA, 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. 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 additional safety studies. Other comparable regulatory authorities outside the United States, such as the CFDA 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.

**Risks Related to Commercialization of Our 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.*

We currently do not have any drug candidates that have gained regulatory approval for sale in the United States, European Union, China or any other country, and we cannot guarantee that we will ever

Table of Contents

have marketable drugs. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without first obtaining regulatory approval to market each drug from the FDA, CFDA, EMA and comparable regulatory authorities. BGB-3111, BGB-A317, BGB-290 and BGB-283 are each currently undergoing clinical trials. We cannot predict whether these trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

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 for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In the United States, we have not submitted an NDA or BLA for any of our drug candidates. An NDA or BLA must include extensive preclinical and clinical data and supporting information to establish, in the case of an NDA, the drug candidate's safety and effectiveness or, in the case of a BLA, safety, purity and potency for each desired indication. The NDA or BLA must also include significant information regarding the chemistry, manufacturing and controls for the drug. 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.

Regulatory authorities outside of the United States, such as the EMA or regulatory authorities in Australia and New Zealand and in emerging markets, such as in the PRC, 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 non-clinical 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.

Specifically, in China, the CFDA categorizes domestically manufactured innovative drug applications as Category 1 and imported innovative drug applications as Category 3. To date, most of local companies' domestically manufactured drug applications are filed in Category 1 if the drug has not already been approved by the FDA or EMA. Most multinational pharmaceutical companies' drug registration applications are filed in Category 3. These two categories have distinct approval pathways, as described in the section of our 2015 Annual Report, incorporated by reference herein, titled "Item 1 Business Regulatory Framework and Structural Advantages of Being a China-Based Research and Development Organization." We believe the local drug registration pathway, Category 1, is a faster and more efficient path to approval in the Chinese market than Category 3. Companies are required to obtain Clinical Trial Application approval before conducting clinical trials in China. This registration pathway has a fast track review and approval mechanism if the drug candidate is on a national priority list. The imported drug registration pathway, Category 3, is more complex and is evolving. China Category 3 registration applications may only be submitted after a drug has obtained an NDA approval and received the Certificate of Pharmaceutical Product granted by a major drug regulatory authority, such as the FDA or EMA.

Table of Contents

Further, in August 2015, the Chinese State Council, or State Council, issued a statement, *Opinions on reforming the review and approval process for pharmaceutical products and medical devices*, that contained several potential policy changes that could benefit the pharmaceutical industry:

A plan to accelerate innovative drug approval with a special review and approval process, with a focus on areas of high unmet medical needs, including drugs for HIV, cancer, serious infectious diseases and orphan diseases, drugs on national priority lists.

A plan to adopt a policy which would allow companies to act as the marketing authorization holder and to hire contract manufacturing organizations to produce drug products.

A plan to improve the review and approval of clinical trials, and to allow companies to conduct clinical trials at the same time as they are being conducted in other countries and encourage local clinical trial organizations to participate in international multi-center clinical trials.

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

A one-time umbrella approval procedure allowing approval of all phases of a new drug's clinical trials at once, rather than the current phase-by-phase approval procedure, will be adopted for new drugs' clinical trial applications.

A fast track drug registration or clinical trial approval pathway will be available for the following applications: (1) registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases; (2) registration of pediatric drugs; (3) registration of geriatric drugs and drugs treating China-prevalent diseases in elders; (4) registration of drugs sponsored by national science and technology grants; (5) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; and (7) concurrent applications for new drug clinical trials which are already approved in the United States or European Union or concurrent drug registration applications for drugs which have applied for marketing authorization and passed onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (8) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and marketing authorization applications for drugs with urgent clinical need and patent expiry within one year.

In February 2016, the CFDA released the *Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog*, which further clarified the following policies potentially accelerating the approval process of certain clinical trials or drug registrations:

A fast track drug registration or clinical trial approval pathway will be available for the following drug registration applications with distinctive clinical benefits: (1) registration application of innovative drugs not sold within or outside China; (2) registration application of innovative drugs transferred to be manufactured in China; (3) registration application of drugs using advanced technology, using innovative treatment methods, or having distinctive treatment advantages; (4) clinical trial applications for drugs with patent expiry within three years, and marketing authorization applications for drugs with patent expiry within one year; (5) concurrent applications for new drug clinical trials which are already approved in the United States or European Union, or concurrent drug registration applications for drugs which have applied for marketing authorization and passed onsite inspections in the United States or European Union and are manufactured using the same production line in China; (6) traditional Chinese medicines (including ethnic medicines) with clear clinical position in prevention and treatment of serious diseases; and (7) registration application of new drugs sponsored by national key technology projects or national key development projects.

Table of Contents

A fast track drug registration approval pathway will be available for drug registration applications with distinctive clinical benefits for prevention and treatment of HIV, phthisis, viral hepatitis, orphan diseases, malignant neoplasms, children's diseases, and geriatrics.

In March 2016, the CFDA released a circular, CFDA Announcement on Reforms of Pharmaceutical Registration Classification, which outlined the re-classifications of drug applications. Under the new categorization, innovative drugs that have not been marketed either within or outside China remain Category 1, while drugs marketed outside China seeking marketing approval in China are now Category 5.

However, because these laws and regulations in relation to such above-mentioned fast track clinical trial approval and drug registration pathway were newly issued, there remains uncertainty with respect to their implementation. We expect that the CFDA review and approval process will improve over time. However, how and when this approval process will be changed is still subject to further policies to be issued by the CFDA and is currently uncertain.

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 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 studies 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, CFDA 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.

***A Category 1 designation by the CFDA may be revoked or may not be granted for any of our drug candidates or may not lead to faster development or regulatory review or approval process and does not increase the likelihood that our drug candidates will receive regulatory approval.***

We believe the local drug registration pathway, Category 1, is a faster and more efficient path to approval in the Chinese market than the drug registration pathway for imported drugs under Category 3. Companies are required to obtain Clinical Trial Application approval before conducting clinical trials in China. This registration pathway has a fast track review and approval mechanism if the drug candidate is on a national priority list. Imported drug candidates under Category 3 cannot qualify for the national priority list to benefit from fast track reviews. Our drug candidates are all new therapeutic agents and we have built both research and development, clinical trial capacities, and commercial manufacturing facilities in China. As a result, we expect all of our current drug candidates to fall within the Category 1 application process, but cannot be sure we will be granted or be able to maintain Category 1 designation.

***Even if any of our drug candidates receives regulatory approval, they 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.***

If any of our drug candidates receives regulatory approval, it may nonetheless 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

Table of Contents

medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates, such as BGB-A317, BGB-3111, BGB-290 and BGB-283. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our 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 drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, CFDA, EMA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, CFDA, EMA or other comparable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;
- 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;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- and
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but 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 currently have no marketing and sales organization and have no experience in marketing drugs. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not be able to generate product sales revenue.***



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

Table of Contents

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all drugs we develop, 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, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates.

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

***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 with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. 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 developing our drug candidates. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. See the section of our 2015 Annual Report, incorporated by reference herein, titled "Item 1 Business Competition."

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 may develop. Our competitors also may obtain approval from the FDA, CFDA, 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.

Table of Contents

***Our drug candidates for which we intend to seek approval as biological or drug products may face competition sooner than expected.***

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively the Affordable Care Act, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created in the United States. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilars, including the possible designation of a biosimilar as "interchangeable," based on their similarity to existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products, including BGB-A317, if approved.

We believe that any of our drugs approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However:

a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version; and

the FDA could consider a combination therapy which contains both drug and biological product components, to be a drug subject to review pursuant to an NDA, and therefore eligible for a significantly shorter marketing exclusivity period as provided under the Drug Price Competition and Patent Term Restoration Act of 1984.

Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, a drug product approved under an NDA, such as BGB-3111, BGB-290 or BGB-283, if they were to be approved, could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012 established a user fee program that will generate hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, could significantly decrease the timeframe for FDA review and approval of generic drug applications.

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

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. 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. In addition,

Table of Contents

we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

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. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. 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 drug candidates may be limited or may not be amenable to treatment with our 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.

Our market opportunities may also be limited by competitor treatments that may enter the market. See " We face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do."

***Even if we are able to commercialize any drug candidates, the drugs may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. For example, according to a statement, *Opinions on reforming the review and approval process for pharmaceutical products and medical devices*, issued by the State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of new drug on PRC mainland market shall not be higher than the comparable market prices of the product in its country of origin or PRC's neighboring markets, as applicable.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for 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 successfully develop.

Table of Contents

There may be significant delays in obtaining reimbursement for approved product 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for new drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our drug candidates, which could make it difficult for us to sell our drug candidates profitably.***

Successful sales of our drug candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our drug candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our drug candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new drug acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

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 payment 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 drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drug candidates. Because our drug candidates have a higher cost of goods than

Table of Contents

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.

The State Council asked central and provincial authorities across the PRC to promote a medical insurance program for major illnesses. By the end by 2015, all urban and rural residents covered by basic medical insurance programs should be covered by the insurance program for major illnesses, according to State Council policy number 2015-57, issued on July 28, 2015. As a complement to basic insurance programs, this program is required to cover at least 50% of the medical cost as incurred by treating major illnesses, but falls out of the coverage of the basic insurance programs. The State Council requires provincial authorities to increase reimbursement rates over the next three years.

According to the PRC Central Government's guidance issued in March 2015, each province will decide which drugs to include in its provincial major illness reimbursement lists and the percentage of reimbursement, based on local funding. For example, Zhejiang province, located in the Yangtze river delta area with a population of 55 million, announced its provincial major illness drug reimbursement list in early 2015. The list includes 31 expensive drugs, among which 15 are targeted therapy agents for cancer, including Glivec, Ireesa, Erbitux, Herceptin, and Rituxan. Although it will take three years to establish a comprehensive national coverage, the affordability of the expensive, novel cancer agents to Chinese patients will improve significantly and the targeted therapy market is expected to enter a fast growing period.

We intend to seek approval to market our drug candidates in the United States, China, Europe and in other selected jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some non-U.S. countries, particularly those in the European Union, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates 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, PRC, European Union and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain regulatory approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and

Table of Contents

health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologics;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;

extension of manufacturers' Medicaid rebate liability;

expansion of eligibility criteria for Medicaid programs;

expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;

new requirements to report financial arrangements with physicians and teaching hospitals;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, 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. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.





Table of Contents

*We may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, 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. The laws that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to

Table of Contents

physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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 regardless of the payor. Many U.S. states have adopted laws similar to the Federal Anti-Kickback Statute, some of which apply to the referral of patients for 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 the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 application 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 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 with 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.

Table of Contents

*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. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these 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;

changes in a specific country's or region's political and cultural climate or economic condition;

differing regulatory requirements for drug approvals and marketing internationally;

difficulty of effective enforcement of contractual provisions in local jurisdictions;

potentially reduced protection for intellectual property rights;

potential third-party patent rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

economic weakness, including inflation or political instability, particularly in non-U.S. economies and markets;

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, and other obligations incidental to doing business in another country;

workforce uncertainty and labor unrest, particularly in non-U.S. countries where labor unrest is more common than in the United States;

the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a non-U.S. market with low or lower prices rather than buying them locally;

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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;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; 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.

Table of Contents

**Risks Related to Our Intellectual Property**

*A significant portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents and if our pending patent applications fail to issue our business will be adversely affected. If we are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.*

Our success depends in large part on our ability to obtain and maintain patent protection in the United States, the PRC and other countries with respect to our proprietary technology and drug candidates. As of November 7, 2016, we own seven issued U.S. patents and seven pending U.S. patent applications as well as corresponding patents and patent applications internationally. In addition, we own 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. 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. We have sought to protect our proprietary position by filing patent applications in the United States, the PRC and other countries related to novel technologies and drug candidates that we consider are important to our business. 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 position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. 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 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. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the Leahy-Smith America Invents Act enacted in 2011, the United States moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in interference *inter partes* review, post-grant review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights.

There can be no assurance that our pending patent applications will result in issued patents in the United States or non-U.S. jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and

Table of Contents

licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

***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 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 affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors increases 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. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Table of Contents

***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 U.S. Patent and Trademark Office 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. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent rights or other intellectual property rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent rights or other intellectual property rights do not cover the technology in question. 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.

If we initiate legal proceedings against a third party to enforce our patent, or any patents that may issue in the future from our patent applications, that relates to one of our drug candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. 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 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.

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as inventors or co-inventors. For example, we may have inventorship disputes arise from conflicting

Table of Contents

obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose rights such as exclusive ownership of, or right to use, our patent rights or other intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***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. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including *inter partes* review, post-grant review, interference and *ex parte* reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, or oppositions and other comparable proceedings in non-U.S. jurisdictions. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. 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 employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to prevent us from commercializing such drug candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Third parties who bring successful claims against us for infringement of their intellectual property rights may obtain 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 of infringement or misappropriation against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure. 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. We cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms, and we may fail to obtain any of these licenses on commercially reasonable terms, if at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business



Table of Contents

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.

Specifically, we are aware of three U.S. patents owned by Ono Pharmaceutical Co., or Ono, and licensed to Bristol-Myers Squibb Co., or BMS, that are relevant to our BGB-A317 drug candidate. These patents are expected to expire in 2023, 2023 and 2024, respectively. In patent infringement actions filed in Delaware Federal District court, BMS and Ono are alleging that Merck & Co.'s KEYTRUDA product, a humanized anti-PD-1 antibody is infringing these U.S. patents. Although Merck has challenged the validity of these patents, the litigation is at an early stage and the outcome is uncertain. Merck also filed an opposition proceeding challenging a corresponding European patent at the European Patent Office, or EPO. The EPO's Opposition Division disagreed with Merck's arguments and maintained the European patent in the form in which it was granted. Merck has appealed the decision. If the validity of the relevant claims in these U.S. patents is upheld and our BGB-A317 drug candidate is approved for sale in the United States before the expiration of these patents, then we will need a license from BMS in order to commercialize our BGB-A317 drug candidate in the United States prior to their expiration. In addition, depending upon circumstances, we may need a license for jurisdictions outside the United States where we wish to commercialize BGB-A317 before the expiration of a corresponding patent covering BGB-A317. There can be no assurance that we will be able to obtain such a license, which could materially and adversely affect our business.

In addition, we are aware of a U.S. patent owned by Pharmacyclics, Inc., which was acquired by AbbVie, Inc., with certain claims directed to a complex of an irreversible BTK inhibitor having a covalent bond to a cysteine residue of a BTK. This patent is expected to expire in 2027. Although we believe that the claims of the patent relevant to our BGB-3111 drug candidate would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, and BGB-3111 is approved for sale in the United States before the expiration of the U.S. patent, then we would need a license in order to commercialize BGB-3111 in the United States. In addition, depending upon circumstances, we may need a license for jurisdictions outside the United States where we wish to commercialize BGB-3111 before the expiration of a corresponding patent covering BGB-3111. However such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

We are also aware of three U.S. patents, owned or licensed by KuDOS Pharmaceuticals, Ltd., which was acquired by AstraZeneca PLC, with claims directed to using PARP inhibitors to treat cancers with certain defects in homologous recombination including, in some cases, a BRCA1 or BRCA2 mutation. These patents are expected to expire between 2027 and 2031 in the United States. Although we believe that the claims of these patents relevant to our BGB-290 drug candidate would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. While we are currently conducting and plan to conduct studies that include cancer patients with a BRCA1 or BRCA2 mutation, we are uncertain whether BGB-290 as commercialized will be used to treat cancer patients limited to having BRCA1 or BRCA2 mutation either in a monotherapy or a combination therapy. If BGB-290 is approved for sale in the United States for patients whose cancers have a BRCA1 or BRCA2 mutation, and if the validity of the relevant claims of these U.S. patents is upheld upon a validity challenge, then we would need a license in order to commercialize BGB-290 prior to expiration of these U.S. patents. In addition, we are also aware of corresponding issued patents in Europe and China. Depending upon circumstances, we may need a license for jurisdictions outside the United States where we wish to commercialize BGB-290 before the expiration of a corresponding patent covering BGB-290. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

Table of Contents

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical personnel, management personnel, or both from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of the 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 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.

***The terms of our patents may not be sufficient to effectively protect our drug candidates and business.***

In most countries in which we file, including the United States, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords, is limited. Even if patents covering our drug candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. If patents are issued on our currently pending patent applications, the resulting patents will be expected to expire on dates ranging from 2031 to 2035, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patent 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.

***If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of

Table of Contents

14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs, and our ability to generate revenues could be materially adversely affected.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that our currently issued patent and any patents that may issue from our pending patent applications directed to our drug candidates if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

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

Table of Contents

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.

***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.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, 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, including the rights to prosecute patent applications and to enforce patents. Certain of these license agreements impose and, for a variety of purposes, we may enter into additional licensing and funding arrangements with third parties that also may impose, diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties on net product sales of our drug candidates once commercialized, pay a percentage of sublicensing revenues, make other specified payments relating to our drug candidates or pay license maintenance and other fees.

Table of Contents

We also have diligence and clinical development obligations under certain of these agreements that we are required to satisfy. 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. 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 does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, CFDA, EMA and other comparable regulatory authorities for all of our drugs in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, CFDA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. 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, non-clinical and preclinical 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 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 requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result,

Table of Contents

delays occur, which can materially influence our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

***We expect to rely on third parties to manufacture at least a portion of our drug candidate supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our drug candidates, if approved. 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, we intend to at least partially rely on outside vendors to manufacture supplies and process our drug candidates. 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. 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, CFDA, EMA or other comparable regulatory authorities must approve any manufacturers as part of their regulatory oversight of our drug candidates. This approval would require new testing and cGMP-compliance inspections by FDA, CFDA, EMA or other comparable regulatory authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs.

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 drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.

contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately.

our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our drugs, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs.

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 drugs.

our third-party manufacturers could breach or terminate their agreement with us.

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.



Table of Contents

our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the FDA, CFDA, EMA or other comparable regulatory authorities, result in higher costs or adversely impact commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our 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 the FDA, CFDA, EMA or other comparable regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

The manufacture of drug and biological products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Currently, our drug raw materials for our manufacturing activities are supplied by 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 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 drug candidate 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 drug candidates and potential drugs, 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 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 FDA, CFDA, EMA or other comparable 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. In addition, drug and biological manufacturing facilities are continuously subject to inspection by the FDA, CFDA, EMA and other comparable regulatory authorities, before and after drug approval, and must comply with cGMPs. Our



Table of Contents

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 the FDA, CFDA, EMA or other comparable regulatory authorities and/or approval of the manufacturing process and procedures in accordance with the FDA, CFDA or EMA's regulations, or comparable 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 the FDA, CFDA, EMA or other comparable 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 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, in 2013, we entered into collaboration agreements with Merck KGaA pursuant to which we have agreed to license the ex-China rights of BGB-283 to Merck KGaA as discussed further in the section of our 2015 Annual Report, incorporated by reference herein, titled "Item 1 Business Collaboration with Merck KGaA." In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic 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. 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.

Further, collaborations involving our 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

Table of Contents

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;

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, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them 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.

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

*Our future success depends on our ability to retain the Chairman of our scientific advisory board and our Chief Executive Officer and other key executives and to attract, retain and motivate qualified personnel.*

We are highly dependent on Xiaodong Wang, Ph.D., our Founder, Chairman of our scientific advisory board and director; John V. Oyler, our Founder, Chief Executive Officer and Chairman of the board; and the other principal members of our management and scientific teams and scientific advisory board. Although we have formal employment agreements with each of our executive officers except for our Chief Executive Officer, 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

Table of Contents

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

As of September 30, 2016, we had 318 employees and consultants and most of our employees are full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we must add a significant number of additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

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

managing our internal development efforts effectively, including the clinical and FDA or other comparable 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 drug candidates will depend, in part, on our ability to effectively manage 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

Table of Contents

to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our drug candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

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

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our drug candidates and begin commercializing those drugs in the United States, our potential exposure under U.S. laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

As a public company, we are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override

Table of Contents

of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of the ADSs.***

Prior to the completion of our initial public offering, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements as of and for the years ended December 31, 2013, 2014 and 2015, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness related to having an insufficient number of financial reporting personnel with an appropriate level of knowledge, experience and training in application of U.S. GAAP and SEC rules and regulations commensurate with our reporting requirements.

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

hiring additional financial professionals with U.S. GAAP and SEC reporting experience;

increasing the number of qualified financial reporting personnel;

improving the capabilities of existing financial reporting personnel through training and education in the accounting and reporting requirements under U.S. GAAP and SEC rules and regulations;

developing, communicating and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes; and

establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our condensed consolidated financial statements and related disclosures.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our initial public offering, which will be our year ending December 31, 2016, provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We do not expect our independent registered public accounting firm to attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

Table of Contents

We are in the process of designing and implementing the internal control over financial reporting required to comply with this obligation, which process will be time-consuming, costly and complicated. If we identify any additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of the ADSs could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

***In order to satisfy our obligations as a public company, we will need to hire additional qualified accounting and financial personnel with appropriate public company experience.***

As a newly public company, we need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and maintain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts.

***If we engage in future 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.***

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

increased operating expenses and cash requirements;

the assumption of additional indebtedness or contingent 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. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.



Table of Contents

***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.***

Although currently our primary operating business is in China, 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. 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.

***Any failure to comply with applicable regulations and industry standards or obtain various licenses and permits could harm our reputation and our business, results of operations and prospects.***

A number of governmental agencies or industry regulatory bodies in the United States, and in non-U.S. jurisdictions including the PRC and European Union, impose strict rules, regulations and industry standards governing pharmaceutical and biotechnology research and development activities, which apply to us. Our failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, prospects for future work and operating results. For example, if we were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

***If we or our CROs 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 CRO, 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 radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We also store certain low level radioactive waste at our facilities until the materials can be properly disposed of. 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, hazardous or radioactive 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.



Table of Contents

***If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and our drugs could be subject to restrictions or withdrawal from the market.***

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our drugs. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

***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 future 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 such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

***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 to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other 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 drug candidates. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. A large portion of our operations is located in a single facility in Changping, Beijing, PRC. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development 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.

Table of Contents

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

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize any drugs. For example, we may be sued if our 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 state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our 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 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 drugs we develop, alone or with collaborators. Although we currently hold \$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. We intend to expand our insurance coverage for products to include the sale of commercial products if

we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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 corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Table of Contents

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

We maintain property insurance policies covering physical damage to, or loss of, our buildings and their improvements, equipment, office furniture and inventory. We hold employer's liability insurance generally covering death or work-related injury of employees. We hold public liability insurance covering certain incidents involving third parties that occur on or in the premises of the company. We hold directors and officers liability insurance. We do not maintain key-man life insurance on any of our senior management or key personnel, or business interruption insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

***We may market our drugs, if approved, globally, and we will be subject to the risks of doing business outside of the United States.***

Because we intend to market drugs, if approved, globally, 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:

efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;

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 countries;

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.

***Our business, financial condition and results of operations may be adversely affected by the downturn in the global economy.***

The global financial markets experienced significant disruptions in 2008 and the United States, Europe and other economies went into recession. The recovery from the lows of 2008 and 2009 was uneven and it is facing new challenges, including the escalation of the European sovereign debt crisis since 2011 and the United Kingdom's decision to withdraw from the European Union. It is unclear whether the European sovereign debt crisis will be contained and what effects it and the United Kingdom's decision to withdraw from the European Union may have. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies that have been adopted by the central banks and financial authorities of some of the world's leading economies, including China's. Economic conditions in United States and China are sensitive to global economic conditions. Although we are uncertain about the extent to which the global financial market disruption and slowdown of the U.S. or Chinese economy may impact our business in the long term, there is a risk that our business, results of operations and prospects would be materially and adversely affected by the global economic downturn and the slowdown of the U.S. or Chinese economy.



Table of Contents

***Recent developments relating to the United Kingdom's referendum vote in favor of withdrawal from the European Union could adversely affect us.***

The United Kingdom held a referendum on June 23, 2016 in which a majority voted for the United Kingdom's withdrawal from the European Union (referred to as "Brexit"). As a result of this vote, negotiations are expected to commence to determine the terms of the United Kingdom's withdrawal from the European Union as well as its relationship with the European Union going forward, including the terms of trade between the United Kingdom and the European Union. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Brexit could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and the European Union; however, the full effects of Brexit are uncertain and will depend on any agreements the United Kingdom may make to retain access to European Union markets.

In addition, we expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pharmaceutical industry, we could face significant new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and European Union. Similarly, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining, maintaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the European Union will cease being enforceable in the United Kingdom absent special arrangements to the contrary, and we are required to refile our trademarks and other intellectual property applications domestically in the United Kingdom. With regard to existing patent rights, the effect of Brexit should be minimal considering enforceable patent rights are specific to the United Kingdom, whether arising out of the European Patent Office or directly through the United Kingdom patent office.

Lastly, as a result of the Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the European Union. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, the full extent to which our business, results of operations and financial condition could be adversely affected by Brexit is uncertain.

***We manufacture and intend to continue to manufacture at least a portion of our drug candidates ourselves. Delays in completing and receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our revenues and growth.***

We currently lease an approximately 140 square meter manufacturing facility in Beijing, PRC, which produces and supplies preclinical and clinical trial materials for some of our small molecule drug candidates. To increase our manufacturing capabilities, we intend to expend substantial amounts for the build-out of an 11,000 square meter manufacturing facility in Suzhou, PRC to house one oral-solid-dosage production line for small molecule drug candidates and one pilot plant for monoclonal antibodies. At the Suzhou manufacturing facility, we intend to produce drug candidates for clinical or, in the future, commercial use. This new manufacturing facility is expected to be completed by 2017. This project may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. If construction or regulatory approval of our new facility is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development activities and our opportunities for growth. Suzhou Industrial Park Biotech Development Co., Ltd. and China Construction Bank have agreed to lend us RMB 120 million for the construction of the Suzhou manufacturing facility and the procurement of the equipment. Cost overruns associated with constructing our Suzhou facility could require us to raise additional funds from other sources.

Table of Contents

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, CFDA, 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 drugs. We also may encounter problems with the following:

achieving adequate or clinical-grade materials that meet FDA, CFDA, 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, CFDA, 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, license revocation, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

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.

In order to produce our drugs in the quantities that we believe will be required to meet anticipated market demand of any 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.

***If our manufacturing facilities, including our Suzhou manufacturing facility once completed, are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.***

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 FDA, CFDA, EMA or and other comparable 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. A number of factors could cause interruptions, including:

equipment malfunctions or failures;

technology malfunctions;

Table of Contents

work stoppages;

damage to or destruction of either facility due to natural disasters;

regional power shortages;

product tampering; or

terrorist activities.

Any disruption that impedes our ability to manufacture our drug candidates 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 the amount of up to RMB 84 million. 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 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.***

Our research operations and manufacturing facilities are in China, which we believe confers clinical, commercial and regulatory advantages. 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. See the section of our 2015 Annual Report, incorporated by reference herein, titled "Item 1 Business Regulatory Framework and Structural Advantages of Being a China-Based Research and Development Organization" for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. 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 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 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.***

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

The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC



Table of Contents

government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the PRC economy has experienced significant growth in the past three decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us. Our financial condition and results of operation could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us and consequently have a material adverse effect on our businesses, financial condition and results of operations.

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

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 three 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 because of the limited number of published decisions and the nonbinding nature of such decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

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

***Substantial uncertainties exist with respect to the enactment timetable, the final version, interpretation and implementation of draft PRC Foreign Investment Law and how it may impact the viability of our current corporate governance.***

The Ministry of Commerce published a discussion draft of the proposed Foreign Investment Law in January 2015 aiming to, upon its enactment, replace the trio of existing laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. The draft Foreign Investment Law embodies an expected

Table of Contents

PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Ministry of Commerce has solicited comments on this draft and substantial uncertainties exist with respect to its enactment timetable, the final version, interpretation and implementation. The draft Foreign Investment Law, if enacted as proposed, may materially impact the viability of our current corporate governance if we, in the future, have PRC shareholders.

Among other things, the draft Foreign Investment Law expands the definition of foreign investment and introduces the principle of "actual control" in determining whether a company is considered a foreign-invested enterprise, or an FIE. The draft Foreign Investment Law specifically provides that entities established in China but "controlled" by foreign investors will be treated as FIEs, whereas an entity set up in a foreign jurisdiction would nonetheless be, upon market entry clearance by the Ministry of Commerce or its local counterparts, treated as a PRC domestic investor provided that the entity is "controlled" by PRC entities and/or citizens. In this connection, "control" is broadly defined in the draft law to cover the following summarized categories: (1) holding 50% or more of the shares, equity or voting rights of the subject entity; (2) holding less than 50% of the voting rights of the subject entity but having the power to secure at least 50% of the seats on the board or other equivalent decision-making bodies, or having the voting power to exert material influence on the board, the shareholders' meeting or other equivalent decision-making bodies; or (3) having the power to exert decisive influence, via contractual or trust arrangements, over the subject entity's operations, financial matters or other key aspects of business operations. Once an entity is determined to be an FIE, it will be subject to the foreign investment restrictions or prohibitions, if the FIE is engaged in the industry listed in the "negative list" which will be separately issued by the State Council later. Unless the underlying business of the FIE falls within the negative list, which calls for market entry clearance by the Ministry of Commerce or its local counterparts, prior approval from the government authorities as mandated by the existing foreign investment legal regime would no longer be required for establishment of the FIE.

The draft Foreign Investment Law, if enacted as proposed, may also materially impact our corporate governance practice and increase our compliance costs. For instance, the draft Foreign Investment Law imposes stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable FIEs. Aside from investment implementation report and investment amendment report that are required at each investment and alteration of investment specifics, an annual report is mandatory, and large foreign investors meeting certain criteria are required to report on a quarterly basis. Any company found to be non-compliant with these information reporting obligations may potentially be subject to fines and/or administrative or criminal liabilities, and the persons directly responsible may be subject to criminal liabilities.

***PRC regulations relating to investments in offshore companies by PRC residents may subject our future PRC-resident beneficial owners or our PRC subsidiaries to liability or penalties, limit our ability to inject capital into our PRC subsidiaries or limit our PRC subsidiaries' ability to increase their registered capital or distribute profits.***

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, on July 4, 2014, which replaced the former circular commonly known as "SAFE Circular 75" promulgated by SAFE on October 21, 2005. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange,

Table of Contents

merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiaries of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Moreover, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls.

We believe that four of our shareholders, each of whom owns our ordinary shares as a result of exercising share options, are PRC residents under SAFE Circular 37. These four 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 the four 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. The failure of PRC-resident beneficial owners to register or amend their SAFE registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future PRC-resident beneficial owners of our company to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our PRC subsidiaries to fines and legal sanctions. Furthermore, SAFE Circular 37 is unclear how this regulation, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant PRC government authorities, and we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiaries and limit our PRC subsidiaries' ability to distribute dividends to us. These risks could in the future have a material adverse effect on our business, financial condition and results of operations.

***Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants 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. Upon completion of our initial public offering, we became an overseas listed company. Pursuant to SAFE Circular 37, PRC residents who participate in share incentive plans in overseas non-publicly-listed companies may submit applications to SAFE or its local branches for the foreign exchange registration with respect to offshore special purpose companies. 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 shares or options may follow SAFE Circular 37 to apply for the foreign exchange registration before our company became an overseas listed company. However, in practice, different local SAFE branches may have different views and procedures on the application and implementation of SAFE regulations, and there remains uncertainty with respect to its implementation. 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 restricted shares or options, including but not limited to the four shareholders referred to above, fail to register the employee equity incentive plans or their exercise of options, we and such employees may be subject to (i) legal or administrative sanctions imposed by the SAFE or other PRC authorities, including fines; (ii) to restrictions on our cross-border investment activities; (iii) to 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) to 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

Table of Contents

applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

Upon completion of our initial public offering, we became 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 shares or options are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, issued by SAFE in February 2012, 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 China 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. Failure to complete the SAFE registrations may subject them to fines and legal sanctions and may also limit our ability to make payments under our equity incentive plans or receive dividends or sales proceeds related thereto, or our ability to contribute additional capital into our wholly-foreign owned enterprises in China and limit our wholly-foreign owned enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law.

In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold applicable income taxes, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

***In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements.***

We are a holding company, incorporated in the Cayman Islands, and may in the future rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries for our offshore cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders, fund inter-company loans, service any debt we may incur outside China and pay our expenses. The laws, rules and regulations applicable to our PRC subsidiaries and certain other subsidiaries permit payments of dividends only out of their retained earnings, if any, determined in accordance with applicable accounting standards and regulations.

Under PRC laws, rules and regulations, each of our subsidiaries incorporated in China is required to set aside a portion of its net income each year to fund certain statutory reserves. These reserves, together with the registered equity, are not distributable as cash dividends. As a result of these laws, rules and regulations, our subsidiaries incorporated in China are restricted in their ability to transfer a portion of their respective net assets to their shareholders as dividends. 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 September 30, 2016, these restricted assets totaled RMB 17.2 million.

The Enterprise Income Tax Law, or the EIT Law, and its implementation rules, both of which became effective on January 1, 2008, 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

Table of Contents

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, or the "Hong Kong Tax Treaty," BeiGene (Hong Kong) Co., Limited, the shareholder 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 (Hong Kong) Co., Limited 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.

Furthermore, if our subsidiaries in China incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us. Any limitation on the ability of our subsidiaries to distribute dividends or other payments to us in the future could materially and adversely limit our ability to make investments or acquisitions that could be beneficial to our businesses, pay dividends, or otherwise fund and conduct our business.

***We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and be subject to PRC tax on our worldwide taxable income at a rate of 25%.***

Under the EIT Law an enterprise established outside China with "de facto management bodies" within China 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 Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, 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. On July 27, 2011, the SAT issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial), or Bulletin 45, which became effective on September 1, 2011 and was most recently amended on October 1, 2016, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration. In 2014, the SAT, released the Announcement of the SAT on Issues Concerning the Recognition of Chinese-Controlled Enterprises Incorporated Overseas as Resident Enterprises on the Basis of Their Actual Management Bodies and supplemented some provisions on the administrative procedures for the recognition of resident enterprise, while the standards used to classify resident enterprises in Circular 82 remain unchanged.

Although BeiGene, Ltd. does not have a PRC enterprise or enterprise group as our 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 the PRC.

Table of Contents

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 our company or any of our overseas subsidiaries should be treated as a PRC resident enterprise.

If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC EIT purposes, a number of unfavorable PRC tax consequences could follow and we may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to PRC EIT reporting obligations. In that case, it is possible that dividends paid to us by our PRC subsidiaries will not be subject to PRC withholding tax.

***Dividends payable to our foreign investors may be subject to PRC withholding tax and gains on the sale of the ADSs or ordinary shares by our foreign investors may be subject to PRC tax.***

If we are deemed a PRC resident enterprise as described under " We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and be subject to PRC tax on our worldwide taxable income at a rate of 25%," 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). It is unclear whether if we or any of our subsidiaries established outside China are considered a PRC resident enterprise, holders of the ADSs or ordinary shares would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas. If dividends payable to our non-PRC investors, or gains from the transfer of the ADSs or ordinary shares by such investors are subject to PRC tax, the value of your investment in the ADSs or ordinary shares may decline significantly.

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

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7, which replaced or supplemented certain previous rules under the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises, or Circular 698, issued by the SAT, on December 10, 2009. Pursuant to this Bulletin, 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 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 China or if its income mainly derives from China; 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

Table of Contents

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 Circular 698/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.

***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 China. A portion of our revenue may in the future be 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, which are wholly-foreign owned enterprises, 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 future revenue may be 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 our shareholders, including holders of 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. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Table of Contents

***Recent litigation and negative publicity surrounding China-based companies listed in the United States may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs and could have a material adverse effect upon our business, including its results of operations, financial condition, cash flows and prospects.***

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

***The audit report included in our 2015 Annual Report is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our shareholders 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 China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, shareholders 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 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 China Securities Regulatory Commission. 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



Table of Contents

in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, United States-listed companies and the market price of the ADSs may be adversely affected.

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 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.

**Risks Related to the American Depositary Shares and This Offering**

*The trading prices of the ADSs is likely to be volatile, which could result in substantial losses to you.*

We completed our initial public offering on February 8, 2016, and there has been a public market for the ADSs for only a short period of time. The trading price of the ADSs is likely to be volatile and could 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 China that have listed their securities in the United States may affect the volatility in the price of and trading volumes for the ADSs. Some of these companies have experienced significant volatility, including significant price declines after their initial public offerings. The trading performances of these PRC companies' securities at the time of or after their offerings may affect the overall investor sentiment towards other PRC companies listed in the United States and consequently may impact the trading performance of the ADSs.

In addition to market and industry factors, the price and trading volume for the 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 or new products by us or our competitors;

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

any adverse changes to our relationship with manufacturers or suppliers;

the results of our testing and clinical trials;

the results of our efforts to acquire or license additional drug candidates;

variations in the level of expenses related to our existing drug candidates or preclinical and clinical development programs;

any intellectual property infringement actions in which we may become involved;

announcements concerning our competitors or the pharmaceutical industry in general;

achievement of expected product sales and profitability;

manufacture, supply or distribution shortages;

Table of Contents

variations in our results of operations;

announcements about our earnings that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on earnings;

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;

announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;

press reports, whether or not true, about our business;

additions to or departures of our management;

fluctuations of exchange rates between the RMB and the U.S. dollar;

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

sales or perceived potential sales of additional ordinary shares or ADSs;

sales of the ADSs by us, our executive officers and directors or our shareholders in the future;

general economic and market conditions and overall fluctuations in the U.S. equity markets;

changes in accounting principles;

changes or developments in the PRC or global regulatory environment; and

the outcome of proceedings recently instituted by the SEC against five PRC-based accounting firms, including the affiliate of our independent registered public accounting firm.

Any of these factors may result in large and sudden changes in the volume and trading price of the ADSs. In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of management, and, if adversely determined, have a material adverse effect on our financial condition and results of operations.

In addition, the stock market, in general, and small 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 ADSs, regardless of our actual operating performance. Further, the current decline in the financial markets and related factors beyond our control may cause the ADSs price to decline rapidly and unexpectedly.

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

The ADS price may be volatile, and in the past companies that have experienced volatility in the market price of their ADSs 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, which could seriously harm our business.

Table of Contents

***Future sales of the ADSs in the public market could cause the ADS price to fall.***

The ADS price could decline as a result of sales of a large number of 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.

Upon completion of this offering, assuming the underwriters do not exercise their option to purchase additional shares, 69.3% of our outstanding ordinary shares immediately after this offering, will not be subject to lock-up agreements and may be freely converted into ADSs after this offering from time to time. In connection with this offering, our directors and executive officers, certain trusts and parties affiliated with such directors and officers and certain holders of our shares, including the selling shareholders, who collectively held 154,706,595 shares as of October 31, 2016, have signed lock-up agreements which, subject to certain exceptions, prevent them from selling any of our ordinary shares or ADSs, or any securities convertible into or exercisable or exchangeable for ordinary shares or ADSs for a period of not less than 90 days from the date of this prospectus without the prior written consent of each of the representatives. Certain trusts and parties affiliated with our directors and officers, who collectively held 106,414,577 shares as of October 31, 2016, have not signed lock-up agreements. The representatives may in their sole discretion and at any time without notice release some or all of the shares or ADSs subject to lock-up agreements prior to the expiration of the 90-day period. See "Underwriting" for a discussion of certain transfer restrictions. When determining whether or not to release shares or ADSs from the lock-up agreements, the representatives may consider, among other factors, the shareholder's reasons for requesting the release, the number of shares or ADSs for which the release is being requested and market conditions at the time. All ADSs representing our ordinary shares sold in this offering will be freely transferable by persons other than our "affiliates" without restriction or additional registration under the Securities Act. The ordinary shares outstanding after this offering will be available for sale, upon the expiration of the 90-day lock-up periods described above beginning from the date of this prospectus (if applicable to such holder), subject to volume and other restrictions as applicable under Rule 144 and Rule 701 under the Securities Act. Any or all of these shares may be released prior to the expiration of the applicable lock-up period at the discretion of one of the designated representatives. To the extent shares are released before the expiration of the applicable lock-up period and sold into the market, the market price of the ADSs could decline significantly.

Furthermore, as of September 30, 2016, approximately 112,308,859 ordinary shares that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

As of November 17, 2016, the holders of approximately 281,378,765 ordinary shares, or 65.5%, of our outstanding ordinary shares, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their ordinary shares or to include their ordinary shares in registration statements that we may file for ourselves or other shareholders. Once we register the offer and sale of ordinary shares for the holders of registration rights, they can be freely sold in the public market.

In addition, in the future, we may issue additional ordinary shares or other equity or debt securities convertible into ordinary shares 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 ADS price to decline.

***We are currently an "emerging growth company." As a result of the reduced disclosure requirements applicable to emerging growth companies, the ADSs may be less attractive to investors.***

We are currently an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on some of the exemptions from

Table of Contents

certain reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include but are not limited to not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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

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

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 investment in the ADSs as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, 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 restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in the ADSs will likely depend entirely upon any future price appreciation of the ADSs. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which you purchased the ADSs. You may not realize a return on your investment in the ADSs and you may even lose your entire investment in the ADSs.

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

The trading market for the 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 establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades the ADSs or publishes inaccurate or unfavorable research about our business, the market price for the 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 ADSs to decline significantly.

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

If you purchase ADSs in this offering, you will pay more for your ADSs than the amount paid by existing shareholders for their ordinary shares on a per ADS basis. As a result, you will experience immediate and substantial dilution of \$22.68 per ADS (assuming no exercise of outstanding options to acquire ordinary shares and no exercise of the underwriters' option to purchase additional ADSs), representing the difference between our pro forma net tangible book value per ADS as of September 30, 2016, after giving effect to this offering, and the public offering price of \$32.00 per ADS. In addition, you will experience further dilution to the extent that our ordinary shares are issued upon the exercise of share options. All of the ordinary shares issuable upon the exercise of currently outstanding share options will be

Table of Contents

issued at a purchase price on a per ADS basis that is less than the public offering price per ADS in this offering.

***We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under U.S. law, shareholders may have fewer shareholder rights than they would have under U.S. law.***

Our corporate affairs are governed by our amended and restated memorandum and articles of association (as may be 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 the United States. In particular, the Cayman Islands has a less developed body of securities law than the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders of these companies with the exception that the shareholders may request a copy of the current amended and restated memorandum and articles of association. Our directors have discretion under our amended and restated 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 United States federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in U.S. federal courts.

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 of directors or controlling shareholders than they would as public shareholders of a U.S. company.

***You may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited because we are incorporated under Cayman Islands law, we currently conduct substantially all of our operations outside the United States and some of our directors and executive officers reside outside the United States.***

We are incorporated in the Cayman Islands and currently conduct substantially all of our operations outside the United States through our subsidiaries. Some of our directors and executive officers reside outside the United States and a substantial portion of their assets are located outside of the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the Cayman Islands or in China in the event that you believe that your rights have been infringed under the securities laws of the United States or otherwise. Even if you are successful in bringing an action of this kind, 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 or China, although the courts of the

Table of Contents

Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

***Your voting rights as a holder of the ADSs are limited by the terms of the deposit agreement, as amended.***

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, as amended. Upon receipt of voting instructions from you in the manner set forth in the deposit agreement, the depository 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 depository 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 reasonable efforts to cause the depository 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 depository to vote your shares. Furthermore, the depository 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.

***Anti-takeover provisions in our charter documents may discourage our acquisition by a third party, which could limit our shareholders' opportunity to sell their shares, including ordinary shares represented by the ADSs, at a premium.***

Our amended and restated memorandum and 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, including ordinary shares represented by ADSs, 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 of directors 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 of directors authorizes the issuance of preferred shares, the market price of the ADSs may fall and the voting and other rights of the holders of our ordinary shares may be materially and adversely affected.

Furthermore, the amended and restated articles of association permit the directors to vary all or any of the rights attaching to any 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 of the holder. The amended and restated 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.



Table of Contents

***Our amended and restated memorandum and 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 amended and restated memorandum and 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 (including any proceeding purportedly filed on behalf of us or any shareholder), and such claiming party (or the third party that received substantial assistance from a claiming party or in whose claim or proceeding such claiming party has a direct financial interest) is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails, then such claiming party may, to the fullest extent permissible by law, be obligated jointly and severally 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, suit, action, or proceeding.

Fee-shifting articles are relatively new and untested in both the Cayman Islands and the United States. 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. For example, it is unclear whether our ability to invoke our fee-shifting article in connection with claims under the federal securities laws, including claims related to any of our public offerings, would be preempted by federal law. Similarly, it is unclear how courts might apply the standard that a claiming party must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of our fee-shifting article in connection with such claims, 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, including any claims related to our public offerings. 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, suit, action 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.

***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.***

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

Table of Contents

we have informed the depository 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 depository, you cannot prevent our ordinary shares underlying your ADSs from being voted, absent the situations described above, and it may make it more difficult for shareholders to influence our management. Holders of our ordinary shares are not subject to this discretionary proxy.

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

Your ADSs are transferable on the books of the depository. However, the depository 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 depository may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 depository 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 depository for the ADSs is entitled to charge holders fees for various services, including annual service fees.***

The depository 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 depository 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.

***You 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 depository 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 depository 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 depository 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 depository. We have no obligation to take any other action to permit the distribution of the ADSs, 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

Table of Contents

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 Securities Act with respect to all holders of ADSs or are registered under the provisions of the 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 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 the ADSs and deprive you of an opportunity to receive a premium for your ADSs.***

Our directors, executive officers and principal shareholders beneficially owned approximately 72.9% of our outstanding ordinary shares as of November 7, 2016. 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 the ADSs. These actions may be taken even if they are opposed by our other shareholders, including the holders of the ADSs. In addition, these persons could divert business opportunities away from us to themselves or others.

***We have incurred increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation and filing of these reports. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We continue to evaluate these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could

Table of Contents

result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2016. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***We may be a "passive foreign investment company," which may have adverse U.S. federal income tax consequences for U.S. shareholders.***

U.S. investors should be aware that, based on current business plans and financial expectations (including that a substantial percentage of our assets are held in cash and cash equivalents), we expect that we may be a passive foreign investment company within the meaning of Section 1297 of the Internal Revenue Code of 1986, as amended, or PFIC, for the current taxable year and in future taxable years. If we are a PFIC for any taxable year during a U.S. shareholder's holding period of the ADSs or ordinary shares, then such U.S. shareholder generally will be required to treat any gain realized upon a disposition of the ADSs or ordinary shares, or any "excess distribution" received on the ADSs or ordinary shares, as ordinary income earned over the U.S. shareholder's holding period for the ADSs or ordinary shares, and to pay the applicable taxes on such ordinary income along with an interest charge at the rate applicable to underpayments of tax on a portion of the resulting tax liability, unless the shareholder makes a timely and effective "qualified electing fund" election, or QEF election, or "mark-to-market" election with respect to the ADSs or ordinary shares. A U.S. shareholder who makes an effective QEF election generally must report on a current basis its share of our net capital gain and ordinary earnings for any taxable year in which we are a PFIC, whether or not we distribute any amounts to our shareholders. If a QEF election is not in effect for the first taxable year in your holding period in which we are a PFIC, a QEF election can only be made if you elect to recognize gain as if you had sold the ADSs or ordinary shares for their fair market value on the first day of your taxable year in which the PFIC becomes a QEF pursuant to the QEF election. The gain recognized on this deemed sale would be subject to the general tax treatment of PFICs discussed above. We intend to determine our PFIC status at the end of each taxable year and to satisfy any applicable record keeping and reporting requirements that apply to a QEF, and will endeavor to provide to you, for each taxable year that we determine we are or may be a PFIC, the information that is necessary for you to make a QEF election with respect to us (and any of our subsidiaries which are lower-tier PFICs). We may elect to provide such information on our website. However, there can be no assurances that we will make the necessary information available to you. You are urged to consult your own tax advisors regarding the availability of, and procedure for making, a QEF election. A U.S. shareholder who makes an effective mark-to-market election generally must include as ordinary income any gain recognized in a year that we are a PFIC in an amount equal to the excess of the fair market value of the ADSs over the shareholder's adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the ADSs or ordinary shares.

Table of Contents

***If you are a "Ten Percent Shareholder," you may be subject to adverse U.S. federal income tax consequences if we are classified as a Controlled Foreign Corporation.***

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own in the aggregate, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a U.S. person (as defined by the Internal Revenue Code of 1986, as amended), who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. We may currently be a CFC and/or we may become one in the future. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

Table of Contents

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This prospectus and the documents incorporated herein by reference contain forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus and the documents incorporated herein by reference include, but are not limited to, statements about:*

the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;

our ability to advance our drug candidates into, and successfully complete, clinical trials;

the ability of our drug candidates to be granted or maintain Category 1 designation with the CFDA;

our reliance on the success of our clinical-stage drug candidates BGB-3111, BGB-A317, BGB-290, and BGB-283 and certain other drug candidates, as monotherapies and in combination with our wholly owned drug candidates and third-party agents;

the timing or likelihood of regulatory filings and approvals;

the commercialization of our drug candidates, if approved;

our ability to develop sales and marketing capabilities;

the pricing and reimbursement of our drug candidates, if approved;

the implementation of our business model, strategic plans for our business, drug candidates and technology;

the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology;

our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;

cost associated with defending against intellectual property infringement, product liability and other claims;

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regulatory developments in the United States, China, the United Kingdom, the European Union and other jurisdictions;

the accuracy of our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;

the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;

our ability to maintain and establish collaborations or obtain additional grant funding;

the rate and degree of market acceptance of our drug candidates;

developments relating to our competitors and our industry, including competing therapies;

the size of the potential markets for our drug candidates and our ability to serve those markets;

our ability to effectively manage our anticipated growth;

our ability to attract and retain qualified employees and key personnel;

Table of Contents

our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;

statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance;

our expected use of proceeds of this offering;

the future trading price of the ADSs and impact of securities analysts' reports on these prices; and

other risks and uncertainties, including those listed under the caption "Risk Factors" and elsewhere in this prospectus and the documents incorporated herein by reference.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus and the documents incorporated herein by reference. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus, the documents we incorporate by reference, and the documents that we reference in this prospectus and have filed with the U.S. Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus and the documents incorporated herein by reference represent our views as of the date of such statements. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date they were made.

This prospectus and the documents incorporated herein by reference contain market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise.



Table of Contents

**USE OF PROCEEDS**

We estimate that the net proceeds to us from the sale of 5,781,250 ADSs in this offering will be approximately \$173.4 million based upon a public offering price of \$32.00 per ADS and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase an additional 937,500 ADSs in full, we estimate that our net proceeds will be approximately \$201.6 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from the sale of ADSs by the selling shareholders.

The principal purpose of this offering is to increase our financial resources to support ongoing and planned clinical development programs. We currently expect to use the net proceeds from this offering as follows:

approximately \$59 million for the ongoing dose-expansion phase of our clinical trial, other planned signal-seeking monotherapy and combination trials, as well as initiating registrational trials globally and in China for BGB-3111;

approximately \$32 million for the ongoing dose-escalation phase of our clinical trial, the ongoing expansion phase of our clinical trial, and other planned monotherapy and combination studies, and potentially initiating registration trials, for BGB-A317 globally and in China;

approximately \$18 million for the ongoing dose-expansion phase of our clinical trial, and other planned monotherapy and combination studies, and potentially initiating registration trials globally and in China, for BGB-290;

approximately \$22 million for supporting our research and development infrastructure and the development of other clinical and preclinical candidates; and

the remainder for working capital, capital expenditure and general corporate purposes, including the potential acquisition and re-acquisition of product rights.

We may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, or for other strategic investments or opportunities, although we have no current understandings, agreements or commitments to do so at this time.

Based on our current operational plans and assumptions, we expect that the net proceeds from this offering, combined with our current operating capital, will not be sufficient to enable us to complete all necessary development or commercially launch our current drug candidates. However, there can be no assurance that these expectations will be correct.

We currently have no specific plans as to how the net proceeds from this offering will be allocated beyond the uses specified above, and therefore management will retain discretion to allocate the remainder of the net proceeds of this offering among these uses.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our drug candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and may change the allocation of use of these proceeds among the uses described above. An investor will not

Table of Contents

have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments, or hold as cash.

Table of Contents**PRICE RANGE OF THE ADSs**

The ADSs have been publicly traded on the NASDAQ under the symbol "BGNE" since our initial public offering on February 3, 2016, which was completed at a price to the public of \$24.00 per ADS. The following table sets forth the high and low closing sale prices per share for our ADSs on the NASDAQ for the periods indicated:

<b>Period</b>	<b>High</b>	<b>Low</b>
<b>2016</b>		
First quarter (beginning February 3)	\$ 33.91	\$ 23.98
Second quarter	\$ 33.11	\$ 26.24
Third quarter	\$ 33.58	\$ 25.72
Fourth quarter (through November 17, 2016)	\$ 37.85	\$ 30.00

On November 17, 2016, the last reported sale price of the ADSs on the NASDAQ was \$32.70 per ADS. As of October 31, 2016, we had approximately 104 holders of record of our ordinary shares and one holder of record of the ADSs. This number does not include beneficial owners whose ADSs are held by nominees in street name.

Table of Contents

**DIVIDEND POLICY**

We have never declared or paid any dividends on our ordinary shares or any other securities. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase the ADSs with the expectation of receiving cash dividends.

Any future determination to pay dividends will be made at the discretion of our board of directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our board of directors may deem relevant. If we pay any dividends, we will pay the ADS holders to the same extent as holders of our ordinary shares, subject to the terms of the deposit agreement, as amended, including the fees and expenses payable thereunder. See "Description of American Depositary Shares." Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

If we pay dividends in the future, in order for us to distribute dividends to our shareholders and ADS holders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See "Risk Factors Risks Related to Our Doing Business in the PRC In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements."

Table of Contents**CAPITALIZATION**

The following table sets forth our cash and cash equivalents, short term investments, long-term bank loan, and capitalization as of September 30, 2016:

on an actual basis; and

on a pro forma as adjusted basis to give effect to our sale in this offering of 5,781,250 ADSs at a public offering price of \$32.00 per ADS after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriters' option to purchase additional ADSs.

You should read the following table together with the consolidated financial statements and related notes appearing in our 2015 Annual Report and our September 2016 Quarterly Report, incorporated by reference herein, as well as the information set forth under the headings "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Selected Consolidated Financial Data" appearing in our 2015 Annual Report and our September 2016 Quarterly Report incorporated by reference herein and "Description of American Depositary Shares" herein.

	Actual	Pro Forma As Adjusted
	(unaudited)	
	(in thousands, except share and per share amounts)	
Cash and cash equivalents	\$ 85,532	\$ 258,922
Short-term investments	\$ 118,086	\$ 118,086
Long-term bank loan	\$ 18,030	\$ 18,030
Shareholders' equity:		
Ordinary shares, \$0.0001 par value; 9,500,000,000 shares authorized, 428,519,031 <sup>(1)</sup> shares issued and outstanding (actual); 9,500,000,000 shares authorized, 503,675,281 shares issued and outstanding (pro forma as adjusted)	43	50
Undesignated shares, \$0.0001 par value; no shares authorized, issued or outstanding (actual); 500,000,000 shares authorized and no shares issued or outstanding (pro forma and pro forma as adjusted)		
Additional paid-in capital	388,568	561,951
Accumulated other comprehensive income	(965)	(965)
Accumulated deficit	(199,814)	(199,814)
Total shareholders' equity	187,832	361,222
Total capitalization	\$ 205,862	\$ 379,252

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(1) Shares issued and outstanding include 1,075,000 issued but unvested restricted shares as of September 30, 2016.

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

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

27,656,012 shares issuable upon the exercise of options outstanding as of September 30, 2016 pursuant to our 2011 Plan at a weighted-average exercise price of \$0.36 per share;

Table of Contents

25,492,593 shares issuable upon the exercise of options outstanding as of September 30, 2016 pursuant to our 2016 Plan at a weighted-average exercise price of \$2.21 per share;

43,959,589 shares reserved for future issuance under our 2016 Plan as of September 30, 2016; and

15,200,667 shares issuable upon the exercise of options granted outside our 2011 Plan or 2016 Plan as of September 30, 2016, at an exercise price of \$0.50 per share.

Table of Contents**DILUTION**

If you invest in the ADSs in this offering, your interest will be diluted to the extent of the difference between the public offering price per ADS and the pro forma as adjusted net tangible book value per ADS immediately after this offering.

Our net tangible book value as of September 30, 2016 was \$188 million, or \$0.44 per outstanding ordinary share as of that date, and \$5.70 per ADS. Net tangible book value represents our total tangible assets less our total tangible liabilities. Pro forma as adjusted net tangible book value per ordinary share is calculated after giving effect to the issuance of ordinary shares in the form of ADSs by us in this offering. Dilution is determined by subtracting pro forma as adjusted net tangible book value per ordinary share from the public offering price per ordinary share.

Without taking into account any other changes in net tangible book value after September 30, 2016, other than to give effect to the issuance and sale by us of 75,156,250 ordinary shares in the form of 5,781,250 ADSs in this offering at a public offering price of \$32.00 per ADS after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2016 would have been \$361.2 million, or \$0.72 per outstanding ordinary share and \$9.32 per ADS. This represents an immediate increase in pro forma net tangible book value of \$0.28 per ordinary share and \$3.62 per ADS to the existing shareholders and an immediate dilution in net tangible book value of \$1.74 per ordinary share and \$22.68 per ADS to investors purchasing ADSs in this offering. The following table illustrates such dilution:

	<b>Per Share</b>	<b>Per ADS</b>
Public offering price per share	\$ 2.46	\$ 32.00
Historical net tangible book value per share as of September 30, 2016	\$ 0.44	\$ 5.70
Increase in pro forma net tangible book value per share attributable to new investors	0.28	3.62
Pro forma as adjusted net tangible book value per share after this offering	0.72	9.32
Dilution per share to investors participating in this offering	\$ 1.74	\$ 22.68

If the underwriters exercise their option to purchase additional ADSs in full, the pro forma as adjusted net tangible book value would be \$0.75 per ordinary shares and \$9.75 per ADS, and the dilution in pro forma as adjusted net tangible book value to investors in this offering would be \$1.71 per ordinary share and \$22.25 per ADS.

The pro forma information discussed above is illustrative only. Our net tangible book value following the closing of this offering is subject to adjustment based on the actual public offering price of the ADSs and other terms of this offering determined at pricing.

The above discussion and tables are based on 428,519,031 ordinary shares issued and outstanding as of September 30, 2016, including 1,075,000 issued but unvested restricted shares, and excludes:

27,656,012 shares issuable upon the exercise of options outstanding as of September 30, 2016 pursuant to our 2011 Plan at a weighted-average exercise price of \$0.36 per share;

25,492,593 shares issuable upon the exercise of options outstanding as of September 30, 2016 pursuant to our 2016 Plan at a weighted-average exercise price of \$2.21 per share;

43,959,589 shares reserved for future issuance under our 2016 Plan as of September 30, 2016; and

15,200,667 shares issuable upon the exercise of options granted outside our 2011 Plan or 2016 Plan as of September 30, 2016, at an exercise price of \$0.50 per share.





Table of Contents

To the extent that outstanding options and warrants are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our shareholders.

Table of Contents

**ENFORCEMENT OF CIVIL LIABILITIES**

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability. We incorporated in the Cayman Islands because of certain benefits associated with being a Cayman Islands corporation, such as political and economic stability, an effective judicial system, a favorable tax system, the absence of foreign exchange control or currency restrictions and the availability of professional and support services. However, the Cayman Islands have a less developed body of securities laws that provide significantly less protection to investors as compared to the securities laws of the United States. In addition, Cayman Islands companies may not have standing to sue before the federal courts of the United States.

A large portion of our assets are located in China. In addition, some of our directors and officers are residents of jurisdictions other than the United States and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us or our directors and officers, or to enforce against us or them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

We have appointed C T Corporation System, located at 111 8th Avenue, New York, New York 10011 as our agent to receive service of process in the United States.

Mourant Ozannes, our counsel as to Cayman Islands law, and Fangda Partners, our counsel as to PRC law, have respectively advised us that there is uncertainty as to whether the courts of the Cayman Islands or the PRC would, respectively, (1) recognize or enforce judgments of U.S. courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States, or (2) entertain original actions brought in the Cayman Islands or the PRC against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States. Furthermore, Mourant Ozannes and Fangda Partners have advised us that, as of the date of this prospectus, no treaty or other form of reciprocity exists between the Cayman Islands and China governing the recognition and enforcement of judgments.

Mourant Ozannes has informed us that the uncertainty with regard to Cayman Islands law relates to whether a judgment obtained from the United States or PRC courts under civil liability provisions of the securities laws will be determined by the courts of the Cayman Islands as penal or punitive in nature. If such a determination is made, the courts of the Cayman Islands will not recognize or enforce the judgment against a Cayman company. As the courts of the Cayman Islands have yet to rule on whether such judgments are penal or punitive in nature, it is uncertain whether they would be enforceable in the Cayman Islands.

Mourant Ozannes has further advised us that although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States or China, a judgment obtained in such jurisdiction will be recognized and enforced in the courts of the Cayman Islands at common law, without any reexamination of the merits of the underlying dispute, by an action commenced on the foreign judgment debt in the Grand Court of the Cayman Islands, provided such judgment (1) is given by a foreign court of competent jurisdiction, (2) imposes on the judgment debtor a liability to pay a liquidated sum for which the judgment has been given, (3) is final, (4) is not in respect of taxes, a fine or a penalty and (5) was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

Fangda Partners has advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedure Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedure Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. Fangda Partners has advised us further that under PRC law, courts in the PRC will not

Table of Contents

recognize or enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC law or national sovereignty, security or social public interest. As there exists no treaty or other form of reciprocity between China and the United States governing the recognition and enforcement of judgments as of the date of this prospectus, including those predicated upon the liability provisions of the United States federal securities laws, there is uncertainty whether and on what basis a PRC court would enforce judgments rendered by United States courts. In addition, because there is no treaty or other form of reciprocity between the Cayman Islands and China governing the recognition and enforcement of judgments as of the date of this prospectus, there is further uncertainty as to whether and on what basis a PRC court would enforce judgments rendered by a Cayman Islands court.

Table of Contents**MANAGEMENT**

The information set forth under the heading "Item 10 Directors, Executive Officers and Corporate Governance" appearing in our 2015 Annual Report, and the other documentation listed under "Incorporation by Reference of Certain Documents" herein, is incorporated by reference herein.

The following executive officers joined our company since the date of our 2015 Annual Report:

Name	Age	Position(s)
<i>Executive Officers:</i>		
Amy Peterson, M.D.	49	Chief Medical Officer, Immuno-Oncology
Jane Huang, M.D.	43	Chief Medical Officer, Hematology
Ji Li, Ph.D.	48	Global Head of Business Development

The following is a biographical summary of the experience of our new executive officers. There are no family relationships among any of our directors or executive officers.

**Amy Peterson, M.D.** joined our company in August 2016 as our Chief Medical Officer, Immuno-Oncology. Prior to joining us, Dr. Peterson served as Vice President of Clinical Development at Medivation, Inc. from December 2012 to July 2016 and as Senior Medical Director from August 2011 to December 2012. At Medivation, she was primarily responsible for the development of enzalutamide and talazoparib in breast cancer and of pidilizumab in diffuse large b-cell lymphoma. Previously, she served as Associate Group Medical Director at Genentech from March 2010 to August 2011 where she was responsible for the development of early stage molecules targeting multiple major pathways in oncology. Prior to joining Genentech, Dr. Peterson was an Instructor of Medicine in Oncology at the University of Chicago, where she conducted translational research in tumor immunology in conjunction with Dr. Thomas F. Gajewski. Dr. Peterson received her M.D. from Thomas Jefferson University, and she completed her residency in Internal Medicine at Northwestern Memorial Hospital and Fellowship in Hematology and Oncology at the University of Chicago. She holds a Bachelor of Arts degree from Wesleyan University.

**Jane Huang, M.D.** joined our company in September 2016 as our Chief Medical Officer, Hematology. Prior to joining us, Dr. Huang served as the Vice President, Clinical Development at Acerta Pharma from April 2015 to September 2016, where she oversaw global clinical development of the BTK inhibitor, acalabrutinib. Previously, she worked at Genentech from 2005 to March 2015, serving most recently as Group Medical Director, where she played a leading role in drug development programs for several molecules at all stages of development, including venetoclax and obinutuzumab. She is also adjunct clinical faculty and an attending physician in Oncology at Stanford University. Dr. Huang received her Bachelor of Science degree in Biological Sciences from Stanford University and her M.D. from University of Washington School of Medicine. She is board certified in hematology, oncology, and internal medicine, and she completed her residency in Internal Medicine and fellowships in Hematology and Oncology at Stanford University.

**Ji Li, Ph.D.** joined our company in May 2016 as our Global Head of Business Development. Prior to joining us, Dr. Li served as Vice President of Business Development and Licensing at Merck Inc. from December 2013 to 2016, where he was responsible for late-stage inbound and outbound business development opportunities across all therapeutic areas globally. From August 2010 to August 2013, Dr. Li served as Executive Licensing Director for External Research and Development at Amgen, where he led the company's efforts in sourcing and evaluation of product partnering opportunities across all therapeutic areas and at all stages of drug development. He served as a member of our board of directors from January 2015 to February 2016. Dr. Li received his B.S. in Pharmacology from Shanghai Medical University and his Ph.D. in Neuroscience from Mount Sinai School of Medicine.

Table of Contents

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

Other than compensation arrangements, we describe below transactions and series of similar transactions, during our last three fiscal years, to which we were a party or will be a party, in which:

the amounts involved exceeded or will exceed \$120,000; and

any of our directors, executive officers or holders of more than 5% of our share capital, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

In connection with the completion of our initial public offering, we adopted a related party transactions policy that requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital shares or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons (as defined in Item 404 of Regulation S-K) or their affiliates, in which the amount involved is greater than \$120,000, be approved in advance by our audit committee. Any request for such a transaction must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, the extent of the related party's interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

Certain of the transactions described below were entered into prior to the adoption of this written policy but each such transaction was approved by our board of directors. Prior to our board of directors' consideration of a transaction with a related person, the material facts as to the related person's relationship or interest in the transaction were disclosed to our board of directors, and the transaction was not approved by our board of directors unless a majority of the directors approved the transaction. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties. Compensation arrangements for our directors and named executive officers are described in the section of our 2015 Annual Report titled "Item 11 Executive Compensation," incorporated by reference herein.

Table of Contents**Sales and Purchases of Securities*****Participation in Our Initial Public Offering***

In our initial public offering, certain of our directors, executive officers and 5% shareholders and their affiliates purchased an aggregate of 2,627,680 ADSs. Each of those purchases was made through the underwriters at the initial public offering price of \$24.00 per ADS. Certain purchases were made at the public offering price through a directed share program offered to our directors, officers, employees and business associated in connection with our initial public offering, or the Directed Share Program. The following table sets forth the aggregate number of ADSs that these directors, executive officers and 5% shareholders and their affiliates purchased in our initial public offering:

<b>Purchaser<sup>(1)</sup></b>	<b>Number of ADSs</b>	<b>Total Purchase Price</b>
Entities affiliated with Baker Bros. Advisors LP <sup>(2)</sup>	1,912,680	\$ 45,904,320
Entities affiliated with Hillhouse Capital Management, Ltd. <sup>(3)</sup>	700,000	\$ 16,800,000
Howard Liang <sup>(4)</sup>	5,000	\$ 120,000
RuiRong Yuan <sup>(5)</sup>	10,000	\$ 240,000

- (1) See the section of our 2015 Annual Report titled "Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for more information about the shares held by the above identified shareholders, directors and executive officers.
- (2) Michael Goller and Ranjeev Krishana, members of our board of directors, are, respectively, a Managing Director and Head of International Investments of Baker Bros. Advisors LP, affiliates of which collectively hold more than 5% of our voting securities.
- (3) Qingqing Yi, a member of our board of directors, is a Principal at Hillhouse Capital Group, affiliates of which collectively hold more than 5% of our voting securities.
- (4) Dr. Liang, our Chief Financial Officer and Chief Strategy Officer, purchased the ADSs through the Directed Share Program.
- (5) Dr. Yuan, our former Chief Medical Officer, purchased the ADSs through the Directed Share Program.

***Preferred Share Financings******Series A Preferred Share Financing***

In October 2014, we issued and sold an aggregate of 116,785,517 shares of our Series A preferred shares for an aggregate consideration of \$74,490,234.23 to certain investors, pursuant to the share purchase agreements entered into with these investors. In connection with the Series A preferred share financing, we also issued warrants to purchase up to 2,592,593 ordinary shares to entities affiliated with Baker Bros. Advisors LP, which have an exercise price of \$0.675 per share, and convertible notes to entities affiliated with Baker Bros. Advisors LP, which converted into Series A preferred shares in the Series A preferred share financing. All of these Series A preferred shares were automatically converted into ordinary shares on a one-for-one basis at the closing of our initial public offering.

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### Table of Contents

The following table summarizes the participation in the Series A preferred share financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

Name	Series A Preferred Shares	Aggregate Purchase Price Paid
Entities affiliated with Baker Bros. Advisors LP <sup>(1)</sup>	49,537,036	\$ 33,437,500.00
Merck Sharp & Dohme Research GmbH <sup>(2)</sup>	18,518,519	\$ 10,000,000.00
Hillhouse BGN Holdings Limited <sup>(3)</sup>	14,814,814	\$ 10,000,000.00
CB Biotech Investment Limited <sup>(4)</sup>	14,814,814	\$ 10,000,000.00
John V. Oyler <sup>(5)</sup>	14,326,356	\$ 7,830,291.51

- (1) Consists of (i) 44,572,171 shares held by Baker Brothers Life Sciences, L.P.; (ii) 582,747 shares held by 14159, L.P.; and (iii) 4,382,118 shares held by 667, L.P. These entities hold, in the aggregate, more than 5% of our capital shares. Each of Michael Goller, Managing Director at Baker Bros. Advisors LP and Ranjeev Krishana, Head of International Investments at Baker Bros. Advisors LP, is a member of our board of directors.
- (2) Ji Li, former Vice President of Business Development and Licensing at Merck Sharp & Dohme Corp., of which Merck Sharp & Dohme Research GmbH is an affiliate, was a member of our board of directors. Dr. Li currently serves as our Global Head of Business Development.
- (3) Qingqing Yi, Principal at Hillhouse Capital, of which Hillhouse BGN Holdings Limited is an affiliate, is a member of our board of directors.
- (4) Ke Tang, Vice President at CITIC PE Private Equity Funds Management Co., Ltd., of which CB Biotech Investment Limited is an affiliated fund, is a member of our board of directors.
- (5) John V. Oyler is our Founder, Chief Executive Officer and Chairman and a member of our board of directors.

### *Series A-2 Preferred Share Financing*

On April 21, 2015, we issued and sold an aggregate of 83,205,124 shares of our Series A-2 preferred shares for an aggregate consideration of \$97,349,995.08 to certain investors, pursuant to the share purchase agreement entered into with these investors. All of these Series A-2 preferred shares were automatically converted into ordinary shares on a one-for-one basis at the closing of our initial public offering.

The following table summarizes the participation in the Series A-2 preferred share financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

Name	Series A-2 Preferred Shares	Aggregate Purchase Price Paid
Entities affiliated with Baker Bros. Advisors LP <sup>(1)</sup>	28,205,128	\$ 32,999,999.76
Merck Sharp & Dohme Research GmbH <sup>(2)</sup>	5,128,205	\$ 5,999,999.85
Hillhouse BGN Holdings Limited <sup>(3)</sup>	15,811,965	\$ 18,499,999.05
CB Biotech Investment Limited <sup>(4)</sup>	4,786,324	\$ 5,599,999.08

- (1) Consists of (i) 26,292,961 shares held by Baker Brothers Life Sciences, L.P.; and (ii) 1,912,167 shares held by 667, L.P. These entities hold, in the aggregate, more than 5% of our capital shares. Each of Michael Goller, Managing Director at Baker Bros. Advisors LP





Table of Contents

and Ranjeev Krishana, Head of International Investments at Baker Bros. Advisors LP, is a member of our board of directors.

- (2) Ji Li, former Vice President of Business Development and Licensing at Merck Sharp & Dohme Corp., of which Merck Sharp & Dohme Research GmbH is an affiliate, was a member of our board of directors. Dr. Li currently serves as our Global Head of Business Development.
- (3) Qingqing Yi, Principal at Hillhouse Capital, of which Hillhouse BGN Holdings Limited is an affiliate, is a member of our board of directors.
- (4) Ke Tang, Vice President at CITIC PE Private Equity Funds Management Co., Ltd., of which CB Biotech Investment Limited is an affiliated fund, is a member of our board of directors.

**Consulting Arrangements**

Donald W. Glazer, a member of our board of directors, has been providing strategic consulting services to our company since our inception in 2010. As full compensation of his consulting services, on November 24, 2010, in connection with the initial formation of our company, we issued 4,000,000 ordinary shares to Mr. Glazer at \$0.0001 per share to vest over five years. Those shares are fully vested. We also reimburse Mr. Glazer for the out of pocket expenses incurred in connection with his consulting services.

Dr. Xiaodong Wang, our Founder, Chairman of the Scientific Advisory Board and director, has been providing scientific and strategic advisory services to us. Dr. Wang currently receives an annual fixed fee of \$100,000 and has a target bonus level of \$86,176. On April 3, 2013, we granted him an option to purchase 1,199,000 ordinary shares at an exercise price of \$0.01 per share. On July 20, 2014, Dr. Wang purchased 1,616,000 ordinary shares from us for an aggregate purchase price of \$16,160. On June 29, 2015, we granted him an option to purchase 500,000 ordinary shares at an exercise price of \$0.50 per share. On July 19, 2015, we granted him an option to purchase 3,800,167 ordinary shares at an exercise price of \$0.50 per share. In March 2016, we granted him a cash bonus in the amount of \$86,176. On November 16, 2016, we granted him an option to purchase 1,613,430 ordinary shares at an exercise price of \$2.84 per share.

**Debt Arrangements**

On February 2, 2011, we issued an 8% senior note for an aggregate principal amount of \$10 million to Merck Sharp & Dohme Research GmbH, or MSD. On January 26, 2016, we entered into a note amendment and exchange agreement with MSD to extend the maturity date of this note to May 2, 2016. On February 8, 2016, the entire outstanding unpaid principal and interest of the MSD note as of February 2, 2016 (i.e., \$14,693,281) was automatically exchanged into 7,942,314 of our ordinary shares at \$1.85 per share, the initial offering price per ordinary share calculated based on the initial public offering price per American Depositary Share divided by 13, the then ordinary share-to-ADS ratio. On February 1, 2013, we issued a \$3 million subordinated convertible promissory note to MSD, which was repaid in full on October 31, 2013.

From 2010 to 2014, Mr. Oyler advanced us funds from time to time pursuant to loan agreements between Mr. Oyler and us, which provide that, at Mr. Oyler's option, the outstanding balance under such loan agreements may convert into securities of our company on the same terms and conditions as the subordinated convertible promissory note we issued to MSD, including a 20% conversion discount at a qualified financing. During 2012, 2013 and 2014, Mr. Oyler advanced \$5,131,000, \$249,000 and \$103,000, respectively, to us. The advances bore interest at 6% to 15%.

In 2013, we repaid advances amounting to \$731,000 in cash and by issuance of 13,433,334 ordinary shares. From January 1, 2014 through October 7, 2014, we repaid advances amounting to \$1,285,000 in cash and by issuance of 6,069,000 ordinary shares. On October 7, 2014, \$7,360,000 remaining outstanding balance of such indebtedness converted into 13,629,629 Series A preferred shares.

Table of Contents

During 2012, we issued 8%-15% convertible promissory notes due March 21, 2017 and warrants to purchase our preferred shares up to 10% of the convertible promissory notes' principal amount concurrently for an aggregate principal amount of \$650,000 to Mr. Oyler. On October 7, 2014, the outstanding balance of such convertible promissory notes converted into 696,727 Series A preferred shares.

**Warrant Exercises**

On February 8, 2016, in connection with the closing of our initial public offering, entities affiliated with Baker Bros. Advisors LP exercised their warrants to purchase 2,592,293 ordinary shares at an exercise price of \$0.675 per share. On February 8, 2016, in connection with the closing of our initial public offering, John V. Oyler exercised his warrants to purchase 57,777 Series A preferred shares at an exercise price of \$0.675 per share, which shares were converted into 57,777 ordinary shares.

**Employment Agreements**

For more information regarding employment agreements with certain of our executive officers, see the information set forth under the heading "Item 11 Executive Compensation Employment Agreements with Our Named Executive Officers" appearing in our 2015 Annual Report incorporated by reference herein.

**Indemnification Agreements**

Cayman Islands law does not limit the extent to which a company's articles of association may provide indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as providing indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association provide that each officer or director shall be indemnified out of assets of our company against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such director or officer in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

In addition, we have previously entered into new agreements to indemnify our directors and executive officers. These agreements, among other things, indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or executive officer.

**Agreements With Our Shareholders**

In connection with our preferred share financings, we entered into (1) an investors' rights agreement, (2) a right of first refusal and co-sale agreement and (3) a voting agreement, in each case, with the purchasers of our preferred shares and certain holders of our ordinary shares. The primary rights under each of these terminated upon the closing of our initial public offering, other than certain registration rights for certain holders of our ordinary shares. On November 16, 2016, we entered into an additional registration rights agreement with certain holders of our ordinary shares. See "Description of Share Capital Registration Rights" for additional information.

**Other Transactions**

We have granted share options to our executive officers. For a description of these share options, see the information set forth under the heading "Item 11 Executive Compensation" appearing in our 2015 Annual Report incorporated by reference herein.

On November 16, 2016, we granted 2,047,500 and 1,752,500 ordinary shares, respectively, to our chief executive officer and chief financial officer and chief strategy officer at an exercise price of \$2.84 per share. On November 16, 2016, we adopted an independent director compensation policy.

Table of Contents

**PRINCIPAL AND SELLING SHAREHOLDERS**

The following table sets forth certain information known to us regarding beneficial ownership of our share capital as of October 31, 2016 by:

each person, our group of affiliated persons, known by us to be the beneficial owner of more than 5% of any class our voting securities;

each of our named executive officers;

each of our directors;

all of our executive officers and directors as a group; and

each selling shareholder.

Beneficial ownership is determined in accordance with the rules of the U.S. Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Except as noted by footnote, and subject to community property laws where applicable, we believe based on the information provided to us that the persons and entities named in the table below have sole voting and investment power with respect to all securities shown as beneficially owned by them.

Certain of our existing shareholders have agreed to purchase an aggregate of approximately \$77.6 million of our ADSs in this offering at the public offering price and on the same terms as the other investors in this offering. The figures in the table below do not reflect any purchases of the ADSs in this offering by these shareholders.

The table lists applicable percentage ownership based on 429,494,031 ordinary shares outstanding as of October 31, 2016, including 1,075,000 issued but unvested restricted shares and also lists applicable percentage ownership based on 504,650,281 ordinary shares assumed to be outstanding after the closing of this offering assuming the underwriters do not exercise their option to purchase additional ADSs (516,837,781 shares if the underwriters exercise their option to purchase additional ADSs in full). Options to purchase ordinary shares that are exercisable within 60 days of October 31, 2016 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage. Beneficial ownership representing less than 1% is denoted with an asterisk (\*).

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### Table of Contents

Unless otherwise noted below, the address of each person listed on the table is: c/o Mourant Ozannes Corporate Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY 1-1108, Cayman Islands.

Name and Address of Beneficial Owner	Ordinary Shares Beneficially Owned Prior to this Offering		Number of Ordinary Shares Offered	Ordinary Shares Beneficially Owned After this Offering		Ordinary Shares Beneficially Owned After this Offering Assuming Underwriters Exercise Option in Full	
	Number	%		Number	%	Number	%
<b>5% or Greater Shareholders</b>							
Entities affiliated with Baker Bros. Advisors LP <sup>(1)</sup>	105,199,597	24.5%		105,199,597	20.8%	105,199,597	20.4%
Entities affiliated with Hillhouse Capital Management, Ltd. <sup>(2)</sup>	39,726,779	9.2%		39,726,779	7.9%	39,726,779	7.7%
Merck Sharp & Dohme Research GmbH <sup>(3)</sup>	31,589,038	7.4%		31,589,038	6.3%	31,589,038	6.1%
FMR LLC <sup>(4)</sup>	29,904,381	7.0%		29,904,381	5.9%	29,904,381	5.8%
<b>Named Executive Officers and Directors</b>							
John V. Oyler <sup>(5)</sup>	81,112,678	18.7%		81,112,678	16.0%	81,112,678	15.6%
Howard Liang <sup>(6)</sup>	1,800,416	*		1,800,416	*	1,800,416	*
RuiRong Yuan	130,000	*		130,000	*	130,000	*
Timothy Chen							
Michael Goller							
Donald W. Glazer <sup>(7)</sup>	4,882,006	1.1%		4,882,006	1.0%	4,882,006	*
Ranjeev Krishana							
Ke Tang							
Qingqing Yi							
Thomas Malley							
Xiaodong Wang <sup>(8)</sup>	18,433,146	4.3%	1,218,750	17,214,396	3.4%	17,214,396	3.3%
<b>All Directors and Executive Officers as a Group (14 persons)<sup>(9)</sup></b>							
	108,619,899	24.8%	1,218,750	107,401,149	21.0%	107,401,149	20.5%
<b>Other Selling Shareholders</b>							
CB Biotech <sup>(10)</sup>	19,601,138	4.6%	4,875,000	14,726,138	2.9%	14,726,138	2.8%

- (1) Based solely on a Schedule 13D filed by Baker Bros. Advisors LP, Baker Bros. Advisors (GP) LLC, Felix J. Baker and Julian C. Baker on February 9, 2016, consisting of (i) 8,994,997 ordinary shares held by 667, L.P., (ii) 95,565,000 ordinary shares held by Baker Brothers Life Sciences, L.P. and (iii) 639,600 ordinary shares held by 14159 L.P. (collectively, "Baker Funds"), as of February 8, 2016. Baker Bros. Advisors LP is the investment advisor to Baker Funds and has sole voting and investment power with respect to the shares held by Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.
- (2) Based solely on a Schedule 13D filed by Hillhouse Capital Management, Ltd. on February 18, 2016, consisting of (i) 8,372,000 ordinary shares held by Gaoling Fund, L.P., (ii) 728,000 ordinary shares held by YHG Investment, L.P., and (iii) 30,626,779 ordinary shares held by BGN Holdings Limited, as of February 8, 2016. Hillhouse Capital Management, Ltd. acts as the sole general partner of YHG Investment, L.P. and the sole management company of Gaoling Fund L.P. and Hillhouse Fund II, L.P., which owns BGN Holdings Limited. Mr. Lei Zhang may be deemed to have controlling power over Hillhouse Capital Management, Ltd. Mr. Lei Zhang disclaims beneficial ownership of all of the shares held by Hillhouse Fund II, L.P., except to the extent of his pecuniary interest therein. The registered address of Hillhouse Capital Management Ltd. is Cayman Corporate Centre, 3 Floor, 18 Fort Street, George Town, Grand Cayman.
- (3) Based solely on a Schedule 13G filed by Merck & Co., Inc., Merck Sharp & Dohme Corp., and Merck Sharp & Dohme Research GmbH on February 12, 2016, consisting of 31,589,038 ordinary shares as of February 8, 2016, held directly by Merck Sharp & Dohme Research GmbH, which is a wholly owned subsidiary of Merck Sharp & Dohme Corp., which is a wholly owned subsidiary of Merck & Co., Inc. The entities reported shared voting and dispositive power over the ordinary shares. The address for this entity is Weysstrasse 20, CH-6000, Lucerne 6, Switzerland.

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- (4) Based solely on a Schedule 13F-HR filed by FMR LLC on August 11, 2016, consisting of (i) 2,068,075 ADSs, representing 26,884,975 ordinary shares, held by FMR LLC as to which FMR LLC reported sole voting power over 300,024 ADSs, representing 3,900,312 ordinary shares; no voting power over 1,768,051 ADS, representing 22,984,663 ordinary shares; and investment power shared with Fidelity Management & Research Company and FMR Co., Inc. and (ii) 232,262 ADSs, representing 3,019,406 ordinary shares, held by FMR LLC as to which FMR reporting no voting power and investment power shared with Fidelity Management & Research Company and Fidelity Management & Research (Hong Kong) Ltd. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.
- (5) Consists of (i) 59,780,349 ordinary shares held directly by Mr. Oyler; (ii) 10,000,000 ordinary shares held for the benefit of Mr. Oyler in a Roth IRA PENSCO trust account; (iii) 102,188 ordinary shares held by The John Oyler Legacy Trust for the benefit of his minor child, for which Mr. Oyler disclaims beneficial ownership; (iv) 8,000,000 ordinary shares held for the benefit of Mr. Oyler in a grantor retained annuity trust; and (v) 3,230,141 shares issuable to Mr. Oyler upon exercise of share options exercisable within 60 days after October 31, 2016.
- (6) Consists of (i) 65,000 ordinary shares held directly by Dr. Liang; and (ii) 1,735,416 shares issuable to Dr. Liang upon exercise of share options exercisable within 60 days after October 31, 2016.
- (7) Consists of (i) 4,881,997 ordinary shares held directly by Mr. Glazer; and (ii) nine ordinary shares held for the benefit of Mr. Glazer in a Roth IRA PENSCO trust account.

Table of Contents

- (8) Consists of (i) 16,344,143 ordinary shares held directly by Dr. Wang; (ii) 1,874,472 shares issuable to Dr. Wang upon exercise of share options exercisable within 60 days after October 31, 2016; and (iii) 214,531 ordinary shares held in a UTMA account for Dr. Wang's minor child, for which Dr. Wang disclaims beneficial ownership.
- (9) Includes 7,826,682 ordinary shares issuable upon exercise of options within 60 days of October 31, 2016.
- (10) Consists of 19,601,138 ordinary shares directly held by CB Biotech Investment Limited, which is wholly owned by CPEChina Fund, L.P., a Cayman Islands limited partnership. CITIC PE Associates, L.P. is a Cayman Islands limited partnership and acts as the sole general partner of CPEChina Fund, L.P. CITIC PE Funds Limited is a Cayman Islands exempted company with limited liability and acts as the sole general partner of CITIC PE Associates, L.P. The directors of CITIC PE Funds Limited, Mr. Lei Nie and Ms. Ching Nar Cindy Chan may be deemed to have controlling power over CITIC PE Funds Limited. Each of Mr. Lei Nie and Ms. Ching Nar Cindy Chan disclaims beneficial ownership of all of the shares held by CB Biotech Investment Limited, except to the extent of his or her pecuniary interest therein. The address for CB Biotech Investment Limited is c/o Maples Corporate Services (BVI) Limited, Kingston Chambers, PO Box 173, Road Town, Tortola, British Virgin Islands.

Table of Contents

**DESCRIPTION OF SHARE CAPITAL**

We are an exempted company incorporated in the Cayman Islands with limited liability and our affairs are governed by our memorandum and articles of association, and the Companies Law (as amended) of the Cayman Islands, which we refer to as the Cayman Companies Law, and the common law of the Cayman Islands.

As of September 30, 2016, our authorized share capital was \$1,000,000 divided into (i) 9,500,000,000 ordinary shares of a par value of \$0.0001 each and (ii) 500,000,000 shares of a par value of \$0.0001 each of such class or classes (howsoever designated) as the board of directors may determine.

Our fourth amended and restated memorandum and articles of association, or our articles, became effective upon completion of our initial public offering. The following are summaries of material provisions of our articles and the Cayman Companies Law insofar as they relate to the material terms of our ordinary shares. Under our articles, our name continues to be BeiGene, Ltd.

The following discussion primarily concerns ordinary shares and the rights of holders of ordinary shares. The holders of ADSs are not be treated as our shareholders and will be required to surrender their ADSs for cancellation and withdrawal from the depositary facility in which the ordinary shares are held in accordance with the provisions of the deposit agreement, as amended, in order to exercise directly shareholders' rights in respect of the ordinary shares. The depositary has agreed, so far as it is practical, to vote or cause to be voted the amount of ordinary shares represented by ADSs in accordance with the non-discretionary written instructions of the holders of such ADSs. See "Description of American Depositary Shares Voting Rights."

**Ordinary Shares**

*General*

All of our issued and outstanding ordinary shares are fully paid and non-assessable. Our ordinary shares are issued in registered form, and are issued when registered in our register of members. Each holder of our ordinary shares will be entitled to receive a certificate in respect of such ordinary shares. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their ordinary shares. We may not issue shares to bearer.

*Dividends*

The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Companies Law, a Cayman Islands company may pay a dividend out of either profit or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business.

*Voting Rights*

Each ordinary share is entitled to one vote on all matters upon which the ordinary shares are entitled to vote.

Voting at any meeting of shareholders is by poll.

An ordinary resolution to be passed by the shareholders requires the affirmative vote of a simple majority of the votes cast by the shareholders entitled to vote who are present in person or by proxy at a general meeting, while a special resolution requires the affirmative vote of at least two-thirds of the votes cast by the shareholders entitled to vote who are present in person or by proxy at a general meeting (except for certain types of winding up of the company, in which case the required majority to pass a special



Table of Contents

resolution shall be 100%). Both ordinary resolutions and special resolutions may also be passed by a unanimous written resolution signed by all the shareholders of our company, as permitted by the Cayman Companies Law and our articles. A special resolution is required for important matters such as a change of name and amendments to our articles. Our shareholders may effect certain changes by ordinary resolution, including increasing the amount of our authorized share capital, consolidating and dividing all or any of our share capital into shares of larger amounts than our existing shares and cancelling any authorized but unissued shares.

*Transfer of Ordinary Shares*

Subject to the restrictions contained in our articles, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in any usual or common form or any other form approved by our board of directors, executed by or on behalf of the transferor (and, if in respect of a nil or partly paid up share, or if so required by our directors, by or on behalf of the transferee).

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share that has not been fully paid up or is subject to a company lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;

the instrument of transfer is in respect of only one class of ordinary shares;

the instrument of transfer is properly stamped, if required;

the ordinary share transferred is fully paid and free of any lien in favor of us;

any fee related to the transfer has been paid to us; and

the transfer is not to more than four joint holders.

If our directors refuse to register a transfer, they are required, within three months after the date on which the instrument of transfer was lodged, to send to each of the transferor and the transferee notice of such refusal.

*Liquidation*

On a winding up of our company, if the assets available for distribution among the holders of our ordinary shares shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus will be distributed among the holders of our ordinary shares on a pro rata basis in proportion to the par value of the ordinary shares held by them. If our assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that the losses are borne by the holders of our ordinary shares in proportion to the par value of the ordinary shares held by them.

The liquidator may, with the sanction of a special resolution of our shareholders and any other sanction required by the Cayman Companies Law, divide amongst the shareholders in specie or in kind the whole or any part of the assets of our company, and may for that purpose value any assets and determine how the division shall be carried out as between our shareholders or different classes of shareholders.

Because we are a "limited liability" company registered under the Cayman Companies Law, the liability of our shareholders is limited to the amount, if any, unpaid on the shares respectively held by them. Our articles contain a declaration that the liability of our shareholders is so limited.

Table of Contents

***Calls on Ordinary Shares and Forfeiture of Ordinary Shares***

Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their ordinary shares. The ordinary shares that have been called upon and remain unpaid are subject to forfeiture by the company. In addition, the holders of partly paid ordinary shares will have no right pursuant to the Cayman Companies Law to dividends nor will they be able to redeem their shares.

***Redemption, Repurchase and Surrender of Ordinary Shares***

We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders thereof, on such terms and in such manner as may be determined by our board of directors. We may also repurchase any of our shares provided that the manner and terms of such purchase have been approved by our board of directors or by ordinary resolution of our shareholders (but no repurchase may be made contrary to the terms or manner recommended by our directors), or as otherwise authorized by our articles. Under the Cayman Companies Law, the redemption or repurchase of any share may be paid out of our company's profits or out of the proceeds of a new issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if our company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Cayman Companies Law no such share may be redeemed or repurchased (1) unless it is fully paid up, (2) if such redemption or repurchase would result in there being no shares outstanding or (3) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

***Variations of Rights of Shares***

If at any time our share capital is divided into different classes of shares, all or any of the rights attached to any class of shares may be varied with the consent in writing of the holders of two-thirds of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights will not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Notwithstanding the foregoing, our board of directors may issue preferred shares, without further action by the shareholders. See "Differences in Corporate Law Directors' Power to Issue Shares."

***General Meetings of***