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Registration Nos. 333-207459 and 333-209349

**PROSPECTUS**

6,600,000 American Depositary Shares  
Representing 85,800,000 Ordinary Shares



BeiGene

**BeiGene, Ltd.**

This is an initial public offering of the American Depositary Shares, or the ADSs. All of the ADSs are being sold by us. We are offering 6,600,000 ADSs to be sold in this offering. Each ADS represents 13 ordinary shares, par value \$0.0001 per share.

Prior to this offering, there has been no public market for the ADSs or our ordinary shares. The initial public offering price is \$24.00 per ADS. The ADSs are approved for listing on the NASDAQ under the symbol "BGNE."

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 14 to read about factors you should consider before buying the ADSs.**

**Neither the Securities and Exchange Commission nor any other regulatory body 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.**

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	<u>Per ADS</u>	<u>Total</u>
Initial public offering price	\$24.00	\$ 158,400,000
Underwriting discounts(1)	\$ 1.68	\$ 11,088,000
Proceeds, before expenses, to us	\$22.32	\$ 147,312,000

(1) We refer you to "Underwriting" beginning on page 269 for additional information regarding total underwriting compensation.

To the extent the underwriters sell more than 6,600,000 ADSs, the underwriters have the option to purchase up to an additional 990,000 ADSs from us at the initial public offering price less the underwriting discounts.

Two existing shareholders, Hillhouse BGN Holdings Limited or its affiliates and entities affiliated with Baker Bros. Advisors LP, have agreed to purchase an aggregate of approximately \$63 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 February 8, 2016.

**Goldman, Sachs & Co.**

**Morgan Stanley**

**Cowen and Company**

**Baird**

February 2, 2016

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**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: We have not, and the underwriters have not, 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 277 for definitions of scientific terms.

## 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 our financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus. 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, molecular targeted and immuno-oncology drugs for the treatment of cancer. We believe the next generation of cancer treatment will utilize therapeutics both as monotherapy 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 five 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, RAF dimer and PARP have demonstrated early activity and favorable safety profiles in the dose-escalation phases of clinical trials conducted in Australia and New Zealand, and our BTK and RAF dimer drug candidates are currently in the dose-expansion phases of their respective clinical trials. Our PD-1 drug candidate is currently in the dose-escalation phase of our clinical trial in Australia and New Zealand. As of January 15, 2016, our four clinical-stage drug candidates have been dosed in a total of 326 patients. We have Investigational New Drug Applications in effect for our BTK and PD-1 inhibitors with the U.S. Food and Drug Administration, or FDA, and have received approval of our Clinical Trial Application for our RAF dimer inhibitor from the China Food and Drug Administration, or CFDA. 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 monotherapy 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 more than 215 individuals in China, the United States, and Australia 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.

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 for 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 subgroups 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.

The following table summarizes our clinical pipeline:



**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 and higher

exposure than ibrutinib, the only BTK inhibitor currently approved by the FDA and the European Medicines Agency, or EMA.

We have completed the 25-patient dose-escalation phase of our clinical trial in Australia, 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 and Waldenström's Macroglobulinemia. We have dosed a total of 84 patients as of January 15, 2016. Available data from our completed dose-escalation trial indicate that BGB-3111 achieved up to approximately a 3.5- to 7-fold higher exposure level than the approved doses of ibrutinib. As of October 19, 2015, the cutoff date for the most recent data analysis, no protocol-defined dose-limiting toxicities, drug-related serious adverse events or treatment discontinuations due to drug-related adverse events have been observed. Subsequent to the last full data cutoff on October 19, 2015 for BGB-3111, a serious adverse event of grade 3 purpura (subcutaneous bleeding) was recently reported in one patient among a total of over 85 patients who had received BGB-3111 as of January 25, 2016, the date of the event. Subsequent to the event, the patient received a blood transfusion, and treatment with BGB-3111 has been temporarily suspended in this patient with treatment reinitiation planned after further recovery of the patient. This event was reported to be possibly drug-related and is still under evaluation. 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. In addition, sustained BTK occupancy was achieved in the lymph node for both 320 mg QD and 160 mg twice daily dosing regimens.

**BGB-283** is a small molecule RAF kinase inhibitor. We are currently developing BGB-283 as a monotherapy and in combination with other therapies 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 titled "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, vemurafenil 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 32-patient dose-escalation phase, and we are currently conducting 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 an abbreviated dose escalation in China. We have dosed a total of 129 patients in Australia, New Zealand, and China as of January 15, 2016. Initial analysis of data from the trials has shown BGB-283 to be well-tolerated with a favorable safety profile. We have achieved proof-of-concept in a range of cancers including those with KRAS and BRAF mutations. 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 titled "Business—Collaboration with Merck KGaA."

**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. On February 2, 2016, we initiated a trial with BGB-290 in combination with BGB-A317 for the treatment of cancers with mutations in the breast cancer susceptibility gene (BRCA) deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal, and pancreatic cancers, as well as platinum sensitive ovarian cancer. We plan to initiate combination trials with chemotherapies for the treatment of gastric cancer, small cell lung cancers, and glioblastoma. 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 are evaluating BGB-290 in the ongoing dose-escalation phase of our clinical trial in Australia. We have dosed a total of 40 patients as of January 15, 2016. Initial analysis of data from this trial has shown BGB-290 to be well-tolerated. Proof-of-concept has also been established, with anti-tumor activity seen starting at the lowest tested dose and data suggestive of a wide therapeutic window. We have a limited collaboration with Merck KGaA on BGB-290.

**BGB-A317** is a 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 are evaluating BGB-A317 in the ongoing dose-escalation phase of our clinical trial in relapsed or refractory solid tumor patients in Australia. We have dosed a total of 73 patients as of January 15, 2016.

**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 18 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 relationships 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. Currently, many global standard-of-care therapies are not approved or available in China, resulting in a significant need for innovative drug 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. 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.

We have a global team of more than 215 employees and consultants, including a global research and development team of 149 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 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.

Since our inception in 2010, we have raised \$170 million in equity financing from our dedicated group of investors, including leading healthcare-focused funds, major mutual funds, China-based funds and our founders.

### **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 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 18 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 believe that we are the only company today to wholly own both a clinical-stage BTK inhibitor 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 therapy.
- **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. 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.

- **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 of over 110 talented scientists. 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 PARP 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.

#### **Recent Developments**

We expect that as of December 31, 2015, our cash and cash equivalents and short-term investments were between \$100 million and \$103 million. Our independent registered public accountants have not audited, reviewed or performed any procedures with respect to this financial data and accordingly do not express an opinion or any other form of assurance with respect thereto. This result could change as a result of further review.

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. In addition, if this offering occurs on or prior to May 2, 2016, subject to certain limitations, the outstanding unpaid principal and interest of this note as of the effectiveness date of this registration statement, or the Exchanged Balance, will be automatically exchanged, effective immediately prior to the closing of this offering, into up to a number of our ordinary shares equal to the quotient of (1) the Exchanged Balance divided by (2) the per ordinary share public offering price in this offering.

#### **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.
- We depend substantially on the success of our drug candidates, particularly BGB-3111, BGB-283, BGB-290 and BGB-A317, 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.



- 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, 百济神州 and our corporate logo. All other trademarks, 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.

### **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 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 this 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.

## The Offering

ADSs offered by us	6,600,000 ADSs
Ordinary shares outstanding immediately after this offering	409,723,027 shares
ADSs outstanding immediately after this offering	6,600,000 ADSs
Underwriters' option to purchase additional ADSs	We have granted a 30-day option to the underwriters to purchase up to an aggregate of 990,000 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 depository 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, 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 \$144.86 million, or \$166.95 million, if the underwriters exercise their option to purchase additional ADSs in full at the initial public offering price of \$24.00 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. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read "Risk Factors" in this prospectus for a discussion of factors that you should consider before deciding to invest in the ADSs.
Directed share program	At our request, the underwriters have reserved up to 5% of the ADSs offered by this prospectus for sale, at the initial public offering price, through a directed share program to our directors, officers, employees and business associates. There can be no assurance that any of the reserved ADSs will be so purchased. If purchased by these persons, these shares will be subject to a 180-day lock-up restriction. The number of ADSs available for sale to the general public in this offering will be reduced to the extent that the reserved ADSs are purchased in the directed share program. Any reserved ADSs not purchased through the directed share program will be offered to the general public on the same basis as the other ADSs offered hereby.
NASDAQ trading symbol	"BGNE."

Indications of Interest

Two existing shareholders, Hillhouse BGN Holdings Limited or its affiliates and entities affiliated with Baker Bros. Advisors LP, have agreed to purchase an aggregate of approximately \$63 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.

The number of ordinary shares to be outstanding after this offering is based on 116,174,094 ordinary shares outstanding as of September 30, 2015 including 177,778 issued but unvested restricted shares, and excludes:

- 30,679,677 shares issuable upon the exercise of options outstanding as of September 30, 2015 pursuant to our 2011 Option Plan, as amended, or the 2011 Plan, at a weighted-average exercise price of \$0.28 per share;
- 66,773,251 shares reserved for future issuance under our 2016 Share Option and Incentive Plan, or the 2016 Plan (which includes 1,743,656 shares reserved for issuance under our 2011 Plan as of September 30, 2015 that will become available under our 2016 Plan);
- 15,200,667 shares issuable upon the exercise of options granted outside our 2011 Plan as of September 30, 2015, at an exercise price of \$0.50 per share;
- 668,127 shares issuable upon the exercise of warrants outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which warrants prior to the closing of this offering are exercisable to purchase our Series A preferred shares;
- 2,592,593 shares issuable upon the exercise of warrants outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which warrants prior to the closing of this offering are exercisable to purchase our ordinary shares; and
- 1,451,586 shares issuable upon the exercise of options outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which options prior to the closing of this offering are exercisable to purchase our ordinary shares.

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

- the effectiveness of our amended and restated memorandum and articles of association, which will occur immediately prior to the closing of this offering;
- the conversion of all of our outstanding 199,990,641 preferred shares into 199,990,641 ordinary shares upon the closing of this offering;
- the exchange of the outstanding balance of the senior promissory note as of September 30, 2015 into 7,758,292 ordinary shares upon the closing of this offering, computed at the initial public offering price of \$24.00 per ADS;
- no issuance or exercise of share options or warrants on or after September 30, 2015; and
- no exercise by the underwriters of their option to purchase up to an additional 825,000 ADSs in this offering.

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### **Summary Financial Data**

The following summary financial data for the years ended December 31, 2013 and 2014 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary financial data as of September 30, 2015 and for the nine months ended September 30, 2014 and 2015 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus. 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 Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and our operating results for the nine-month period ended September 30, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015 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.

	Years Ended December 31,		Nine Months Ended September 30,	
	2013	2014	2014	2015 (unaudited)
(in thousands, except share and per share data)				
<b>Statements of Operations Data:</b>				
Revenue	\$ 11,148	\$ 13,035	\$ 11,654	\$ 4,139
Operating expenses				
Research and development	(13,463)	(21,862)	(15,654)	(30,147)
General and administrative	(3,143)	(6,930)	(5,304)	(4,361)
Total operating expenses	(16,606)	(28,792)	(20,958)	(34,508)
Loss from operations	(5,458)	(15,757)	(9,304)	(30,369)
Interest income	2	40	4	1,286
Interest expense	(3,155)	(3,552)	(3,239)	(840)
Changes in fair value of financial instruments	133	(2,760)	(2,778)	(502)
Gain on debt extinguishment	—	2,883	—	—
Disposal loss on available-for-sale securities	—	—	—	(298)
Other income	694	806	616	996
Other expense	(110)	(206)	(107)	(125)
Net loss	(7,894)	(18,546)	(14,808)	(29,852)
Less: net loss attributable to non-controlling interests	(400)	(268)	(281)	—
Net loss attributable to ordinary shareholders	<u>\$ (7,494)</u>	<u>\$ (18,278)</u>	<u>\$ (14,527)</u>	<u>\$ (29,852)</u>
Loss per ordinary share attributable to ordinary shareholders, basic and diluted <sup>(1)</sup>	<u>\$ (0.08)</u>	<u>\$ (0.18)</u>	<u>\$ (0.15)</u>	<u>\$ (0.28)</u>
Weighted-average ordinary shares outstanding, basic and diluted	<u>91,484,521</u>	<u>99,857,623</u>	<u>96,939,630</u>	<u>107,015,707</u>
Pro forma net loss per ordinary share attributable to ordinary shareholders, basic and diluted <sup>(1)</sup>		<u>\$ (0.08)</u>		<u>\$ (0.10)</u>
Pro forma weighted-average ordinary shares outstanding, basic and diluted		<u>216,643,140</u>		<u>307,006,348</u>
Comprehensive loss	<u>\$ (7,718)</u>	<u>\$ (18,761)</u>	<u>\$ (14,873)</u>	<u>\$ (31,085)</u>

- (1) See Note 17 to our audited consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of ordinary shares and pro forma basic and diluted net loss per share of ordinary shares.

	<b>As of September 30, 2015</b>		
	<u>Actual</u>	<u>Pro Forma(1)</u> <u>(unaudited)</u> <u>(in thousands)</u>	<u>Pro Forma</u> <u>As</u> <u>Adjusted(2)</u>
<b>Balance sheet data:</b>			
Cash and cash equivalents	\$ 27,450	\$ 27,450	\$ 172,305
Short-term investments	93,894	93,894	93,894
Working capital	99,894	114,217	114,217
Total assets	135,608	135,608	280,463
Senior promissory note	14,323	—	—
Total liabilities	35,531	21,208	21,208
Preferred shares	176,084	—	—
Total shareholders' (deficit) equity	(76,007)	114,400	259,255

- (1) Pro forma balance sheet data give effect to (i) the conversion of all outstanding shares of our preferred shares into an aggregate of 199,990,641 ordinary shares upon the completion of this offering, and (ii) the exchange of the outstanding balance of the senior promissory note into 7,758,292 ordinary shares upon the completion of this offering, computed at the initial public offering price of \$24.00 per ADS.
- (2) Pro forma as adjusted basis gives effect to (i) the conversion of all of our preferred shares into 199,990,641 ordinary shares upon the completion of this offering, (ii) the exchange of the outstanding balance of the senior promissory note into 7,758,292 ordinary shares upon the completion of this offering, computed at the initial public offering price of \$24.00 per ADS, and (iii) the sale of 85,800,000 ordinary shares in the form of 6,600,000 ADSs by us in this offering at the initial public offering price of \$24.00 per ADS after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

## 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, including our consolidated financial statements and the related notes, 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.*

### **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-283, BGB-290 and BGB-A317. We have not yet demonstrated 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. For the years ended December 31, 2013 and December 31, 2014, we reported a net loss of \$7.9 million and \$18.5 million, respectively, and had a deficit accumulated of \$90.9 million as of September 30, 2015. Substantially all of our operating losses have resulted from costs 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-283, BGB-290 and BGB-A317. Furthermore, if we obtain regulatory approval for our drug candidates, we expect to incur increased sales and marketing expenses. In addition, once we are a public company, 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-283, BGB-290 and BGB-A317, 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 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;

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- 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;
- 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. A decline in the value of our company could also cause you to lose all or part of your investment.

***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, 2015, we have raised approximately \$170 million in equity financing and \$10 million in non-convertible debt financings. To date, we have received a total of \$33 million in upfront payments and milestone payments through our collaboration arrangements with Merck KGaA for BGB-283 and BGB-290. 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. The net cash used for our operating activities was \$8.7 million for the year ended December 31, 2014 and the net cash provided and used for our operating activities was \$1.9 million and \$23.1 million, respectively, for the nine months ended September 30, 2014 and 2015. 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-283, BGB-290 and BGB-A317. 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.

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 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 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 existing cash and cash equivalents, will not be sufficient to enable us to complete all necessary 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. dollars, in particular, the Renminbi 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 United States dollars. 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 Renminbi 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 Renminbi to the U.S. dollar. Following the removal of the U.S. dollar peg, the Renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted and the exchange rate between the Renminbi and the U.S. dollar remained within a narrow band. Since June 2010, the PRC government has allowed the Renminbi 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 Renminbi exchange rate fluctuation. On August 11, 2015, China's central bank executed a 2% devaluation in the Renminbi. 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, Renminbi, 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 Renminbi 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 Renminbi, 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 Renminbi 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 receive from this offering into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we would receive. Conversely, if we decide to convert our Renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amount we would receive.

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

We had cash and cash equivalents of \$3.9 million and \$13.9 million and short term investments of \$0 and \$30.5 million at December 31, 2013 and 2014, respectively, and \$27.5 million and \$93.9 million at September 30, 2015. At September 30, 2015, our short-term investments mainly consisted of high credit quality corporate fixed income bonds and U.S. Treasury securities. 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. 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-283, BGB-290 and BGB-A317, 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-283, BGB-290 and BGB-A317, which are still in development, and other drugs we may develop. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates. The success of our drug candidates, including BGB-3111, BGB-283, BGB-290 and BGB-A317, 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; and
- continued acceptable safety profile for our drug candidates following regulatory approval, if and when received.

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 product 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 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;

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- 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-283, BGB-290 and BGB-A317, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators 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 product 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. For example, as of January 2016 we voluntarily decided to temporarily suspend new patient accrual to our dose-escalation trial for BGB-283 in China to allow evaluation of pharmacokinetics, safety and efficacy after we found more frequent observation of thrombocytopenia in the China trial as compared to the Australia / New Zealand trial. 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-283, BGB-290 and BGB-A317, 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.

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;

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- 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.

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 safe, pure, and potent for its proposed indication;

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- 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 Risk Evaluation Mitigation Strategies, 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.

***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-283, BGB-290 and BGB-A317, 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;

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- 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 protocols;
- clinical sites and investigators deviating from 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 trial managers 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;
- 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 the company, 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 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-283 may include, but are not limited to, thrombocytopenia, fatigue, rash, hand-foot syndrome, hypertension, and anorexia. 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. 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 of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a REMS for the drug or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- 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 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 make 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.

***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.

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 different 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 Practices, 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 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 cGMPs and Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval.

The FDA may impose consent decrees or withdraw 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 the approved indications and 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 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-283, BGB-290 and BGB-A317 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 "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. 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.

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.

The CFDA is soliciting public opinions on detailed policies regarding such abovementioned fast track clinical trial approval and drug registration pathway, and 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 medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates, such as BGB-3111, BGB-283, BGB-290 and BGB-A317. 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.***

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.

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 "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.

***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-283 or BGB-290, 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, 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.

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 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 of 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 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;

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- 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.

***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 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 imposes 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 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 Health 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 Health 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.

***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.

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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;
- 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.

## 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 December 31, 2015, we own two issued U.S. patents and ten pending U.S. patent applications as well as corresponding patents and patent applications internationally. In addition, we own six 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 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 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.

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.



**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 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 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.

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 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.

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. 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, 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.



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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 do 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. 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 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 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.
- 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 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 titled "Business—Collaboration with Merck KGaA" in this prospectus. 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 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 Operation**

***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 and Chairman of our scientific advisory board; John V. Oyler, our Founder and Chief Executive Officer; 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, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided share option 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 December 31, 2015, we had over 215 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 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 proposed and 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.***

Upon completion of this offering, we will become subject to the periodic reporting requirements of the U.S. Securities Exchange Act of 1934, as amended, or 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 U.S. Securities and Exchange Commission, or 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 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 our common stock.***

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements as of and for the years ended December 31, 2014 and 2013, 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 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 will be 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 this 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.

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 our common stock 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 will need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We will 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.

***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.

***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.

***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 carry an aggregate maximum coverage amount of approximately \$82 million of clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

***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. It is unclear whether the European sovereign debt crisis will be contained and what effects it 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.

***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 a 9,000 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 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.

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.

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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;
- 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 72 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 "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 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 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.

***Any future requirement to obtain prior approval under the M&A Rules and/or any other regulations promulgated by relevant PRC regulatory agencies in the future could delay this offering and failure to obtain any such approvals, if required, could have a material adverse effect on our business, operating results and reputation as well as the trading price of the ADSs, and could also create uncertainties for this offering.***

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

While the application of the M&A Rules remains unclear, we believe, based on the advice of our PRC counsel, Fangda Partners, that the CSRC approval is not required in the context of this offering because we are not a special purpose vehicle defined under the M&A Rules and have set up our PRC subsidiaries through foreign direct investment. However, we cannot assure you that the relevant PRC government agencies, including the CSRC, would reach the same conclusion as our PRC counsel. If the CSRC or other PRC regulatory body subsequently determines that we need to obtain the CSRC's approval for this offering or if the CSRC or any other PRC government authorities promulgates any interpretation or implements rules before our listing that would require us to obtain CSRC or other governmental approvals for this offering, we may face adverse actions or sanctions by the CSRC or other PRC regulatory agencies. In any such event, these regulatory agencies may impose fines and penalties on our operations in China, limit our operating privileges in China, delay or restrict the repatriation of the proceeds from this offering into the PRC or take other actions that could have a material adverse effect on our business, financial condition, results of operations, reputation and prospects, as well as our ability to complete this offering. The CSRC or other PRC regulatory agencies may also take actions requiring us, or making it advisable for us, to halt this offering before settlement and delivery of the ADSs offered by this prospectus. Consequently, if you engage in market trading or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that such settlement and delivery may not occur.

***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, 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 plan. Upon completion of our initial public offering, we will become 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 becomes 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 since SAFE Circular No. 37 was issued 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 applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected. After our company becomes an overseas listed company upon completion of our initial public offering, 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 will be 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, 2015, these restricted assets totaled RMB 24.6 million (\$3.9 million).

The PRC Enterprise Income Tax Law, or 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 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 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: senior management personnel and departments that are responsible for daily production, operation and management; financial and personnel decision-making bodies; key properties, accounting books, company seal, and minutes of board meetings and shareholders' meetings; and 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, 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.

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 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 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 Renminbi 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 Renminbi. 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 Renminbi 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 Renminbi, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in Renminbi 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.



***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 this prospectus 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 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 the delay or abandonment of this offering, or deregistration from the SEC, or both, 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**

##### ***An active public trading market for the ADSs may not develop and the ADSs may trade below the public offering price.***

Prior to this offering, there has been no public market for the ADSs or our ordinary shares underlying the ADSs. The ADSs are approved for listing on the NASDAQ. However, a liquid public market for the ADSs may not develop. If an active trading market for the ADSs does not develop after this offering, the market price and liquidity of the ADSs may be materially and adversely affected. The public offering price for the ADSs has been determined by negotiation among us and the underwriters based upon several factors, and the price at which the ADSs trade after this offering may decline below the public offering price. Investors in the ADSs may experience a significant decrease in the value of their ADSs regardless of our operating performance or prospects. Further, certain of our existing shareholders have agreed to purchase an aggregate of approximately \$63 million of our ADSs offered in this offering, and fewer ADSs may be actively traded in the public market because these shareholders may be restricted from selling the ADSs under applicable securities laws, which would reduce the liquidity of the market for the ADSs.

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

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;
- 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 Renminbi 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.

***Substantial future sales or perceived potential sales of the ADSs, ordinary shares or other equity securities in the public market could cause the price of the ADSs to decline significantly.***

Sales of the ADSs, ordinary shares or other equity securities in the public market after this offering, or the perception that these sales could occur, could cause the market price of the ADSs to decline significantly. Upon completion of this offering, we will have 409,723,027 ordinary shares outstanding, including 85,800,000 ordinary shares represented by 6,600,000 ADSs, assuming the underwriters do not exercise their option to purchase additional shares, of which 10,640,734 of our ordinary shares, representing 2.6% 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. 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 lock-up periods described elsewhere in this prospectus beginning from the date of this prospectus (if applicable to such holder), subject to volume and other restrictions as applicable under Rules 144 and 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.

Certain major holders of our ordinary shares will have the right to cause us to register under the Securities Act the sale of their shares, subject to the applicable lock-up periods in connection with this offering. Registration of these shares under the Securities Act would result in ADSs representing these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. Sales of these registered shares in the form of ADSs in the public market could cause the price of the ADSs to decline significantly.

***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 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. 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 \$15.81 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, 2015, after giving effect to this offering and the initial public offering price of \$24.00 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 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 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.***

You may exercise your voting rights with respect to the ordinary shares underlying your ADSs only in accordance with the provisions of the deposit agreement. Upon receipt of voting instructions from you in the manner set forth in the deposit agreement, the 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 preference 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. Preference 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 preference 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.

***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, which will become effective immediately prior to the closing of this offering, 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 this offering, would be pre-empted 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 this offering. 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 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;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting;
- a matter to be voted on at the meeting would have a material adverse impact on shareholders; or
- voting at the meeting is made on a show of hands.

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

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

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

The depositary for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs and annual service fees. In the case of ADSs issued by the depositary into The Depository Trust company, 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. For further information, see "Description of American Depositary Shares—Fees and Charges."

***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 depositary of the ADSs has agreed to pay you the cash dividends or other distributions it or the custodian for the ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares that your ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act but that are not



properly registered or distributed pursuant to an applicable exemption from registration. The 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 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 depository 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 depository 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 81.1% of our outstanding ordinary shares as of December 31, 2015. 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 will incur 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 are evaluating 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 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 this offering will result in a substantial percentage of our assets being 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 our 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. This paragraph is qualified in its entirety by the discussion in the section titled "Taxation—Material United States Federal Income Tax Considerations." 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.

***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 be a CFC after the completion of the offering. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This prospectus, including the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains 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 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;
- our ability for 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-283 and BGB-290 and certain other drug candidates;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our drug candidates, if approved;
- our ability to develop sales and marketing capabilities;
- the pricing and reimbursement of our drug candidates, if approved;
- 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 intellectual property infringement, product liability and other claims;
- regulatory development in the United States, China and other jurisdictions;
- estimates of our expenses, future revenues, capital requirements and our needs 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;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;

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- 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."

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "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. 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 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 represent our views as of the date of this prospectus. 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 of this prospectus.

This prospectus contains 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.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of 6,600,000 ADSs in this offering will be approximately \$144.86 million based upon the initial public offering price of \$24.00 per ADS and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional ADSs in full, we estimate that our net proceeds will be approximately \$166.95 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, create a public market for the ADSs, and to facilitate our access to the public equity markets. We currently expect to use the net proceeds from this offering as follows:

- approximately \$35 million for the ongoing dose-expansion phase of our clinical trial, other planned signal-seeking monotherapy and combination trials, as well as potentially initiating a registrational trial for BGB-3111;
- approximately \$12 million for the ongoing dose-expansion phase of our clinical trial, and other planned monotherapy and combination trials for BGB-283;
- approximately \$9 million for the ongoing dose-escalation phase of our clinical trial, the planned expansion phase of our clinical trial, and other planned monotherapy and combination studies for BGB-290;
- approximately \$23 million for the ongoing dose-escalation phase of our clinical trial, the planned expansion phase of our clinical trial, and other planned monotherapy and combination studies for BGB-A317;
- approximately \$22 million for supporting our research and development infrastructure and the early development of our 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

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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 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.

## DIVIDEND POLICY

We have never declared or paid any dividends on our ordinary shares or preferred shares. 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, 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."



**CAPITALIZATION**

The following table sets forth our cash and cash equivalents, short term investments, senior promissory note and capitalization as of September 30, 2015:

- on an actual basis;
- on a pro forma basis to give effect to (1) the conversion of all of our outstanding preferred shares into an aggregate of 199,990,641 ordinary shares upon the closing of this offering, (2) the exchange of the outstanding balance of the senior promissory note into 7,758,292 ordinary shares upon the closing of this offering, computed at the initial public offering price of \$24.00 per ADS, and (3) the effectiveness of our amended and restated memorandum and articles of association, which will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our sale in this offering of 6,600,000 ADSs at the initial public offering price of \$24.00 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Description of American Depositary Shares," and the financial statements and related notes appearing elsewhere in this prospectus.

	<b>As of September 30, 2015</b>		
	<b>Actual</b>	<b>Pro Forma (unaudited)</b>	<b>Pro Forma As Adjusted</b>
	<b>(in thousands, except share and per share amounts)</b>		
Cash and cash equivalents	\$ 27,450	\$ 27,450	\$ 172,305
Short-term investments	\$ 93,894	\$ 93,894	\$ 93,894
Senior promissory note	\$ 14,323	\$ —	\$ —
Series A preferred shares, \$0.0001 par value; 120,000,000 shares authorized, 116,785,517 issued and outstanding (actual); no shares authorized, issued or outstanding (pro forma and pro forma as adjusted)	\$ 78,809	—	—
Series A-2 preferred shares, \$0.0001 par value; 100,000,000 shares authorized, 83,205,124 issued and outstanding (actual); no shares authorized, issued or outstanding (pro forma and pro forma as adjusted)	97,275	—	—
Shareholders' (deficit) equity:			
Ordinary shares, \$0.0001 par value; 500,000,000 shares authorized, 116,174,094(1) shares issued and outstanding (actual), 9,500,000,000 shares authorized, 323,923,027 shares issued and outstanding (pro forma); 9,500,000,000 shares authorized, 409,723,027 shares issued and outstanding (pro forma as adjusted)	12	32	41
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	16,059	206,446	351,292
Accumulated other comprehensive income	(1,133)	(1,133)	(1,133)
Accumulated deficit	(90,945)	(90,945)	(90,945)
Total shareholders' (deficit) equity	(76,007)	114,400	259,255
<b>Total capitalization</b>	<b>\$ 100,077</b>	<b>\$ 114,400</b>	<b>\$ 259,255</b>

(1) Shares issued and outstanding include 177,778 issued but unvested restricted shares as of September 30, 2015.

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

- 30,679,677 shares issuable upon the exercise of options outstanding as of September 30, 2015 pursuant to our 2011 Plan at a weighted-average exercise price of \$0.28 per share;
- 15,200,667 shares issuable upon the exercise of options granted outside our 2011 Plan as of September 30, 2015, at an exercise price of \$0.50 per share;
- 66,773,251 shares reserved for future issuance under our 2016 Plan (which includes 1,743,656 shares reserved for issuance under our 2011 Plan as of September 30, 2015 that will become available under our 2016 Plan);
- 668,127 shares issuable upon the exercise of warrants outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which warrants prior to the closing of this offering are exercisable to purchase our Series A preferred shares;
- 2,592,593 shares issuable upon the exercise of warrants outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which warrants prior to the closing of this offering are exercisable to purchase our ordinary shares; and
- 1,451,586 shares issuable upon the exercise of options outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which options prior to the closing of this offering are exercisable to purchase our ordinary shares.

## DILUTION

If you invest in the ADSs in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per ADS and the pro forma as adjusted net tangible book value per ADS immediately after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the book value per ordinary share attributable to the existing shareholders for our presently outstanding ordinary shares and holders of our preferred shares which will convert into our ordinary shares concurrently with the closing of this offering.

Our net tangible book value as of September 30, 2015 was \$100.1 million, or \$0.86 per outstanding ordinary share as of that date, and \$11.18 per ADS. Net tangible book value represents our total tangible assets less our total tangible liabilities. Pro forma net tangible book value per ordinary share is calculated after giving effect to the conversion of all of our issued and outstanding preferred shares and the exchange of the outstanding balance of the senior promissory note into ordinary shares. Pro forma as adjusted net tangible book value per ordinary share is calculated after giving effect to the conversion of all our issued and outstanding preferred shares, the exchange of the outstanding balance of the senior promissory note into ordinary shares and the issuance of ordinary shares in the form of ADSs by us in this offering. Dilution is determined by subtracting pro forma as adjusted net tangible book value per ordinary share from the public offering price per ordinary share.

Without taking into account any other changes in net tangible book value after September 30, 2015, other than to give effect to (1) the conversion of all of our issued and outstanding preferred shares into 199,990,641 of our ordinary shares concurrently with the closing of this offering, (2) the exchange of the outstanding balance of the senior promissory note as of September 30, 2015 into 7,758,292 ordinary shares upon the closing of this offering, computed at the initial public offering price of \$24.00 per ADS, and (3) the issuance and sale by us of 85,800,000 ordinary shares in the form of 6,600,000 ADSs in this offering at the initial public offering price of \$24.00 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, 2015 would have been \$259.26 million, or \$0.63 per outstanding ordinary share and \$8.19 per ADS. This represents an immediate increase in pro forma net tangible book value of \$0.28 per ordinary share and \$3.64 per ADS to the existing shareholders and an immediate dilution in net tangible book value of \$1.22 per ordinary share and \$15.81 per ADS to investors purchasing ADSs in this offering. The following table illustrates such dilution:

	<u>Per Share</u>	<u>Per ADS</u>
Initial public offering price per share	\$ 1.85	\$ 24.00
Historical net tangible book value per share as of September 30, 2015	\$ 0.86	\$ 11.18
Pro forma decrease in net tangible book value per share as of September 30, 2015	<u>(0.51)</u>	<u>(6.63)</u>
Pro forma net tangible book value per share as of September 30, 2015	0.35	4.55
Increase in pro forma net tangible book value per share attributable to new investors	<u>0.28</u>	<u>3.64</u>
Pro forma as adjusted net tangible book value per share after this offering	<u>0.63</u>	<u>8.19</u>
Dilution per share to investors participating in this offering	<u>\$ 1.22</u>	<u>\$ 15.81</u>

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If the underwriters exercise their option to purchase additional ADSs in full, the pro forma as adjusted net tangible book value would be \$0.67 per ordinary shares and \$8.71 per ADS, and the dilution in pro forma as adjusted net tangible book value to investors in this offering would be \$1.18 per ordinary shares and \$15.29 per ADS.

The following table summarizes, on a pro forma as adjusted basis as of September 30, 2015, the differences between existing shareholders, including holders of our preferred shares and senior promissory note exchangeable into ordinary shares, and new investors with respect to the number of ordinary shares (in the form of ADSs or shares) purchased from us, the total consideration paid, and the average price per ordinary share/ADS paid before deducting underwriting discounts and commissions and estimated offering expenses payable by us at the initial public offering price of \$24.00 per ADS. The total number of ordinary shares does not include ordinary shares underlying the ADSs issuable upon the exercise of the option to purchase additional ADSs granted to the underwriters.

	Ordinary Shares Purchased		Total Consideration		Average Price per Ordinary Share	Average Price per ADS
	Number	Percent	Amount	Percent		
Existing shareholders(1)	323,923,027	79%	\$ 206,478,000	57%	\$ 0.64	\$ 8.32
New investors(1)	85,800,000	21%	\$ 158,400,000	43%	\$ 1.85	\$ 24.00
Total	409,723,027	100%	\$ 364,878,000	100%		

- (1) Certain of our existing shareholders have agreed to purchase an aggregate of approximately \$63 million of our ADSs in this offering at the initial public offering price. The presentation in this table regarding ownership by existing shareholders does not give effect to any purchases in this offering by such shareholders.

The above discussion and tables are based on 116,174,094 ordinary shares issued and outstanding as of September 30, 2015, including 177,778 issued but unvested restricted shares, and also reflects (1) the conversion of all outstanding preferred shares into an aggregate of 199,990,641 ordinary shares immediately prior to the closing of this offering and (2) the exchange of the outstanding balance of the senior promissory note as of September 30, 2015 into 7,758,292 ordinary shares upon the closing of this offering, computed at the initial public offering price of \$24.00 per ADS and excludes:

- 30,679,677 shares issuable upon the exercise of options outstanding as of September 30, 2015 pursuant to our 2011 Plan at a weighted-average exercise price of \$0.28 per share;
- 66,773,251 shares reserved for future issuance under our 2016 Plan (which includes 1,743,656 shares reserved for issuance under our 2011 Plan as of September 30, 2015 that will become available under our 2016 Plan);
- 15,200,667 shares issuable upon the exercise of options granted outside our 2011 Plan as of September 30, 2015, at an exercise price of \$0.50 per share;
- 668,127 shares issuable upon the exercise of warrants outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which warrants prior to the closing of this offering are exercisable to purchase our Series A preferred shares;
- 2,592,593 shares issuable upon the exercise of warrants outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which warrants prior to the closing of this offering are exercisable to purchase our ordinary shares; and

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- 1,451,586 shares issuable upon the exercise of options outstanding as of September 30, 2015 at an exercise price of \$0.675 per share, which options prior to the closing of this offering are exercisable to purchase our ordinary shares.

If the underwriters exercise their option to purchase additional ADSs in full, the number of ordinary shares held by existing shareholders will be reduced to 77% of the total number of ordinary shares to be outstanding after this offering, and the number of ordinary shares held by investors participating in this offering will be further increased to 98,670,000, or 23% of the total number of ordinary shares to be outstanding after this offering.

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.

## 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 CT 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 United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States, or (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 re-examination of the merits of the underlying dispute, by an action commenced on the foreign judgment debt in the Grand Court of the Cayman Islands, provided such judgment (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 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.

## SELECTED FINANCIAL DATA

The following selected statements of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2013 and 2014 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The selected statements of operations data for the nine months ended September 30, 2014 and 2015 and the balance sheet data as of September 30, 2015 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus. In our opinion, these unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and 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 appearing elsewhere in this prospectus and the information under the captions "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and our operating results for the nine-month period ended September 30, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015 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.



	Years Ended December 31,		Nine Months Ended September 30,	
	<u>2013</u>	<u>2014</u>	<u>2014</u>	<u>2015</u>
	(unaudited)			
	(in thousands, except share and per share data)			
<b>Statements of Operations Data:</b>				
Revenue	\$ 11,148	\$ 13,035	\$ 11,654	\$ 4,139
Operating expenses				
Research and development	(13,463)	(21,862)	(15,654)	(30,147)
General and administrative	(3,143)	(6,930)	(5,304)	(4,361)
Total operating expenses	(16,606)	(28,792)	(20,958)	(34,508)
Loss from operations	(5,458)	(15,757)	(9,304)	(30,369)
Interest income	2	40	4	1,286
Interest expense	(3,155)	(3,552)	(3,239)	(840)
Changes in fair value of financial instruments	133	(2,760)	(2,778)	(502)
Gain on debt extinguishment	—	2,883	—	—
Disposal loss on available-for-sale securities	—	—	—	(298)
Other income	694	806	616	996
Other expense	(110)	(206)	(107)	(125)
Net loss	(7,894)	(18,546)	(14,808)	(29,852)
Less: net loss attributable to non-controlling interests	(400)	(268)	(281)	—
Net loss attributable to ordinary shareholders	<u>\$ (7,494)</u>	<u>\$ (18,278)</u>	<u>\$ (14,527)</u>	<u>\$ (29,852)</u>
Loss per ordinary share attributable to ordinary shareholders, basic and diluted(1)	<u>\$ (0.08)</u>	<u>\$ (0.18)</u>	<u>\$ (0.15)</u>	<u>\$ (0.28)</u>
Weighted-average ordinary shares outstanding, basic and diluted	<u>91,484,521</u>	<u>99,857,623</u>	<u>96,939,630</u>	<u>107,015,707</u>
Pro forma net loss per ordinary share attributable to ordinary shareholders, basic and diluted(1)	—	<u>\$ (0.08)</u>	—	<u>\$ (0.10)</u>
Pro forma weighted-average ordinary shares outstanding, basic and diluted	—	<u>216,643,140</u>	—	<u>307,006,348</u>
Comprehensive loss	<u>\$ (7,718)</u>	<u>\$ (18,761)</u>	<u>\$ (14,873)</u>	<u>\$ (31,085)</u>

- (1) See Note 17 to our audited consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of ordinary shares and pro forma basic and diluted net loss per share of ordinary shares.

	<u>As of December 31,</u>		<u>As of</u>
	<u>2013</u>	<u>2014</u>	<u>September 30,</u>
			<u>2015</u>
			(unaudited)
	(in thousands)		
<b>Balance sheet data:</b>			
Cash and cash equivalents	\$ 3,926	\$ 13,898	\$ 27,450
Short-term investments	—	30,497	93,894
Working capital	(27,300)	33,817	99,894
Total assets	11,798	53,621	135,608
Total liabilities	48,757	27,853	35,531
Preferred shares	—	78,809	176,084
Non-controlling interests	1,767	—	—
Total shareholders' deficit	(38,726)	(53,041)	(76,007)

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

*You should read the following discussion and analysis of our financial condition and results of operations together with the section titled "Selected Financial Data" and the consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in the section titled "Risk Factors" and in other parts of this prospectus. Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. Our functional currency is U.S. dollar.*

### 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 monotherapy 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 develop a pipeline of drug candidates with the potential to be best-in-class monotherapies and also important components of multiple-agent combination regimens.

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. Our clinical-stage drug candidates include three molecularly targeted agents, BGB-3111, BGB-283 and BGB-290 and one immuno-oncology agent, BGB-A317. BGB-3111 is a potent and selective small molecule inhibitor of BTK. BGB-283 is a small molecule inhibitor of both the monomer and dimer forms of RAF. BGB-290 is a highly selective small molecule inhibitor of PARP1 and PARP2. For each of our molecularly targeted drug candidates, we have achieved proof-of-concept by demonstrating objective responses in the defined patient populations. Our clinical-stage immuno-oncology agent, BGB-A317, is a humanized monoclonal antibody against the immune checkpoint receptor, PD-1. In addition to our clinical-stage drug candidates, we have a robust pipeline of preclinical programs and are planning to advance one or more of these programs into the clinic in the next 18 months. We have licensed the ex-China rights of BGB-283 to Merck KGaA. We retain full global rights for all of our other clinical and preclinical drug candidates and programs.

Since our inception on October 28, 2010, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any drug candidates approved for sale and have not generated any revenue from product sales. We have financed operations through a combination of debt and equity financings and private and public grants and contracts, including the net proceeds from the issuance of a senior and convertible promissory note to Merck Sharp & Dohme Research GmbH, or MSD, an affiliate of Merck Sharp & Dohme Corp., the private placements of our Series A preferred shares and Series A-2 preferred shares, and our collaboration with Merck KGaA, or Merck KGaA Collaboration. From January 1, 2014 to September 30, 2015, we raised an aggregate of \$150.3 million of gross proceeds from sales of our preferred shares, and additionally received \$33.0 million from the Merck KGaA Collaboration to fund

our operations. At September 30, 2015, we had cash, cash equivalents and short-term investments of \$121.3 million. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, and assuming successful completion of this offering, we believe we have sufficient cash to meet our projected operating requirements for at least the next 12 months. See "—Liquidity and Capital Resources."

Since inception we have incurred significant operating losses. Our net losses were \$18.5 million and \$7.9 million for the years ended December 31, 2014 and 2013, respectively, and \$29.9 million for the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of \$90.9 million. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue investment in our cancer biology platform;
- continue preclinical and clinical development of our programs;
- continue investment in our manufacturing facilities;
- hire additional research, development and business personnel;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional costs associated with operating as a public company upon the completion of this offering.

## **Financial Operations Overview**

### **Revenue**

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future.

We have licensed BGB-283 to Merck KGaA for markets outside China, but we still own the worldwide rights to our other drug candidates and retain exclusive rights to BGB-283 in China. We also have a limited collaboration with Merck KGaA on BGB-290.

On May 24, 2013, we entered into license agreements with Merck KGaA, which we amended and restated on December 10, 2013, and further amended on October 1, 2015 and December 3, 2015, pursuant to which (1) we granted to Merck KGaA an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA exercises its continuation option, to commercialize and manufacture our compound BGB-283, and any other compound covered by the same existing patent rights with primary activity to inhibit wildtype or certain mutant BRAF, in all countries of the world excluding The People's Republic of China, which we refer to as the Ex-PRC Territory, and (2) Merck KGaA granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the RAF dimer inhibitor in The People's Republic of China, which we refer to as the PRC Territory, subject to certain non-compete restrictions. Under these agreements, we received \$13 million in non-refundable payments in 2013 following their execution and \$5 million in milestone payment in 2014. We are eligible to receive up to \$32 million, \$33 million and \$145 million in payments upon the successful achievement of pre-specified clinical, regulatory and commercial milestones in the Ex-PRC Territory, and another \$18 million in payments upon the successful achievement of pre-specified clinical milestones in the PRC Territory. Merck KGaA also is required to pay us tiered royalties ranging from the mid single-digit to the low-teens, on a country-by-country and licensed

product-by-licensed product basis, on aggregate net sales of licensed products in the Ex-PRC Territory. In consideration for the licenses Merck KGaA grants to us, we are required to pay Merck KGaA a high single-digit royalty on aggregate net sales of Licensed BRAF inhibitors in the PRC Territory.

On October 28, 2013, we entered into license agreements with Merck KGaA, pursuant to which (1) we granted to Merck KGaA an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA exercises a certain continuation option, to commercialize and manufacture our compound BGB-290 and any other compound covered by the same existing patent rights with primary activity to inhibit PARP 1, 2 or 3 enzymes in the Ex-PRC Territory; and (2) Merck KGaA granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the licensed PARP inhibitors in the PRC Territory. On October 1, 2015, pursuant to a purchase of rights agreement, we repurchased all of Merck KGaA's worldwide rights under the ex-PRC license agreement, in consideration for, among other things, a one-time payment of \$10 million and reduction of future milestone payments we are eligible to receive under the PRC license agreement. In connection with such repurchase, the ex-PRC license agreement terminated except for certain provisions therein. Under these license agreements, we received \$6 million in non-refundable payments in November 2013 following their execution and \$9 million in milestone payments in 2014. We are eligible to receive up to \$7 million and \$2.5 million, respectively, in payments upon the successful achievement of pre-specified clinical and regulatory milestones in the PRC Territory. In addition, if Merck KGaA exercises its PRC commercialization option, as further described in the section titled "Business—Collaboration with Merck KGaA," Merck KGaA is required to pay us a \$50 million non-refundable payment upon such exercise, and we are eligible for a \$12.5 million milestone payment upon the successful achievement of a certain additional regulatory event in the PRC Territory. In consideration for the licenses granted to us, we are required to pay Merck KGaA a high single-digit royalty on aggregate net sales of licensed products in the PRC Territory.

For more information on our collaborations with Merck KGaA, see "Business—Collaboration with Merck KGaA."

We recognized \$13.0 million and \$11.1 million of collaboration revenue from the Merck KGaA Collaboration for the years ended December 31, 2014 and 2013, respectively, and \$4.1 million and \$11.7 million for the nine months ended September 30, 2015 and 2014, respectively. The following table summarizes the revenue recognition schedule of an aggregate of \$33.0 million upfront non-refundable license fee and Phase 1 research and development fees received from Merck KGaA, comprised of an aggregate of \$18.0 million related to BGB-283 and \$15.0 million related to BGB-290. In accordance with our revenue recognition policy, we recognize these amounts as shown in the table below:

	<u>BGB-283</u>	<u>BGB-290</u>	<u>Total</u>
		(in thousands)	
2013	\$ 8,317	\$ 2,823	\$ 11,140
2014	5,906	7,048	12,954
2015	2,707	5,129	7,836
2016	1,070	—	1,070
<b>Total</b>	<b>\$ 18,000</b>	<b>\$ 15,000</b>	<b>\$ 33,000</b>

For the foreseeable future, we expect substantially all of our revenue will be generated from the Merck KGaA Collaboration, and any other strategic relationships we may enter into. If our development efforts are successful, we may also generate revenue from product sales.

## **Expenses**

### *Research and Development Expenses*

Research and development expenses consist of the costs associated with our research and development activities, conducting preclinical studies and clinical trials and activities related to regulatory filings. Our research and development expenses consist of:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, and consultants that conduct and support clinical trials and preclinical studies;
- costs associated with preclinical activities and development activities;
- costs associated with regulatory operations; and
- other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in research and development activities.

Our current research and development activities mainly relate to the clinical development of the following programs:

- BGB-3111, a potent and selective small molecule inhibitor of BTK;
- BGB-283, a small molecule inhibitor of both the monomer and dimer forms of BRAF;
- BGB-290, a highly selective small molecule inhibitor of PARP1 and PARP2; and
- BGB-A317, a humanized monoclonal antibody against PD-1.

We expense research and development costs when we incur them. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us. We do not allocate employee related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified as unallocated research and development expenses.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our drug candidates. This is due to the numerous risks and uncertainties associated with developing such drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the drug candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;

- continued acceptable safety profiles of the products following approval; and
- retention of key research and development personnel.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs, timing and viability associated with the development of that drug candidate.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, including as we continue to support the clinical trials of BGB-3111, BGB-283, BGB-290 and BGB-A317 as a treatment for various cancers and move such drug candidate into additional clinical trials. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related benefit costs, including share-based compensation for administrative personnel. Other general and administrative expenses include professional fees for legal, patents, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in general and administrative activities. We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities, including the continuation of the clinical trials of BGB-3111, BGB-283, BGB-290 and BGB-A317 as a treatment for various cancers and the initiation of our clinical trials for our other drug candidates. These increases will likely include increased headcount, increased share compensation charges, expanded infrastructure and increased costs for insurance. We also anticipate increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

#### *Interest Expense, Net*

Interest expense consists primarily of interest on our \$10 million 8% senior promissory note maturing in May 2016 and \$10 million 8% subordinated convertible promissory note, compounded annually, both issued to MSD in 2011. We also issued an aggregate principal amount of \$3.1 million convertible promissory notes to several other investors in 2012 and 2014, all bearing interest of 8% per annum for the first three years and 15% per annum for the remaining term. In October 2014, we completed a Series A preferred share financing, as a result of which, the \$10 million MSD subordinated convertible promissory note was automatically converted into 18,518,519 Series A preferred shares, and the other \$3.1 million principal amount of convertible promissory notes, along with accrued interest was automatically converted into 5,470,705 Series A preferred shares. We recognized a gain on debt extinguishment of \$2.9 million due to the forfeiture of interest upon the conversion, as only the principal amount of the Merck subordinated convertible promissory note was eligible for conversion.

Interest income is currently not considered significant to our financial statements but we expect interest income to increase following this offering as we invest the net proceeds from this offering pending their use in operations.

*Changes in Fair Value of Financial Instruments*

Changes in fair value of financial instruments consists primarily of the non-cash expense related to changes in the fair value of our warrant and option liabilities arising from the share purchase warrants and options and also the changes in fair value of the redemption feature bifurcated from the MSD subordinated convertible promissory note.

*Gain on Debt Extinguishment*

Gain on debt extinguishment consists of forfeited interest of the MSD subordinated convertible promissory note as only the principal amount was eligible for conversion into Series A preferred shares in our October 2014 Series A preferred share financing.

*Other Income (Expense), Net*

Other income consists primarily of government grants received that involve no conditions or continuing performance obligations by us. Other expense consists primarily of loss from property and equipment disposals and donations made to sponsor certain events.

**Results of Operations****Comparison of Nine Months Ended September 30, 2015 and 2014**

The following table summarizes the results of our operations for the nine months ended September 30, 2015 and 2014, respectively, together with the changes in those items in dollars:

	<b>Nine Months Ended September 30,</b>		<b>Change</b>
	<b>2015</b>	<b>2014 (unaudited) (in thousands)</b>	
Collaboration revenue	\$ 4,139	\$ 11,654	\$ (7,515)
Operating expenses:			
Research and development	(30,147)	(15,654)	(14,493)
General and administrative	(4,361)	(5,304)	943
<b>Loss from operations</b>	<b>(30,369)</b>	<b>(9,304)</b>	<b>(21,065)</b>
Net interest income (expense)	446	(3,235)	3,681
Changes in fair value of financial instruments	(502)	(2,778)	2,276
Disposal loss on available-for-sale securities	(298)	—	(298)
Net other income	871	509	362
<b>Net loss</b>	<b>\$ (29,852)</b>	<b>\$ (14,808)</b>	<b>\$ (15,044)</b>

*Revenue*

Revenue from the Merck KGaA Collaboration decreased by \$7.5 million to \$4.1 million for the nine months ended September 30, 2015 from \$11.7 million for the nine months ended September 30, 2014. The decrease was mainly due to a \$5.0 million 5th patient dosing payment for BGB-283 and a \$9.0 million 5th patient dosing payment for BGB-290 received during the nine months ended September 30, 2014, which was not received during the nine months ended September 30, 2015.



*Research and Development Expense*

Research and development expense increased by \$14.5 million to \$30.1 million for the nine months ended September 30, 2015 from \$15.7 million for the nine months ended September 30, 2014. The following table summarizes our research and development expense by program for the nine months ended September 30, 2015 and September 30, 2014, respectively:

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(unaudited) (in thousands)</b>	
Clinical programs	\$ 10,025	\$ 6,789
Preclinical programs	4,131	171
Unallocated research and development expenses	15,991	8,694
<b>Total research and development expenses</b>	<b>\$ 30,147</b>	<b>\$ 15,654</b>

The increase in research and development expense was primarily attributable to the advancement of our clinical and preclinical pipeline, and included the following:

- \$5.3 million for increased compensation expenses, which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the nine months ended September 30, 2015 and the grants of new share options to certain employees; and
- \$7.8 million related to increased external research and development services mainly attributable to the expansion of clinical trials for BGB-3111 and BGB-283, preparation for clinical trials of BGB-A317, and preclinical studies for our additional RAF dimer inhibitor.

During the nine months ended September 30, 2015, 42% and 58% of our total research and development expenses were attributable to external research and development expenses and internal research and development expenses, respectively. During this period, approximately 66% of our external research and development expenses were attributable to external contract clinical, preclinical and manufacturing costs for our BGB-A317, BGB-3111, BGB-290, and BGB-283 programs, in descending order. The external research and development expenses of our largest program by spending during this period, the BGB-A317 program, represented approximately 10% of our total research and development expenses in this period. Though we maintain our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.

In comparison, during the nine months ended September 30, 2014, 31% and 69% of our total research and development expenses were attributable to external research and development expenses and internal research and development expenses, respectively. During this period, approximately 96% of our external research and development expenses were attributable to external contract clinical, preclinical and manufacturing costs for our BGB-A317, BGB-290, BGB-3111, and BGB-283 programs, in descending order. The external research and development expenses of our single largest program by spending during this period, the BGB-290 program, represented approximately 10% of our total research and development expenses in this period.

*General and Administrative Expense*

General and administrative expense decreased by \$0.94 million to \$4.4 million for the nine months ended September 30, 2015 from \$5.3 million for the nine months ended September 30, 2014. The decrease in general and administrative expense was primarily attributable to decreased compensation expense, offset by the additional legal services required in connection with our Series A-2 preferred share financing and an increase in accounting services associated with the preparation for this offering and becoming a public company, and included the following:

- \$1.8 million of decreased compensation expense related to the fair value of the Series A preferred shares that was in excess of the indebtedness surrendered by a senior executive for our Series A preferred shares in 2014;
- \$0.58 million for professional fees, in connection with the Series A-2 preferred share financing; and
- \$0.16 million for travel expense, in connection with the set up of additional subsidiaries.

*Interest Income and Expense, Net*

Interest expense (net) decreased by \$3.7 million from \$3.2 million for the nine months ended September 30, 2014, resulting in net interest income of \$0.45 million for the nine months ended September 30, 2015. The decrease in interest expense was primarily attributable to the decrease in interest expenses following conversion of the subordinated convertible promissory note and convertible promissory notes in the Series A preferred share financing, offset by the interest income attributable to short-term investments municipal bonds and corporate fixed income bonds.

*Changes in Fair Value of Financial Instruments*

Loss from changes in fair value of financial instruments decreased by \$2.3 million to \$0.5 million for the nine months ended September 30, 2015 from \$2.8 million for the nine months ended September 30, 2014. The decrease in loss from change in fair value of financial instruments was primarily attributable to changes in fair value of the redemption feature bifurcated from the MSD subordinated convertible promissory note of \$2.5 million recorded in the nine months ended September 30, 2014 before conversion to Series A preferred shares in October 2014.

*Disposal Loss on Available-for-Sale Securities*

The \$298,000 disposal loss on available-for-sale securities was recorded for the nine months ended September 30, 2015 following the disposal of the available-for-sale securities.

*Other Income, Net*

Other income increased by \$362,000 to \$871,000 for the nine months ended September 30, 2015 from \$509,000 for the nine months ended September 30, 2014. Other income primarily consisted of government grants received and foreign exchange gains recognized.

**Comparison of the Years Ended December 31, 2014 and 2013**

The following table summarizes the results of our operations for the years ended December 31, 2014 and 2013, respectively, together with the changes in those items in dollars:

	<b>Year Ended December 31,</b>		<b>Change</b>
	<b>2014</b>	<b>2013</b>	
	(in thousands)		
Collaboration revenue	\$ 13,035	\$ 11,148	\$ 1,887
Operating expenses:			
Research and development	(21,862)	(13,463)	(8,399)
General and administrative	(6,930)	(3,143)	(3,787)
<b>Loss from operations</b>	<b>(15,757)</b>	<b>(5,458)</b>	<b>(10,299)</b>
Net interest expense	(3,512)	(3,153)	(359)
Changes in fair value of financial instruments	(2,760)	133	(2,893)
Gain on debt extinguishment	2,883	—	2,883
Net other income	600	584	16
<b>Net loss</b>	<b>\$ (18,546)</b>	<b>\$ (7,894)</b>	<b>\$ (10,652)</b>

**Revenue**

We recognized \$13.0 million and \$11.1 million of collaboration revenue from the Merck KGaA Collaboration for the years ended December 31, 2014 and 2013, respectively. The slight increase in revenue was primarily due to the 5th patient payments received in 2014.

**Research and Development Expense**

Research and development expense increased by \$8.4 million to \$21.9 million for the year ended December 31, 2014 from \$13.5 million for the year ended December 31, 2013. The following table summarizes our research and development expense by program for the years ended December 31, 2014 and December 31, 2013, respectively:

	<b>Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
	(in thousands)	
Clinical programs	\$ 10,107	\$ 5,462
Preclinical programs	296	1,316
Unallocated research and development expenses	11,459	6,685
<b>Total research and development expenses</b>	<b>\$ 21,862</b>	<b>\$ 13,463</b>

During the year ended December 31, 2014, 37% and 63% of our total research and development expenses were attributable to external research and development expenses and internal research and development expenses, respectively. During this period, approximately 95% of our external research and development expenses were attributable to external contract clinical, preclinical and manufacturing costs for our BGB-283, BGB-A317, BGB-3111, and BGB-290 programs, in descending order. The external research and development expenses of our largest program by spending during this period, the BGB-283 program, represented approximately 11% of

our total research and development expenses in this period. Though we maintain our external research and development expenses by program we do not allocate our internal research and development expenses by program, because our employees and internal resources may be engaged in projects for multiple programs at any time.

In comparison, during the year ended December 31, 2013, 35% and 65% of our total research and development expenses were attributable to external research and development expenses and internal research and development expenses, respectively. During this period, nearly 68% of our external research and development expenses were attributable to external contract clinical, preclinical and manufacturing costs for our BGB-283, BGB-290, BGB-3111, and BGB-A317 programs, in descending order. The external research and development expenses of our largest program by spending during this period, the BGB-283 program, represented approximately 9% of our total research and development expenses in this period.

The increase in research and development expense was primarily attributable to the advancement of our clinical and preclinical pipeline, and included the following:

- \$4.6 million for increased compensation expenses, which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during 2014 and the grants of new share options to certain employees; and
- \$3.5 million related to increased procuring external research and development services mainly attributable to the initiation of clinical trials for BGB-290, BGB-3111 and preparation for clinical trials of BGB-A317.

#### *General and Administrative Expense*

General and administrative expense increased by \$3.8 million to \$6.9 million for the year ended December 31, 2014 from \$3.1 million for the year ended December 31, 2013. The increase in general and administrative expense was primarily attributable to the additional legal services required by our research and development activities to protect our intellectual property rights and an increase in professional legal and accounting services associated with the preparation for this offering and becoming a public company, and included the following:

- \$0.9 million for increased employee compensation costs, which was mainly due to the grants of restricted shares to certain employees during 2014; and
- \$1.1 million for professional fees, including legal and accounting services in connection with the public offering and patent applications.

#### *Interest Expense, Net*

Interest expense increased by \$0.4 million to \$3.6 million for the year ended December 31, 2014 from \$3.2 million for the year ended December 31, 2013. The increase in interest expense was primarily attributable to net effect of the interest expenses incurred in relation to secured guaranteed convertible promissory notes in 2014 which were later converted into Series A preferred shares and the decrease in interest expenses following conversion of the convertible promissory note to MSD.

**Changes in Fair Value of Financial Instruments**

The \$2.8 million loss from changes in fair value of financial instruments for the year ended December 31, 2014 was primarily attributable to the \$2.5 million loss recognized from the change in fair value of the redemption feature of the MSD subordinated convertible promissory note. The remaining \$0.3 million loss was related to the fair value increase of our ordinary shares underlying the financial instruments we issued.

**Gain on Debt Extinguishment**

The \$2.9 million gain on debt extinguishment recorded for the year ended December 31, 2014 resulted from forfeiture of interest of the MSD subordinated convertible promissory note upon automatic conversion of the note in October 2014.

**Other Income, Net**

Other income increased by \$16,000 to \$600,000 for the year ended December 31, 2014 from \$584,000 for the year ended December 31, 2013. The other income consisted of government grants received, offset by losses arising from disposal of fixed assets.

**Liquidity and Capital Resources**

Since inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We incurred net losses of \$18.5 million and \$7.9 million for the years ended December 31, 2014 and 2013, respectively, and \$29.9 million and \$14.8 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of \$90.9 million. Our primary use of cash is to fund research and development costs. Our operating activities used \$8.7 million and provided \$4.1 million of cash flows during the years ended December 2014 and 2013, respectively, and used \$23.1 million and provided \$1.9 million of cash flows during the nine months ended September 30, 2015 and 2014, respectively. Historically, we have financed our operations principally through proceeds from private placements of preferred shares, promissory notes and convertible notes of \$184.4 million and proceeds from the Merck KGaA Collaboration of \$33 million. At September 30, 2015, we had cash, cash equivalents and short-term investments of \$121.3 million. We expect that as of December 31, 2015, our cash and cash equivalents and short-term investments were between \$100 million and \$103 million. Our independent registered public accountants have not audited, reviewed or performed any procedures with respect to this financial data and accordingly do not express an opinion or any other form of assurance with respect thereto. This result could change as a result of further review.

The following table provides information regarding our cash flows for the years ended December 31, 2014 and 2013 and the nine months ended September 30, 2015 and 2014:

	<b>Year Ended December 31,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2015</b>	<b>2014</b>
	<b>(unaudited)</b>			
	<b>(in thousands)</b>			
Net cash (used in)/ provided by operating activities	\$ (8,694)	\$ 4,073	\$ (23,081)	\$ 1,851
Net cash (used in) investing activities	(33,641)	(250)	(66,208)	(265)
Net cash (used in)/ provided by financing activities	52,165	(482)	103,324	17,833
Net effect of foreign exchange rate changes	142	(41)	(483)	(13)
Net increase (decrease) in cash and cash equivalents	<u>\$ 9,972</u>	<u>\$ 3,300</u>	<u>\$ 13,552</u>	<u>\$ (19,406)</u>

**Net Cash Used in Operating Activities**

The use of cash in all periods presented resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The primary use of our cash in all periods presented was to fund the development of our research and development, regulatory and other clinical trial costs, and related supporting administration. Our prepaid expenses and other current assets, accounts payable and accrued expense balances in all periods presented were affected by the timing of vendor invoicing and payments.

During the nine months ended September 30, 2015, operating activities used \$23.1 million of cash, which resulted principally from our net loss of \$29.9 million, adjusting for non-cash charges of \$10 million and interest expense of \$0.8 million, and by cash used in our operating assets and liabilities of \$4.0 million. Our net non-cash charges during the nine months ended September 30, 2015 primarily consisted of a \$1.1 million depreciation charge, \$8.0 million of share-based compensation expense and a \$0.5 million loss from changes in the fair value of financial instruments.

During the nine months ended September 30, 2014, operating activities provided \$1.9 million of cash, which resulted principally from our operating loss of \$14.8 million, adjusting for interest expense of \$3.1 million and non-cash charges of \$10.1 million and by cash provided by our operating assets and liabilities of \$3.5 million.

During the year ended December 31, 2014, our operating activities used \$8.7 million of cash, which resulted principally from our net loss of \$18.5 million, adjusted for non-cash charges of \$11.0 million and interest expense of \$3.3 million, gain on debt extinguishment of \$2.9 million, and by cash used in our operating assets and liabilities of \$1.6 million. Our net non-cash charges during the year ended December 31, 2014 primarily consisted of \$1.6 million of depreciation expense, \$6.6 million of share-based compensation expense, a \$2.8 million loss from changes in fair value of financial instruments.

During the year ended December 31, 2013, our operating activities provided \$4.1 million of cash, principally resulted from cash provided from changes in our operating assets and liabilities of \$7.7 million, adjusted for \$2.8 million of interest expense and non-cash charges of \$1.5 million, offset by our net loss of \$7.9 million. Our net non-cash charges during the year ended December 31, 2013 primarily consisted of \$1.6 million in depreciation expense.

**Net Cash Used in Investing Activities**

Net cash used in investing activities was \$66.2 million for the nine months ended September 30, 2015 compared to \$0.3 million for the nine months ended September 30, 2014. The increase in cash used in investing activities was primarily due to a net purchase of \$64.3 million worth of short-term investments and \$1.9 million paid to purchase property and equipment.

Net cash used in investing activities was \$33.6 million for the year ended December 31, 2014 compared to \$250,000 for the year ended December 31, 2013. The increase in cash used in investing activities was primarily due to a net purchase of \$30.5 million worth of available-for-sale investment and \$2.4 million paid to repurchase non-controlling interest in BeiGene Beijing from Zhongguancun Development Group.

**Net Cash Used in/Provided by Financing Activities**

Net cash provided by financing activities was \$103.3 million for the nine months ended September 30, 2015 compared to \$17.8 million cash provided by financing activities for the nine months ended September 30, 2014. The increase was primarily due to the issuance of \$97.4 million Series A-2 preferred shares to certain investors and loan proceeds of \$6.3 million from Suzhou Industrial Park and China Construction Bank.

Net cash provided by financing activities was \$52.2 million for the year ended December 31, 2014 compared to \$482,000 cash used in financing activities for the year ended December 31, 2013. The increase was primarily due the net proceeds of \$35.5 million from the issuance of Series A preferred shares and the issuance of \$17.5 million secured guaranteed convertible promissory notes, which later converted to Series A preferred shares, and partially offset by \$1.3 million repayment of promissory notes to a related party.

### **Operating Capital Requirements**

We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future drug candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our drug candidates and begin to commercialize any approved products. Upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our drug candidates, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of September 30, 2015, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. In that time, we expect that our expenses will increase substantially as we fund clinical development of BGB-3111, BGB-283, BGB-290 and BGB-A317, fund new and ongoing research and development activities and working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

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

- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our drug candidates to progress through clinical development successfully;
- the initiation, progress, timings, costs and results of non-clinical studies and clinical trials for our other programs and potential drug candidates;
- the number and characteristics of the drug candidate we pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as an ADS holder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third

parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

### **Internal Control over Financial Reporting**

In connection with the audit of our financial statements as of and for the years ended December 31, 2013 and 2014, we identified a material weakness in our internal control over financial reporting. 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 U.S. Securities and Exchange Commission, or 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 consolidated financial statements and related disclosures.

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

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2014 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act after the completion of this offering.



**Contractual Obligations and Commitments**

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2014:

	<b>Payments Due by Period</b>				
	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1–3 Years</u>	<u>3–5 Years</u>	<u>More Than 5 Years</u>
	(in thousands)				
<b>Contractual obligations</b>					
Operating lease commitments	\$ 6,011	\$ 1,109	\$ 2,002	\$ 1,830	\$ 1,070
Senior promissory note	13,516	—	13,516	—	—
<b>Total</b>	<u>\$ 19,527</u>	<u>\$ 1,109</u>	<u>\$ 15,518</u>	<u>\$ 1,830</u>	<u>\$ 1,070</u>

We lease office facilities in Beijing, PRC under non-cancelable operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of the respective leases, and the terms of the leases do not contain rent escalation, contingent rent, renewal or purchase options. The future minimum payments under these non-cancelable operating leases are summarized in the table above. In addition, we lease office facilities in the Greater Boston area and New Jersey, United States.

We expect to lease a manufacturing facility in Suzhou, PRC, and recently entered into a loan agreement with Suzhou Industrial Park and China Construction Bank in connection with our planned lease and construction of such manufacturing facility. Under the terms of this loan agreement, we may borrow up to RMB 120 million at a 7% fixed annual interest rate, and we have currently drawn down RMB 40 million. Fifty percent of the loan must be repaid on September 30, 2018, and the balance must be repaid on September 30, 2019. This loan is secured by certain of our assets.

We enter into agreements in the normal course of business with CROs and institutions to license intellectual property. We have not included these future payments in the table of contractual obligations above since the contracts are cancelable at any time by us with prior written notice.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

**Quantitative and Qualitative Disclosures about Market Risk*****Interest and Credit Risk***

We had cash and cash equivalents of \$3.9 million and \$13.9 million and short term investments of \$0 and \$30.5 million at December 31, 2013 and 2014, respectively, and \$27.5 million and \$93.9 million at September 30, 2015. At September 30, 2015, our short-term investments consisted primarily of high credit quality corporate fixed income bonds and U.S. Treasury securities. The primary objectives of our investment activities are to preserve principle, provide liquidity and maximize income without significant increasing risk. Our primary exposure to market risk relates to fluctuations in the interest rates which are affected by changes in the general level of PRC and U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. The senior note issued to MSD carries a fixed interest rate and, as such, we are not subject to interest rate risk on outstanding indebtedness or otherwise.

We do not believe that our cash, cash equivalents and short-term investments have significant risk of default or illiquidity. 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.

### **Foreign Currency Exchange Rate Risk**

We are exposed to foreign exchange risk arising from various currency exposures. Our functional currency is U.S. dollars, but a portion of our operating transactions and assets and liabilities are in other currencies, such as Renminbi, Australian dollar and euro. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge exposure to such risk.

Renminbi is not freely convertible into foreign currencies for capital account transactions. The value of Renminbi against the U.S. dollar and other currencies is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange prices. From July 21, 2005, the Renminbi is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. There was appreciation of Renminbi against U.S. dollars of approximately 2.9% in the year ended December 31, 2013 and depreciation of approximately 2.4% in the year ended December 31, 2014. While the international reaction to the Renminbi appreciation has generally been positive, there remains significant international pressure on the PRC government to adopt an even more flexible currency policy, which could result in a further and more significant appreciation of the Renminbi against the U.S. dollars. On August 11, 2015, China's central bank executed a 2% devaluation in the Renminbi. 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.

To the extent that we need to convert U.S. dollars into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we receive from the conversion. Conversely, if we decide to convert Renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amounts available to us.

We estimate that we will receive net proceeds of approximately \$144.86 million from this offering if the underwriters do not exercise their option to purchase additional ADSs, after deducting underwriting discounts and commissions and the estimated offering expenses payable by us, at the initial offering price of \$24.00 per ADS. Assuming that we convert the full amount of the net proceeds from this offering into Renminbi, a 10% appreciation of the U.S. dollar against Renminbi, from a rate of 6.5932 to \$1.00 to a rate of Renminbi 7.2525 to \$1.00, will result in an increase of Renminbi 95.51 million in our net proceeds from this offering. Conversely, a 10% depreciation of the U.S. dollar against the Renminbi, from a rate of Renminbi 6.5932 to \$1.00 to a rate of Renminbi 5.9338 to \$1.00, will result in a decrease of Renminbi 95.51 million in our net proceeds from this offering.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the periods. We evaluate our estimates and judgments on an ongoing basis, including but not limited to, estimating the useful lives of long-lived assets, identifying separate accounting units and estimating the best estimate selling price of each deliverable in our revenue arrangements, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets and the fair value of warrant and option liabilities. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors

that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

### **Revenue Recognition**

We recognize revenues from research and development collaborative arrangements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed or determinable, and there is reasonable assurance that the related amounts are collectible in accordance with ASC 605, *Revenue Recognition*, or ASC 605. Our collaborative arrangements may contain multiple elements, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The deliverables under such arrangements are evaluated under ASC 605-25, *Multiple-Element Arrangements*. Pursuant to ASC 605-25, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The collaborative arrangements do not include a right of return for any deliverable. The arrangement's consideration that is fixed or determinable, excluding contingent payments, is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of selling price or third-party evidence, or TPE, of selling price if VSOE does not exist. If neither VSOE nor TPE exists, we use the best estimate of the selling price, or BESP, for the deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as advances from customers.

Upfront non-refundable payments for licensing our intellectual property are evaluated to determine if the licensee can obtain stand-alone value from the license separate from the value of the research and development services and other deliverables in the arrangement to be provided by us. We act as the principal under our arrangements and licensing intellectual property is part of our ongoing major or central operations. The license right is not contingent upon the delivery of additional items or meeting other specified performance conditions. Therefore, when stand-alone value of the license is determinable, the allocated consideration is recognized as collaboration revenue upon delivery of the license rights.

As we act as the principal under our arrangements, and research and development services are also part of our ongoing major or central operations, we recognize the allocated consideration related to reimbursements of research and development costs as collaboration revenue when delivery or performance of such services occurs.

Product development, royalties and commercial event payments, collectively referred to as target payments, under collaborative arrangements are triggered either by the results of our research and development efforts, achievement of regulatory goals or by specified sales results by a third-party collaborator. Under ASC 605-28, *Milestone Method of Revenue Recognition*, an accounting policy election can be made to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. We elected not to adopt the milestone method of revenue recognition under ASC 605-28.

Targets related to our development-based activities may include initiation of various phases of clinical trials and applications and acceptance for product approvals by regulatory agencies. Due to the uncertainty involved in meeting these development-based targets, we would account for development-based targets as collaboration revenue upon achievement of the respective

development target. Royalties based on reported sales of licensed products will be recognized as collaboration revenue based on contract terms when reported sales are reliably measurable and collectability is reasonably assured. Targets related to commercial activities may be triggered upon events such as first commercial sale of a product or when sales first achieve a defined level. Since these targets would be achieved after the completion of our development activities, we would account for the commercial event targets in the same manner as royalties, with collaboration revenue recognized upon achievement of the target. Hence, no revenue has been recognized related to the product development targets, royalties or commercial event based targets in any of the periods presented.

Any subsequent payments to be made to the collaborator such as profit sharing payments based on net sales that are not related to research and development services would be recorded as expenses from the collaborative arrangement. To date, no payments have been made to the collaborator.

### ***Accrued Research and Development Expenses***

Research and development expenses represent costs associated with the collaborative arrangements, which primarily include (1) payroll and related costs (including share-based compensation) associated with research and development personnel; (2) costs related to clinical trials and preclinical testing of our technologies under development; (3) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses; (4) expenses for research services provided by universities and contract laboratories, including sponsored research funding; and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

Clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on behalf of us in the ongoing development of our product candidates. Expenses related to clinical trials are accrued based on our estimates of the actual services performed by the third parties for the respective period. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we will modify the related accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

The process of estimating our accrued research and development expenses involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

## **Share-Based Compensation**

### *Awards Granted to Employees*

We apply ASC 718, *Compensation—Stock Compensation*, or ASC 718, to account for our employee share-based payments. In accordance with ASC 718, we determine whether an award should be classified and accounted for as a liability award or equity award. All our grants of share-based awards to employees were classified as equity awards and are recognized in the financial statements based on their grant date fair values. We have elected to recognize compensation expense using the straight-line method for all employee equity awards granted with graded vesting based on service conditions provided that the amount of compensation cost recognized at any date is at least equal to the portion of the grant-date value of the options that are vested at that date. We use the accelerated method for all awards granted with graded vesting based on performance conditions. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in the subsequent period if actual forfeitures differ from initial estimates.

Forfeiture rates are estimated based on historical and future expectations of employee turnover rates and are adjusted to reflect future changes in circumstances and facts, if any. Share-based compensation expense is recorded net of estimated forfeitures such that expense is recorded only for those share-based awards that are expected to vest. To the extent we revise these estimates in the future, the share-based payments could be materially impacted in the period of revision, as well as in following periods. We, with the assistance of an independent third-party valuation firm, determined the fair value of the share options granted to employees. The binomial option pricing model was applied in determining the estimated fair value of the options granted to employees.

### *Awards Granted to Non-employees*

We have accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 718 and ASC 505, *Equity*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if we had paid cash for the services provided by the non-employees in accordance with ASC 505-50, *Equity-based payments to non-employees*.

### *Modification of Awards*

A change in any of the terms or conditions of the awards is accounted for as a modification of the award. Incremental compensation cost is measured as the excess, if any, of the fair value of the modified award over the fair value of the original award immediately before its terms are modified, measured based on the fair value of the awards and other pertinent factors at the modification date. For vested awards, we recognize incremental compensation cost in the period the modification occurs. For unvested awards, we recognize over the remaining requisite service period, the sum of the incremental compensation cost and the remaining unrecognized compensation cost for the original award on the modification date. If the fair value of the modified award is lower than the fair value of the original award immediately before modification, the minimum compensation cost we recognize is the cost of the original award.

*Modification of Employment Status*

When a nonemployee becomes an employee and continues to vest in the award, the fair value of the award should be remeasured on the date the individual becomes an employee. Compensation charges based on the remeasured fair value will be accounted for prospectively from the date of the change in employment status over the remaining vesting period. The fair value of the award subsequently will not be remeasured unless the award is modified or settled.

*Significant Factors, Assumptions and Methodologies Used in Determining Fair Value*

The fair value of each share option grant is estimated using the binomial option-pricing model. The model requires the input of highly subjective assumptions including the estimated expected share price volatility and, the share price upon which (i.e. the exercise multiple) the employees are likely to exercise share options. We historically have been a private company and lack information on our share price volatility. Therefore, we estimate our expected share price volatility based on the historical volatility of a group of similar companies, which are publicly-traded. When selecting these public companies on which we have based our expected share price volatility, we selected companies with characteristics similar to us, including the invested capital's value, business model, development stage, risk profiles, position within the industry, and with historical share price information sufficient to meet the contractual life of our share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available. For the exercise multiple, as a private company, we were not able to develop an exercise pattern as reference, thus the exercise multiple is based on management's estimation, which we believe is representative of the future exercise pattern of the options. The risk-free interest rates for the periods within the contractual life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. Expected dividend yield is based on the fact that we have never paid, and do not expect to pay cash dividends in the foreseeable future.

The assumptions adopted to estimate the fair value of share options using the binomial option pricing model were as follows:

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Risk-free interest rate	2.1–2.5%	1.5%–2.4%
Expected exercise multiple	2.8	2.2–2.8
Expected volatility	95%–107%	94%–103%
Expected dividend yield	0%	0%
Contractual life	10 years	10 years

	<b>Year Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Risk-free interest rate	1.9%–2.6%	1.4%–3.0%
Expected exercise multiple	2.2–2.8	2.2–2.8
Expected volatility	99%–104%	102%–107%
Expected dividend yield	0%	0%
Contractual life	10 years	10 years

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards

that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised.

These assumptions represented our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates when valuing our share options, our share-based compensation expense could be materially different. Total compensation cost recorded in the statements of comprehensive loss, which includes share-based compensation expense, share options and restricted shares issued to our founders and employees, which were subject to vesting conditions and are fully vested, and the value of share options and restricted shares issued to non-employees for services are allocated as follows:

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in thousands)</b>	
Research and development	\$ 7,765	\$ 3,489
General and administration	278	760
Total	<u>\$ 8,043</u>	<u>\$ 4,249</u>

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>	
Research and development	\$ 4,030	\$ (79)
General and administration	2,607	55
Total	<u>\$ 6,637</u>	<u>\$ (24)</u>

As of September 30, 2015, there was \$11.1 million of total unrecognized share-based compensation expenses, net of estimated forfeitures, related to unvested share-based awards which are expected to be recognized over a weighted-average period of 4.15 years. As of December 31, 2014, there was \$1.15 million of total unrecognized share-based compensation expenses, net of estimated forfeitures, related to unvested share-based awards which are expected to be recognized over a weighted-average period of 1.92 years. In future periods, our share-based compensation expense is expected to increase as a result of recognizing our existing unrecognized share-based compensation for awards that will vest and as we issue additional share-based awards to attract and retain our employees.

#### *Fair Value Estimate*

We are required to estimate the fair value of the ordinary shares underlying our share-based awards when performing the fair value calculations with the binomial option model. Therefore, our board of directors has estimated the fair value of our ordinary shares at various dates, with input from management, considering the third-party valuations of ordinary shares at each grant date. The valuations of our ordinary shares were performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the AICPA Practice Guide. In addition, our board of directors considered various objective and subjective factors, along with input from management and the independent third-party valuation firm, to determine the fair value of our ordinary shares, including: external market conditions affecting the biopharmaceutical industry, trends within the biopharmaceutical industry,

the prices at which we sold preferred shares, the superior rights and preference of the preferred shares or other senior securities relative to our ordinary shares at the time of each grant, the results of operations, financials position, status of our research and development efforts, our stage of development and business strategy, and the lack of an active public market for our ordinary shares, and the likelihood of achieving a liquidity event such as an initial public offering. The option-pricing method was used to allocate the invested capital's enterprise value to preferred shares or other senior securities and ordinary shares, taking into account the guidance prescribed by the AICPA Practice Guide. This method treats ordinary shares and preferred shares or other senior securities as call options on the invested capital's value, with exercise prices based on their respective payoffs upon a liquidity event.

In determining the invested capital's value, we applied the discounted cash flow analysis based on our projected cash flow using our best estimate as of the valuation date. The determination of our invested capital's value requires complex and subjective judgments to be made regarding our projected financial and operating results, our unique business risks, and our operating history and prospects at the time of valuation.

Our board of directors determined the fair value of our share options and the restricted shares as of the date of grant, taking into consideration the various objective and subjective factors described above, including the conclusion of valuation of our ordinary shares as of dates close to the grant dates of our share options and the restricted shares discussed below. We computed the per share weighted-average estimated fair value for share option grants based on the binomial option pricing model and the per share weighted-average estimated fair value for restricted shares based on per share estimated fair value of ordinary shares as of the date of grant.

Once public trading market of the ADSs has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our ordinary shares in connection with our accounting for granted share options and restricted shares.

### ***Derivative Instruments***

ASC 815, *Derivatives and Hedging*, requires all contracts which meet the definition of a derivative to be recognized in the consolidated financial statements as either assets or liabilities and recorded at fair value. Changes in the fair value of derivative financial instruments are either recognized periodically in income/loss or in shareholders' deficit as a component of other comprehensive income depending on the use of the derivative and whether it qualifies for hedge accounting. Changes in fair values of derivatives not qualified as hedges are reported in the consolidated statements of comprehensive loss. The estimated fair values of derivative instruments are determined at discrete points in time based on the relevant market information. We calculated these estimates with reference to the market rates using industry standard valuation techniques with the assistance of an independent third-party valuation firm.

As presented in the prior subsection, "Fair Value Estimate," we applied the discounted cash flow analysis to estimate the invested capital's value as of various valuation dates and the option-pricing method was used to allocate the invested capital's value to preferred shares or other senior securities and ordinary shares. The derived fair value of ordinary share and preferred shares was then further used as inputs to the Black-Scholes option pricing model to estimate the fair value of the derivative instruments. The Black-Scholes option pricing model requires the input of highly subjective assumptions, including the risk-free interest rate, the expected volatility of the underlying stock and the expected life of the derivative instruments. These estimates involve inherent risk and uncertainties and the application of management's judgment. To determine the expected life of the derivative instruments, we have considered factors including the timing of expected various liquidity



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events and their respective probabilities as well as the contractual life of the derivative instruments. The risk-free interest rates for the periods within the expected life of the option are based on the U.S. Treasury yield curve. We historically have been a private company and lack company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on the historical volatility of a group of similar companies, which are publicly-traded.

We have measured the warrant and option liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of the years ended December 31, 2013 and 2014. The significant unobservable inputs used in the fair value measurement and the corresponding impacts to the fair values are presented below:

Financial Instrument	Valuation Techniques	Unobservable Inputs	Estimation	
			2014	2013
Option to purchase shares by rental deferral	Invested capital value allocation by option-pricing model and Black-Scholes option pricing model	Invested capital value	\$145,300	\$19,500
		Volatility for invested capital value allocation	72%	225%–303%
		Volatility for Black-Scholes option pricing model	72%–101%	105%–288%
		Discount for lack of marketability (DLOM)	17%	44%
Warrants in connection with the Convertible Promissory Notes	Invested capital value allocation by option-pricing method and Black-Scholes option pricing model	Invested capital value	\$145,300	\$19,500
		Volatility for invested capital value allocation	72%	225%–303%
		Volatility for Black-Scholes option pricing model	72%–104%	95%–288%
		DLOM	17%	44%

**Income Taxes**

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We evaluate our uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current

conventions. It is our policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

### Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, which will supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance when it becomes effective. ASU 2014-09 affects any entity that enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principle of ASU 2014-09 is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. On August 13, 2015, the FASB approved Accounting Standards Update 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which is a one year deferral of ASU 2014-09. ASU 2014-09 is now effective for annual and interim reporting periods beginning after December 15, 2017, and entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. We are currently in the process of evaluating the impact of adoption of ASU 2014-09 on the consolidated financial statements and related disclosures.

In June 2014, the FASB issued Accounting Standards Update No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*, or ASU 2014-10. ASU 2014-10 removes all incremental financial reporting requirements from GAAP for development stage entities. We early adopted this standard in our consolidated financial statements on January 1, 2012. As a result of the early adoption of ASU 2014-10, the accompanying consolidated financial statements do not include the incremental reporting requirements previously required by Topic 915.

In June 2014, the FASB issued Accounting Standards Update No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*, or ASU 2014-12. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. For all entities, the amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The adoption of ASU 2014-12 is not expected to have a material impact on our financial position, results of operations or cash flows.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASU 2014-15. ASU 2014-15 requires management to evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued or are available to be issued. ASU 2014-15 also requires management to disclose certain information depending on the results of the going concern evaluation. The provisions of ASU 2014-15 are effective for annual periods ending after December 15, 2016, and for interim and annual periods thereafter. Early adoption is permitted. We will be required to perform an

annual assessment of its ability to continue as a going concern when this standard becomes effective on January 1, 2017; however, the adoption of this guidance is not expected to impact our financial position, results of operations or cash flows.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, *Interest—Imputation of Interest*, or ASU 2015-03. To simplify presentation of debt issuance costs, ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this Update. ASU 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. We are currently in the process of evaluating the impact of adoption of ASU 2015-03 on the consolidated financial statements and related disclosures.

#### **JOBS Act**

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards at the same time as other public companies that are not emerging growth companies. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an emerging growth company, we are exempt from Sections 14A(a) and (b) of the Exchange Act which would otherwise require us to (1) submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency" and "golden parachutes;" and (2) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our chief executive officer's compensation to our median employee compensation. We also intend to rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and the rule requiring us to comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will continue to remain an "emerging growth company" until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering, (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than \$1 billion, (3) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years, or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

## BUSINESS

### 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 monotherapy 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 five 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, RAF dimer and PARP have demonstrated early activity and favorable safety profiles in the dose-escalation phases of clinical trials conducted in Australia and New Zealand, and our BTK and RAF dimer drug candidates are currently in the dose-expansion phases of their respective clinical trials. Our PD-1 drug candidate is currently in the dose-escalation phase of our clinical trial in Australia and New Zealand. As of January 15, 2016, our four clinical-stage drug candidates have been dosed in a total of 326 patients. We have Investigational New Drug Applications, or INDs, in effect for our BTK and PD-1 inhibitors with the U.S. Food and Drug Administration, or FDA, and have received approval of our Clinical Trial Application for our RAF dimer inhibitor from the China Food and Drug Administration, or CFDA. 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 relationships 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 currently not approved or available. We have assembled a team of more than 215 individuals in China, the United States, and Australia 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.

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, such as lung, colorectal or ovarian, to one of specific molecular characteristics, such as abnormalities in HER2, BRCA, BRAF, ALK and EGFR genes and proteins. As a result, many more specific disease subpopulations can be targeted for 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 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. We expect to continue investing in and enhancing our cancer biology platform to further advance our capabilities for the discovery of drug candidates with best-in-class characteristics and the potential for use in immuno-oncology combination therapies.

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. Our clinical-stage drug candidates include three molecularly targeted agents, BGB-3111, BGB-283 and BGB-290 and one immuno-oncology agent, BGB-A317. BGB-3111 is a potent and selective small molecule inhibitor of BTK. BGB-283 is a small molecule designed to inhibit both the monomer and dimer forms of the RAF kinase. BGB-290 is a highly selective small molecule inhibitor of PARP1 and PARP2. For each of our molecularly targeted drug candidates, we have achieved proof-of-concept by demonstrating objective responses in the defined patient populations. Our clinical-stage immuno-oncology agent, BGB-A317, is a humanized monoclonal antibody designed to act against the immune checkpoint receptor, programmed cell death-1, or PD-1. In addition to our clinical-stage drug candidates, we have a robust pipeline of preclinical programs and are planning to advance one or more of these programs into the clinic in the next 18 months. We have granted exclusive licenses of the rights to develop and commercialize BGB-283 worldwide (outside of China) to Merck KGaA. We have not granted commercial rights for our other clinical and preclinical drug candidates and programs.

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 relationships 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. Currently, many global standard-of-care therapies are not approved or available in China, resulting in a significant need for innovative therapeutics 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, or Category 1 drugs. 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.

We have a global team of more than 215 employees and consultants, including a global research and development team of 149 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 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.

Since our inception in 2010, we have raised \$170 million in equity financing from our dedicated group of investors, including leading healthcare-focused funds, major mutual funds, China-based funds and our founders.

### Next Generation of Cancer Treatment

We believe that oncology treatment is rapidly evolving, offering patients the promise of high rates of more durable responses that improve survival from weeks to years while avoiding the severe toxicities typically associated with chemotherapy. While these outcomes may occasionally be achieved with monotherapy, the promise largely rests on the understanding that oncology treatment, like the treatment of infectious diseases, will often be most effective against the emergence of resistance when it consists of regimens combining multiple drugs.

The next generation in cancer therapies stems from advances in four areas:

- **Reclassification of disease based on underlying molecular defect.** Due to breakthroughs in gene sequencing and methods of tumor characterization, cancer is increasingly being redefined from a paradigm of tumor classification based on originating tissue type, such as lung, colorectal or ovarian, to one of characterization based on the genetic aberrations and signature gene expression patterns, such as in HER2, BRCA, BRAF, ALK and EGFR. As a result, many more disease subpopulations can be specifically targeted, resulting in more effective treatment than was possible in the past. Disease classifications are substantially more sophisticated than 10 years ago, and we believe they will become increasingly so in the future.
- **Effective molecularly targeted therapy, but often limited durability.** The ability to better understand the mechanisms underlying cancer has allowed the development of effective drugs that target important molecular drivers and generate high response rates in tumors with these drivers. Examples of approved drugs include gefitinib and erlotinib for patients with EGFR mutations, crizotinib and ceritinib for patients with ALK translocations, and vemurafenib and dabrafenib for patients with BRAF mutations. Unfortunately, in many of these cases, responses have been relatively short-lived as cancers can develop alternative mechanisms to compensate and ultimately bypass these drugs' blockade of molecular signaling. For example, while 52% of previously treated metastatic melanoma patients with BRAF V600E achieved an objective response once treated with vemurafenib, the median duration of response was only 6.5 months.
- **Immune checkpoint inhibitors have shown remarkable clinical benefit, demonstrating the power of the immuno-oncology approach.** Improved understanding of cancer immunology has led to the identification of critical immune checkpoints, or mechanisms by which cancer cells evade the surveillance of the immune system. Inhibitors of the immune checkpoints CTLA-4 and PD-1 have shown success in the clinic. Two PD-1 monoclonal

antibodies, nivolumab and pembrolizumab, have been approved by the FDA, for treating certain patients with metastatic melanoma and in the case of nivolumab, squamous non-small cell lung cancer. The results from clinical trials with several immune checkpoint inhibitors as monotherapy have shown at least a signal of efficacy in a wide spectrum of cancers including melanoma, lung cancer, kidney cancer, head and neck cancer, liver cancer, bladder cancer, gastric cancer, esophagus cancer, ovarian cancer, Hodgkin's lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, triple-negative breast cancer, and a subtype of colorectal cancer. In addition, these agents can be effective against large tumors. In some tumors, including squamous and non-squamous non-small cell lung cancer, renal cell carcinoma and melanoma, randomized Phase 3 trials have reportedly demonstrated superior overall survival using PD-1 antibodies compared to chemotherapy. Although certain distinct toxicities associated with PD-1 and PD-L1 antibodies have been observed, these agents have been generally well-tolerated.

- ***The need for and early promise of combination therapy.*** While clinical data with molecularly targeted drugs as monotherapy have been encouraging, achieving a high rate of durable responses remains difficult in most cancer types. Clinical results of immuno-oncology agents such as checkpoint inhibitors including PD-1, PD-L1 and CTLA-4 antibodies have been reported. However, objective responses have been achieved in only a minority of unselected, solid tumor patients even in highly immunogenic tumors such as melanoma. Although the biological mechanisms underlying combinations are not yet well understood, recent third-party clinical studies have demonstrated the potential of combination therapy to achieve high tumor response rates, as are often seen with targeted therapy, but with greater durability, as is seen with immuno-therapy agents. The combination of targeted and immuno-therapies may generate durable responses with much better survival rates.

We believe that combinations of next-generation cancer drugs including targeted and immuno-oncology agents tailored to particular tumor types have potential to provide high rates of more durable responses in many cancers. However, we believe that the industry-standard for cancer biology models has not evolved along with current oncology research and drug discovery and thus is an insufficient framework from which to develop the next generation of oncology drugs we envision. In response, we have built a comprehensive cancer biology platform specifically to address a new generation of cancer treatments.

### **Next-Generation Cancer Biology Platform**

Fundamental changes in cancer research led us early in our history to develop a cancer biology platform that incorporates improved models and processes better suited to drug discovery in the new world of immuno-oncology combinations and addresses the importance of tumor-immune system interactions and the value of primary biopsies. Conventional models for oncology drug discovery have used cultured cell lines that are often decades old and have characteristics that are not representative of the tumors in actual cancer patients and tumors from these cell lines have been grown xenographically in immune-compromised hosts. Therefore, animal models utilizing these cell lines have limited predictive value for new therapies. While animal models derived from surgical samples, such as patient derived xenograft models, or PDX models, are an improvement over the old cell lines, a surgical sample is unlikely to represent the state of the cancer at the time of intended treatment. Because conventional models, including PDX models, require the use of immune-deficient animals, they cannot mimic interactions between the tumor and the host immune system.

The cancer biology platform we developed enables us to test a large panel of tumor models for sensitivity to the drug candidates we generated, identify drug-resistance mechanisms in many

cancers, explore combination strategies and regimens, and improve our understanding of the contributions of tumor micro- and macro-environments in cancer treatments.

**Scientific Approach.** Our platform brings together the following:

- Access to a broad array of primary patient biopsies and tissue samples, enabled by our proximity to and relationships with leading China-based oncology centers, allows us to build novel *in vivo*, *ex vivo* and *in vitro* models that we believe more accurately represent patients' cancer disease states at the time of treatment.
- Methods for better approximating the interactions between a tumor and a patient's immune system, including:
  - Introduction of elements of the human immune system into our *in vivo*, *ex vivo* and *in vitro* models; and
  - Creation of a variety of novel assays to investigate the effects of drug combinations and study their impacts on the human immune system and the tumor microenvironment.
- An effective screening cascade for oncology drug development that incorporates all of these elements.

**Sustainable Leadership Position.** We believe that our early recognition of the importance of tumor-immune system interactions and the value of primary biopsies in developing new models for future cancer research has allowed us to develop a proprietary cancer biology platform that provides significant competitive advantages in developing the next generation of cancer therapeutics

We believe that several of these advantages are sustainable:

- Our close relationships with clinicians and our proximity to major oncology centers in China provide us convenient and difficult-to-replicate access to primary tissue samples that greatly enhance the effectiveness of our oncology models.
- Our time and effort in developing and validating new models and processes, through the commitment and focus of our large scientific team, has allowed us to advance our capabilities meaningfully ahead of many current cancer drug development approaches. Over the last five years, our team of over 50 biologists has been focused on the continued development of our cancer biology platform.
- Our non-hierarchical structure and highly cooperative organizational culture allows us to access the cross-functional capabilities needed to develop, maintain and continually improve our new generation cancer biology platform.

Our robust preclinical and clinical pipeline demonstrates our significant commitment and ability to devote the necessary time, energy and resources required to build, validate and continue to advance our cancer biology platform. Our platform has enabled us to advance four candidates to the clinic and to become, we believe, the only company today to wholly own both a clinical-stage BTK inhibitor 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 therapy. We believe that our cancer biology platform is critical to developing rational combinations that enable us to become a leader in next-generation cancer therapies.



## Our Products

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.

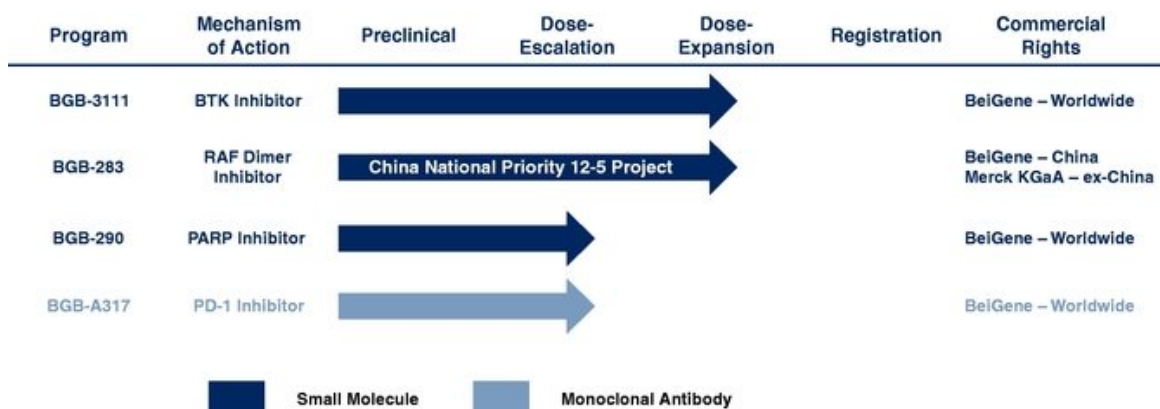
Moreover, we believe that compounds in our clinical and preclinical pipeline have the potential to be first-in-class therapeutics in China, and, as locally developed compounds, to qualify for a separate, and potentially accelerated, regulatory path.

Over time, we intend to strengthen our position with additional drug combinations utilizing our own drugs and in some cases third-party drugs to compete globally as first-in-combination and best-in-combination cancer therapies.

### Our Initial Clinical Candidates

We have a pipeline of four clinical-stage drug candidates. Based on preclinical and clinical data, we believe all of our drug candidates have the potential of becoming, alone and in combination, demonstrably better than drugs currently approved to treat several types of cancers. We believe our research team's discovery of these drug candidates and our extensive preclinical portfolio of drug candidates demonstrates the value of our proprietary cancer biology platform.

The following table summarizes our clinical pipeline:



**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 and higher exposure than ibrutinib, the only BTK inhibitor currently approved by the FDA and EMA.

We have completed the 25-patient dose-escalation phase of our clinical trial in Australia, 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 and Waldenström's Macroglobulinemia. We have dosed a total of 84 patients as of January 15, 2016. Available data from our completed dose-escalation trial indicate that BGB-3111 achieved up to approximately a 3.5- to 7-fold higher exposure level than the approved doses of ibrutinib. As of October 19, 2015, the cutoff date for the most recent data analysis, no protocol-defined dose-limiting toxicities, drug-related serious adverse events or treatment discontinuations due to drug-related adverse events have been observed. Subsequent to the last full data cutoff on October 19, 2015 for

BGB-3111, a serious adverse event of grade 3 purpura (subcutaneous bleeding) was recently reported in one patient among a total of over 85 patients who had received BGB-3111 as of January 25, 2016, the date of the event. Subsequent to the event, the patient received a blood transfusion, and treatment with BGB-3111 has been temporarily suspended in this patient with treatment reinitiation planned after further recovery of the patient. This event was reported to be possibly drug-related and is still under evaluation. 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. In addition, sustained BTK occupancy was achieved in the lymph node for both 320 mg QD and 160 mg twice daily, or BID, dosing regimens.

Responses as defined by standard criteria were seen in 29 of 39 patients treated in the dose-escalation and dose-expansion phases of our clinical trial who were enrolled before August 1, 2015. As of October 19, 2015, the cutoff date for the most recent data analysis, 31 of the 39 treated patients, including all 29 responders, remained on study treatment, free of disease progression.

We plan to advance BGB-3111 to global registration studies in 2016. In addition to monotherapy studies, we have initiated a combination study of BGB-3111 with obinutuzumab, an anti-CD20 molecule monoclonal antibody recently approved for chronic lymphocytic leukemia in the United States, and we plan to initiate a combination study with BGB-A317, our proprietary PD-1 monoclonal antibody, in blood-borne and solid organ tumors.

We also filed a Clinical Trial Application in China in December 2014. With ongoing clinical trials in Australia, we believe that BGB-3111 is the first BTK inhibitor being developed in China under the domestic regulatory pathway to enter the clinic. We plan to initiate registration studies for BGB-3111 in China in 2016.

**BGB-283** is a small molecule RAF inhibitor. We are currently developing BGB-283 as a monotherapy and in combination with other therapies for the treatment of cancers with aberrations in the mitogen-activated protein kinase, or MAPK, pathway, including BRAF 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 titled "—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. We believe BGB-283 has the potential to be a first-in-class RAF dimer inhibitor globally.

Currently approved first-generation BRAF inhibitors, vemurafenib and dabrafenib, are only active against the BRAF monomer. However, dimerization has been reported to be one of the key mechanisms of resistance to first generation BRAF inhibitors. BGB-283 inhibits not only the monomer but also the dimer forms of BRAF. BGB-283 has also shown encouraging results as a monotherapy and in combination therapy in our proprietary preclinical models including KRAS-driven tumors where first generation BRAF inhibitors are not effective.

We have completed the 32-patient dose-escalation phase, and we are currently conducting 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 an abbreviated dose-escalation trial in China. We have dosed a total of 129 patients in Australia, New Zealand, and China as of January 15, 2016. Initial analysis of data from these trials has shown

BGB-283 to be well-tolerated with a favorable safety profile. We have achieved proof-of-concept in a range of cancers including those with KRAS and BRAF mutations.

We received approval of our Clinical Trial Application for BGB-283 in China on July 16, 2015 and patient dosing in the abbreviated dose-escalation phase of our clinical trial in China has been initiated. We believe that BGB-283 is the first BRAF inhibitor to enter the clinic in China under the domestic regulatory pathway. 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 titled "—Collaboration with Merck KGaA."

**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. On February 2, 2016, we initiated a trial with BGB-290 in combination with BGB-A317 for the treatment of cancers with mutations in the breast cancer susceptibility gene (BRCA) or deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal, and pancreatic cancers, as well as platinum-sensitive ovarian cancer. We plan to initiate combination trials with chemotherapies for the treatment of gastric cancer, small cell lung cancer, and glioblastoma.

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 are evaluating BGB-290 in the ongoing dose-escalation phase of our clinical trial in Australia. We have dosed a total of 40 patients as of January 15, 2016. Initial analysis of data from this trial has shown BGB-290 to be well-tolerated. Proof-of-concept has also been established, with anti-tumor activity seen starting at the lowest tested dose and data suggestive of a wide therapeutic window.

With an ongoing clinical trial in Australia, we believe BGB-290 is the first PARP inhibitor being developed in China under the domestic regulatory pathway to enter the clinic.

**BGB-A317** is a 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 cell 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, or Fc  $\gamma$  RI, 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 are evaluating BGB-A317 in the ongoing dose-escalation phase of our clinical trial in relapsed or refractory solid tumor patients in Australia. We have dosed a total of 73 patients as of January 15, 2016.

With an ongoing clinical trial in Australia, we believe that BGB-A317 is the first PD-1 antibody being developed in China under the domestic regulatory pathway to enter the clinic.

### **Our Preclinical Programs**

Our proprietary cancer biology platform has also allowed us to develop several preclinical-stage drug candidates in potentially important 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 18 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.

### **Merck KGaA Collaboration**

We have granted exclusive licenses to the rights to develop and commercialize BGB-283 to Merck KGaA worldwide (outside of China). We have not granted commercial rights to our other drug candidates and retain exclusive rights to BGB-283 in China. In the area of BRAF, we are limited from competing within the licensed individual patents for BGB-283, but are otherwise free to develop drug candidates directed to those targets and have active programs in those areas. We also have a limited collaboration with Merck KGaA on our BGB-290 PARP program. For more information on our collaborations with Merck KGaA, please see the section titled "—Collaboration with Merck KGaA."

### **Regulatory Framework and Structural Advantages of Being a China-Based Research and Development Organization**

We believe that basing our research and development effort in China offers important regulatory advantages that differentiate us from most multinational biopharmaceutical and biotechnology companies. These advantages include the following:

- Potential for more rapid approval in the world's second largest commercial market, China, due to a separate regulatory framework for locally developed drug candidates. This faster and more efficient pathway to approval creates the potential for our drug candidates to be first-in-class locally and to obtain approval in China prior to ex-China developed candidates. By developing our compounds preclinically and manufacturing them in China, we have the ability to seek product approval from the CFDA as a domestic Category 1 drug. This domestic Category 1 designation allows us to use a faster route for bringing our products to market than the Category 3 regulatory process available to multinational companies with drugs approved for marketing by major foreign drug regulatory authorities, such as the FDA or EMA. We believe the Category 1 regulatory pathway will allow us to provide patients in China more rapid access to safe and effective cancer therapies.
- The opportunity to supplement and accelerate global clinical development by accessing the Category 1 China local regulatory path for locally developed drug candidates to enable more rapid clinical trial enrollment from a pool of approximately 20–25% of the world's cancer patients. The prevalence rates for some cancers, such as lung, gastric, liver and esophageal are higher in China, and for others, such as breast and cervical, are lower.
- Currently, many global standard-of-care therapies are not approved or available in China, resulting in a significant need for innovative therapeutics with strong efficacy and safety profiles. As a result, we believe there is a higher likelihood that drug candidates that have demonstrated proof-of-concept in the clinic and become qualified for the Category 1 regulatory pathway will receive regulatory approval in China.

We believe our strategy and approach is aligned with the Chinese government's policies, and we intend to continue to work with local authorities to bring innovative therapeutics to patients in China as quickly as possible. Our commitment for advancing oncology care in China is shared by our investors, including Hillhouse Capital and CITIC PE, which have significant local market expertise.

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, orphan diseases and 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 in other countries and encourage local clinical trial organizations to participate in international multi-center clinical trials.

In November 2015, the CFDA released *Circular Concerning Several Policies on Drug Registration Review and Approval*, or the No. 230 Circular, 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 application.
- 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; (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; (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.

The CFDA is soliciting public opinions on detailed policies regarding such abovementioned fast track clinical trial approval and drug registration pathway, and we expect that the CFDA review and approval process will improve over time.

### **Regulatory Framework for Novel Drugs in China**

The CFDA categorizes domestically-manufactured innovative drug applications as Category 1 and imported innovative drug applications as Category 3.

To date, most Chinese companies' 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 discussed below.

#### *Category 1 Registration Process*

Under Category 1, companies are required to obtain approval of a Clinical Trial Application before conducting Phase 1 clinical trials in China. The Category 1 registration pathway has a fast track review and approval mechanism if the drug candidate is on a national priority list. We believe the local drug registration process, Category 1, is a faster and more efficient path to approval in the Chinese market than Category 3.

#### *Category 3 Registration Process*

A Category 3 new drug is a drug that has received marketing approval in other countries, but is not yet approved in China.

In order to market an imported drug in China, companies must follow the Category 3 registration process to apply for an Import Drug License, or IDL, after the drug has received marketing approval and a Certificate of Pharmaceutical Product, or CPP, from a major foreign drug regulatory authority, such as the FDA or EMA. Compared with the Category 1 registration process, the Category 3 registration process is more complex and evolving.

The first step in the process after receipt of a CPP, is to obtain approval of a Clinical Trial Application to conduct registration studies. A pharmacokinetic study in Chinese subjects is also required. Once this study is completed, the applicant must submit the clinical data package to the CFDA along with other required information for the issuance of an IDL. The total IDL approval process typically takes more than five years from the receipt of foreign marketing approval.

Currently, the most common strategy for multinational companies is using multi-regional clinical trial, or MRCT, data to support IDL approval. Companies can apply to conduct these MRCTs prior to receiving global regulatory approval, with China as a subset within a broader MRCT. However, these MRCTs are often not designed in a way that accounts for the unique characteristics of the Chinese patient population and local standards of care. If the MRCT data does not meet the CFDA's registration requirements, the company may be required to conduct additional local clinical trials that can potentially delay market access in China for imported drugs by an additional three to four years.

It is clear that the August 2015 statement issued by the State Council, *Opinions on reforming the review and approval process for pharmaceutical products and medical devices*, as well as the No. 230 Circular issued by the CFDA, will affect the approval process for new drugs, as well as those marketed in other countries but not yet in China. 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.

Our drug candidates are all new therapeutic agents and we have built both research and development, clinical trial capabilities, and commercial manufacturing facilities in China. As a result, we expect all of our current drug candidates will fall within the Category 1 application process. For example, we filed a Clinical Trial Application for BGB-283 as Category 1 and recently received CFDA approval for conducting clinical trials in China. In July 2015 the CFDA approved our Clinical Trial Application including all phases of our clinical trials for BGB-283. We have filed similar Clinical Trial Applications for BGB-3111, BGB-290, and BGB-A317.

#### **Commercial Opportunities in China**

In addition to the structural and clinical advantages afforded to us by basing our research and development operations in China, we see an attractive and growing commercial oncology

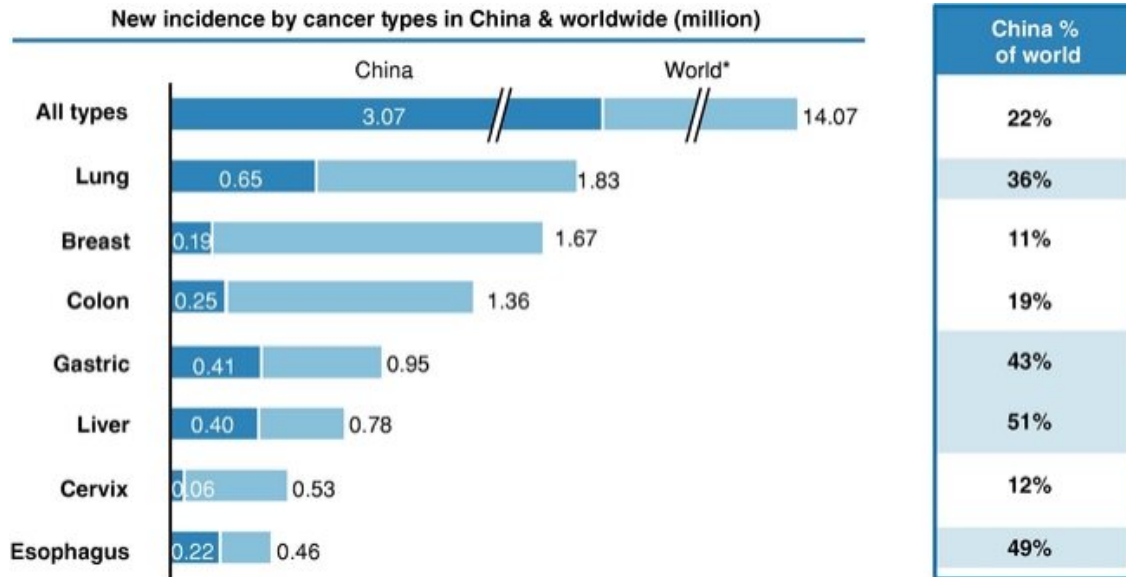
opportunity in our home market. We continue to retain commercial rights in China for all four of our clinical programs and all preclinical programs.

**China's Pharmaceutical Market**

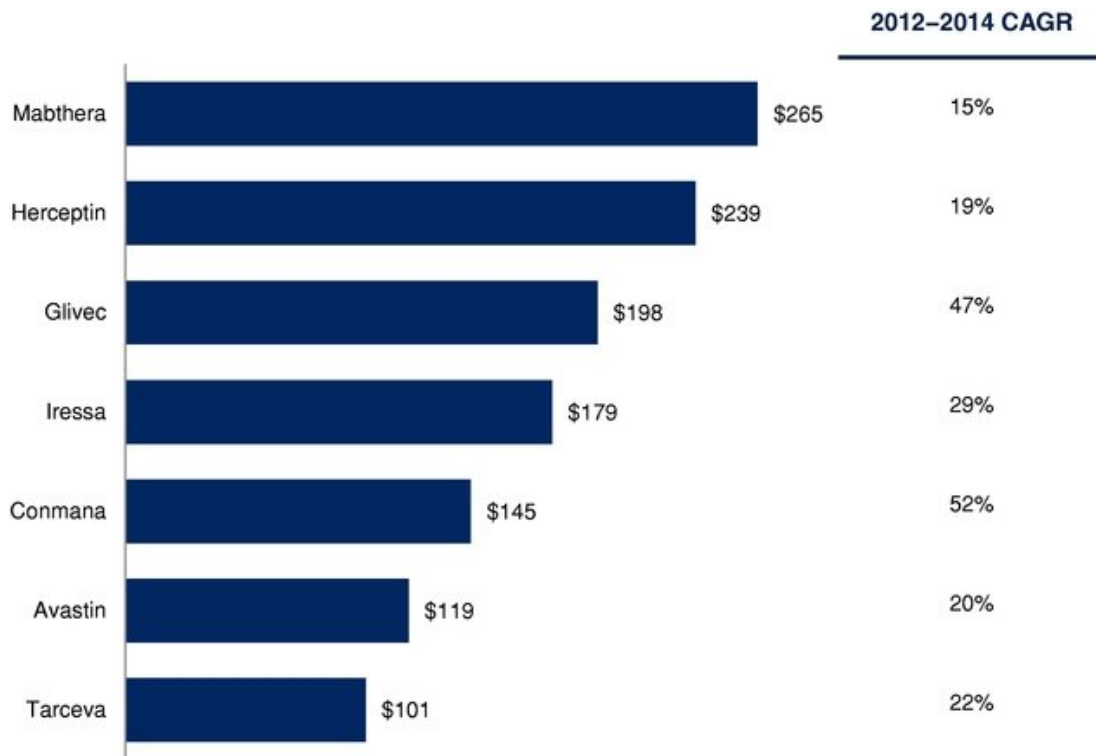
China's pharmaceutical market has grown robustly and replaced Japan as the second largest pharmaceutical market in 2013, according to IMS Health. According to the IMS Market Prognosis published in March 2015, the Chinese pharmaceutical market was \$109 billion in 2014, as compared to a \$373 billion U.S. pharmaceutical market in 2014, and is expected to grow at a compound annual growth rate, or CAGR, of 9.3% over the next five years reaching \$171 billion by 2019. The growth of the Chinese pharmaceutical market is attributable, in particular to:

- An aging population, modern diet, lack of exercise and environmental issues that are increasing the prevalence of chronic diseases.
- Increases in disease prevalence, awareness, diagnostics and treatment rates.
- The continuous and rapid increase of personal disposable income and the establishment of basic national health insurance coverage; making health care more accessible to more patients.

China provides an opportunity to access largely untapped clinical trial pools and develop drugs for a population for whom global standard of care therapies are not available. China has nearly a quarter of the world's cancer patient population and one third to half of cancer patients in certain tumor types are in China.



The oncology market in China is estimated to have grown at a CAGR of 24% in the last decade through 2014. In recent years, sales of targeted therapy drugs in retail channels have increased rapidly. Although expensive targeted therapy drugs are not included in basic national healthcare insurance and have historically had very little coverage by provincial insurance plans, the targeted therapy drug market has continued to grow rapidly despite being an out-of-pocket market. This growth is attributable to patients' needs, willingness to pay and newly launched drugs.

**2014 revenue for targeted oncology therapies in China (USD in millions) and two year historical CAGRs**

Source: CFDA Southern Medicine Economic Research Institute

**Introduction of Reimbursement**

The State Council requires central and provincial authorities across the PRC to promote a medical insurance program for major illnesses. By the end of 2015, all urban and rural residents covered by basic medical insurance programs are required to be covered by the insurance program for major illnesses, according to a State Council policy 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 incurred in connection with treating major illnesses and is supplemental to basic insurance programs. The State Council now 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 high-priced drugs, 15 of which are targeted therapy agents for cancer, including Glivec, Iressa, Erbitux, Herceptin, and Rituxan. Although it will take three years to establish comprehensive national coverage, the affordability of the high-priced, novel cancer agents to Chinese patients will improve significantly and the targeted therapy market is expected to enter a rapid growth period.



## 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. For BGB-3111, we have initiated a monotherapy dose-expansion trial for a variety of lymphomas. For BGB-283, we have initiated a monotherapy dose-expansion trial for a variety of BRAF, KRAS and NRAS mutated cancers. For BGB-3111 and BGB-283, we will continue to enroll multiple expansion cohorts and significantly increase the number of sites globally participating in these trials. For BGB-290, we plan to initiate a monotherapy dose-expansion trial in selected tumor types that may have sensitivity to PARP inhibition. For BGB-A317, we plan to initiate a monotherapy dose-expansion trial for various cancers. 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 18 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, PARP inhibitor, RAF dimer inhibitor and PD-1 inhibitor. We believe that we are the only company today to wholly own both a clinical-stage BTK inhibitor 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 therapy. In addition to monotherapy trials, we are planning combination trials using internally discovered 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 we plan to initiate a combination trial with BGB-A317. For BGB-283, we plan to initiate combination trials with other agents such as chemotherapy and BGB-A317. For BGB-290, we plan to initiate a combination trial with temozolomide and initiated a combination trial with BGB-A317 on February 2, 2016. For BGB-A317, in addition to our combination trial with BGB-290, we plan to initiate combination trials with our other clinical-stage molecularly targeted drug candidates.
- **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 five years, we 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 plan to seek approval from the CFDA for our cancer drugs as domestic Category 1 drugs and 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 of over 110 talented scientists. 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 PARP program. We intend to protect our ability to direct global preclinical studies and clinical trials for our drug candidates as monotherapy and combination therapy 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.

## Product Pipeline

### ***BGB-3111, Bruton's Tyrosine Kinase Inhibitor***

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 U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, and appears to exhibit greater target inhibition as well.

We have completed the 25-patient dose-escalation phase of our clinical trial in Australia, and we are currently conducting the dose-expansion phase in patients with select lymphoid malignancies including chronic lymphocytic leukemia, diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma and Waldenström's Macroglobulinemia. We have dosed a total of 84 patients as of January 15, 2016. Available data from our completed dose-escalation trial indicate that BGB-3111 achieved up to approximately a 3.5- to 7-fold higher exposure level than the approved doses of ibrutinib. As of October 19, 2015, the cutoff date for the most recent data analysis, no protocol-defined dose-limiting toxicities, drug-related serious adverse events or treatment discontinuations due to drug-related adverse events have been observed. Subsequent to the last full data cutoff on October 19, 2015 for BGB-3111, a serious adverse event of grade 3 purpura (subcutaneous bleeding) was recently reported in one patient among a total of over 85 patients who had received BGB-3111 as of January 25, 2016, the date of the event. Subsequent to the event, the patient received a blood transfusion, and treatment

with BGB-3111 has been temporarily suspended in this patient with treatment reinitiation planned after further recovery of the patient. This event was reported to be possibly drug-related and is still under evaluation. 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 QD.

#### *Mechanism of Action*

BTK is a key component of the B-cell receptor, or BCR, signaling pathway and is an important regulator of cell proliferation and cell survival in various lymphomas. BTK inhibitors block BCR-induced BTK activation and its downstream signaling, leading to growth inhibition and cell death in certain malignant white blood cells called B-cells. BGB-3111 is an orally active inhibitor of BTK that covalently binds to the cysteine Cys-481 of BTK, resulting in irreversible inactivation of the kinase. Nine other kinases in the human genome, including ITK, EGFR and JAK3, contain this similar cysteine residue. It has also been shown that BTK inhibitors can inhibit solid tumor growth by regulating the tumor microenvironment in preclinical animal models.

#### *Market Opportunity*

Lymphomas are a group of blood-borne cancers involving lymphatic cells of the immune system. They can be broadly categorized into non-Hodgkin's lymphomas, chronic B-cell leukemias, predominantly chronic lymphocytic leukemia, and acute B-cell leukemias. Depending on the origin of the cancer cells, lymphomas are also characterized as B-cell or T-cell lymphomas. B-cell lymphomas make up approximately 85% of non-Hodgkin's lymphomas and comprise a variety of specific diseases involving B-cells at differing stages of maturation or differentiation. Preliminary data from animal models involving BGB-3111 and third-party BTK inhibitors also suggest potential applications in solid tumors and inflammatory diseases, which could substantially expand our market opportunity.

#### *Current Therapies and Limitations*

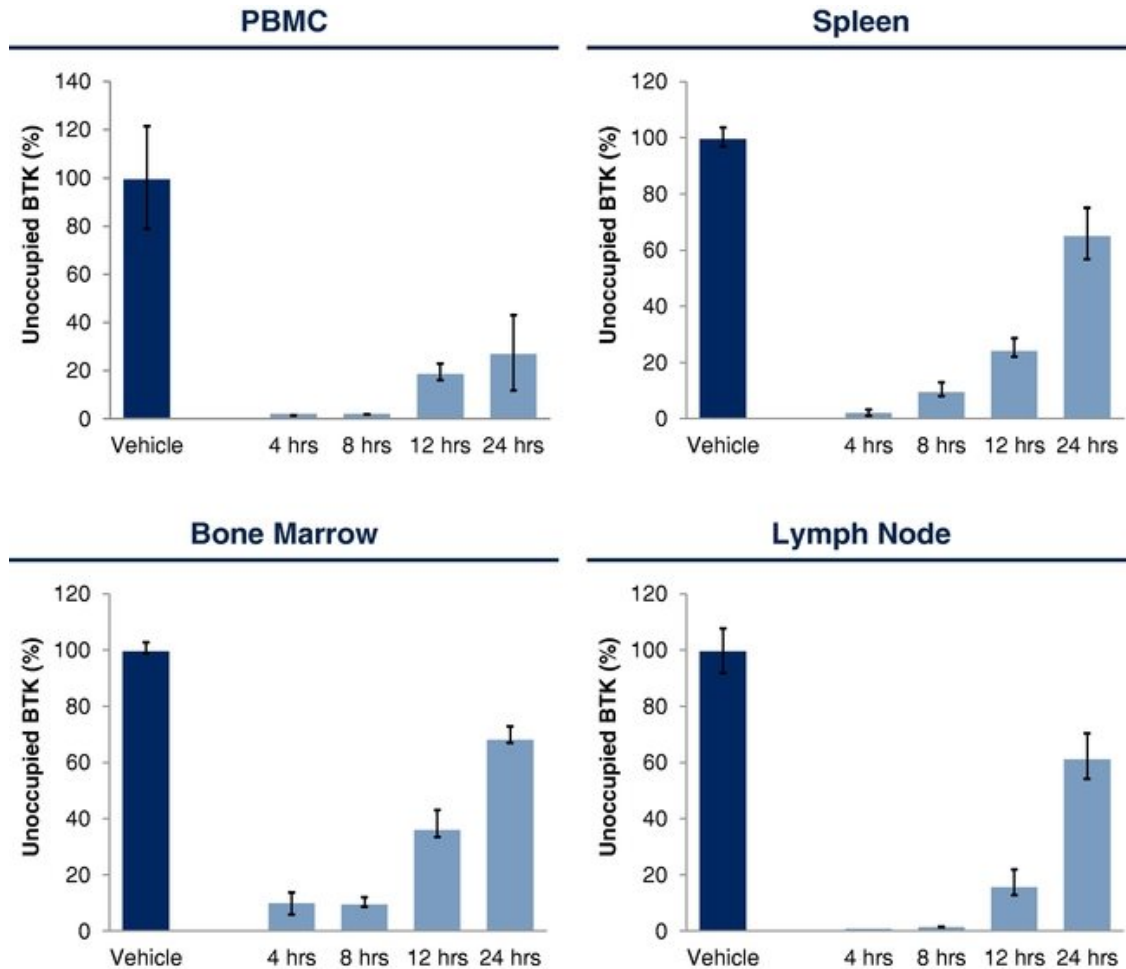
Conventional methods of treatment of lymphomas vary according to the specific disease or histology, but generally include chemotherapy, antibodies directed at CD20, and, less frequently, radiation. Recently, significant progress has been made in the development of new therapies for lymphomas, including BCR signaling inhibitors, primarily with the BTK inhibitor ibrutinib and the PI3K delta inhibitor idelalisib. In addition, there are other inhibitors of BCR signaling pathways in development, such as PI3K delta/gamma, IRAK4 and SYK.

The BTK inhibitor ibrutinib was first approved by the FDA in 2013 for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy. Since 2013, ibrutinib has received supplemental FDA approvals for the treatment of patients with chronic lymphocytic leukemia who have received at least one prior therapy, chronic lymphocytic leukemia patients with 17p deletion, and patients with Waldenström's Macroglobulinemia. Ibrutinib is also approved by the EMA for treatment of patients with relapsed or refractory mantle cell lymphoma, patients with chronic lymphocytic leukemia who have received at least one prior therapy, or first line in chronic lymphocytic leukemia patients with 17p deletion or TP53 gene mutation and are unsuitable for chemoimmunotherapy. The EMA has also accepted an application for potential label expansion for patients with Waldenström's Macroglobulinemia. Ibrutinib has subsequently been approved in over 40 countries, but not China. Reported U.S. sales of ibrutinib were \$492 million in 2014, the first full year after launch, and \$267 million in the third quarter of 2015. In addition to the approved indications, positive Phase 3 results have been announced for ibrutinib in treatment-naive chronic lymphocytic leukemia or small lymphocytic lymphoma patients aged 65 or older. Clinical data also suggest that ibrutinib has activity in other common lymphomas, such as diffuse large B-cell lymphoma and follicular lymphoma.

Despite the clinical and commercial success of ibrutinib, we believe based on its product profile that meaningful differentiation is possible in at least the following aspects:

- **Safety and tolerability.** Although ibrutinib has shown a favorable safety profile compared to traditional chemotherapies, it is associated with adverse reactions that can limit its tolerability as a chronic treatment, and in some cases can be treatment-limiting or life-threatening. These adverse reactions—including diarrhea, thrombocytopenia, or low blood platelet count, bleeding and atrial fibrillation—are believed to be due to ibrutinib's broad inhibition of kinases other than BTK, including EGFR, JAK3 and TEC.
- **Sustainable target inhibition in disease originating tissue.** Although ibrutinib induced sustained BTK inhibition when measured in the plasma of patients, our preclinical studies 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. As shown below, assays measuring the occupancy of BTK show that while a majority of BTK is occupied by a drug molecule in the blood 24 hours after dosing, less than 40% of BTK was occupied in spleen tissue, bone marrow, and lymph nodes, 24 hours after dosing.

**Ibrutinib's target suppression in rats is less sustainable in tissues than in the peripheral blood mononuclear cells, or PBMCs, in blood**



Note: 50 mg/kg ibrutinib used in this study, which we believe is the equivalent to the approved human dose.

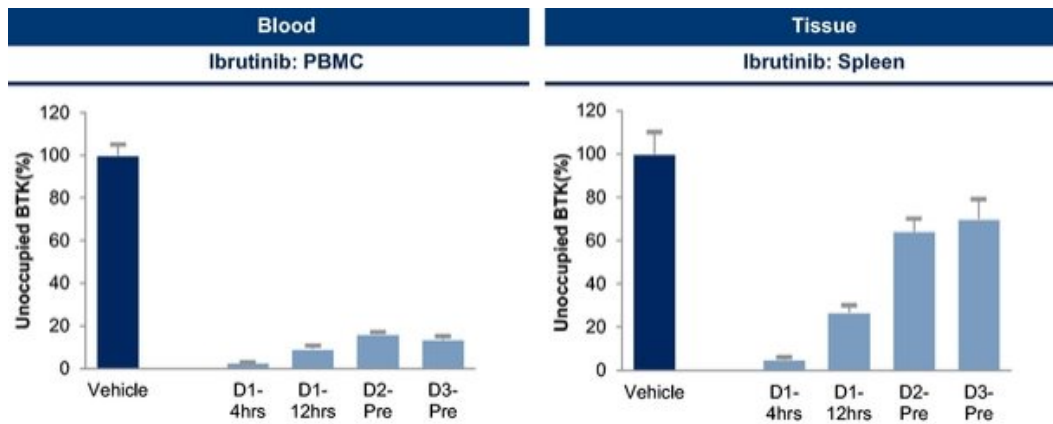
- **Oral bioavailability.** Ibrutinib has shown 7–23% oral bioavailability in preclinical studies, as evidenced by the daily dose of 420 mg or 560 mg required in the clinic.
- **Combinability with ADCC-dependent antibodies.** Anti-CD20 agents, such as rituximab, obinutuzumab and ofatumumab, are considered very effective therapies for lymphomas. Several preclinical studies have demonstrated that ibrutinib, potentially due to its inhibitory activity against ITK, interferes with rituximab-mediated ADCC, which is the mechanism by which rituximab and other anti-CD20 antibodies are believed to exert their immune defense activities. Therefore, these preclinical data suggest that the activity of rituximab and other ADCC-dependent antibodies may be reduced when combined with ibrutinib.

#### *Potential Advantages of BGB-3111*

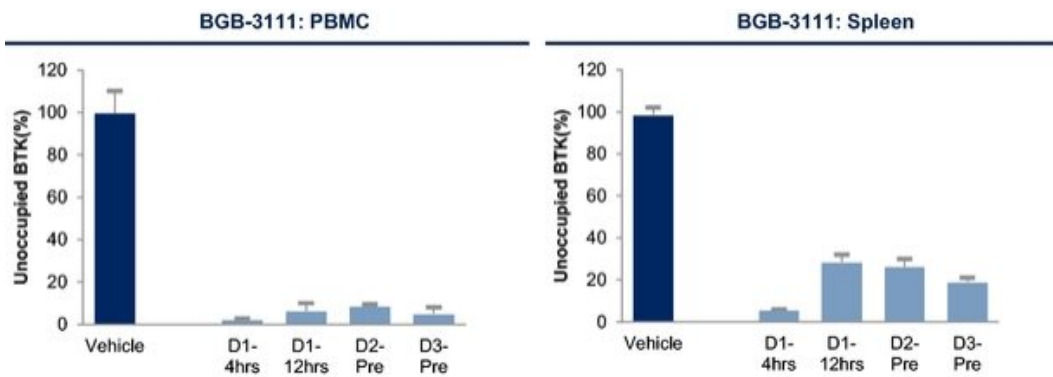
We believe, based on our preclinical and clinical data, that BGB-3111 has the potential to be differentiated from ibrutinib in the following aspects:

- **Better safety and tolerability.** Based on our preclinical studies, we believe BGB-3111 is more selective than ibrutinib in the inhibition of BTK and has less off target inhibition of other kinases, including EGFR, ITK, JAK3, HER2 and TEC, which we believe are associated with ibrutinib toxicity. Results from our preclinical biochemical and cellular assays show that BGB-3111 has similar potency for BTK as compared to ibrutinib while being less active against other kinase targets than ibrutinib, as reflected by the higher dose required to inhibit half the enzymatic activity, or IC<sub>50</sub>. Based on the selectivity of BGB-3111 relative to ibrutinib, a 2- to 70-fold higher concentration of BGB-3111 is required to achieve similar levels of inhibition in these other targets as compared to ibrutinib. Therefore, BGB-3111 has the potential to be associated with fewer toxicities. Available data from our completed dose-escalation trial indicate that BGB-3111 achieved up to approximately a 7-fold higher exposure level than the approved doses of ibrutinib.
- **More sustained inhibition in disease originating tissue.** In our preclinical studies, BGB-3111 has demonstrated favorable pharmacokinetic properties. The comparatively high drug level of BGB-3111 in disease originating tissue as demonstrated in the clinic could potentially translate into a more complete and sustainable inhibition and a better quality of response than ibrutinib. Ibrutinib demonstrated a dose-dependent BTK occupancy in PBMCs during its dose-escalation study. However, even at 420 mg, its approved dose for chronic lymphocytic leukemia, ibrutinib did not achieve complete or sustained target occupancy in PBMCs in a significant proportion of patients. In addition, BGB-3111's favorable safety profile may allow higher doses and more frequent dosing, which could result in more sustained target inhibition. This is currently being investigated in the clinic. At their respective clinically relevant doses in mice (QD for ibrutinib at 50 mg/kg; BID for BGB-3111 at 50 mg/kg), BGB-3111 showed more sustained BTK occupancy in spleen than ibrutinib, albeit similar BTK occupancy in blood.

**BGB-3111 achieved more sustained BTK inhibition in mice than Ibrutinib using clinically relevant dosing regimens**



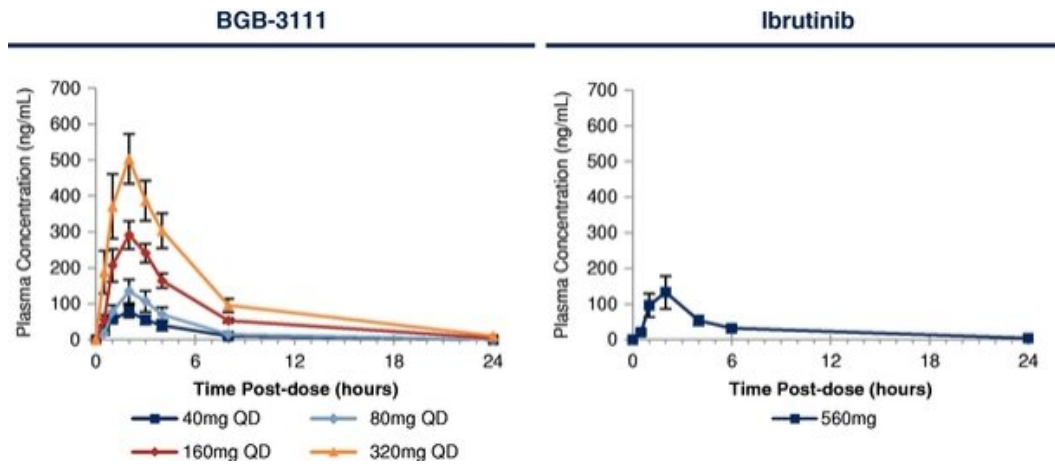
Note: Ibrutinib is given 50 mg/kg once a day; D1 stands for day 1; D2 stands for day 2; D3 stands for day 3; Pre stands for pre-dose.



Note: BGB-3111 is given 50 mg/kg twice a day; D1 stands for day 1; D2 stands for day 2; D3 stands for day 3; Pre stands for pre-dose.

- Better oral bioavailability.** BGB-3111 has shown oral bioavailability of 25–47% in our preclinical animal studies. Based on human data generated in our dose-escalation trial compared to reported data for ibrutinib, BGB-3111 has better oral bioavailability than ibrutinib. As illustrated in the graph below, pharmacokinetic clinical data show a robust and dose-dependent increase in drug exposure and the drug exposure of BGB-3111 at 80 mg QD was comparable to that reported for ibrutinib at 560 mg QD. In addition, the free drug concentration of BGB-3111 at 40 mg QD was comparable to that reported for ibrutinib at 560 mg QD. Lastly, pharmacokinetics data for BGB-3111 suggest that there appears to be far less interpatient variability in drug exposure as compared to ibrutinib.

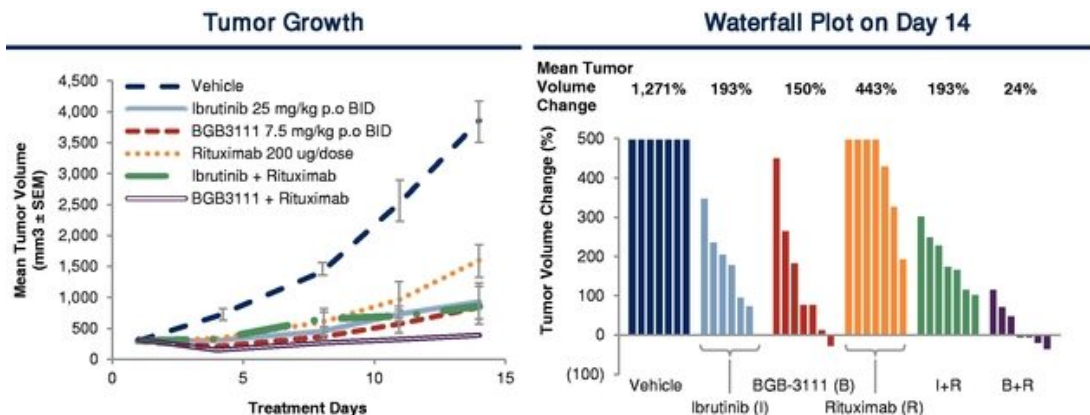
**Human pharmacokinetics of BGB-3111 and ibrutinib**



Source: Adapted from Advani et al., JCO (2013)

- Better combinability with ADCC-dependent antibodies.** Our preclinical data show that BGB-3111 has less off-target inhibition for ITK than ibrutinib in biochemical and cell models. BGB-3111 displayed a more limited inhibitory effect on rituximab-induced ADCC than ibrutinib in cell-based studies. As shown in the graph below, in a human mantle cell lymphoma xenograft model the addition of rituximab to ibrutinib did not improve tumor activity as compared to ibrutinib as a monotherapy. However, the combination of rituximab and BGB-3111 demonstrated improved anti-tumor activity as compared to either as a monotherapy. We believe this may translate into better activity in patients when BGB-3111 is combined with rituximab or other ADCC-dependent antibody therapies.

**BGB-3111 exhibited better combination activity with rituximab than ibrutinib in animal models**



**Summary of Clinical Results**

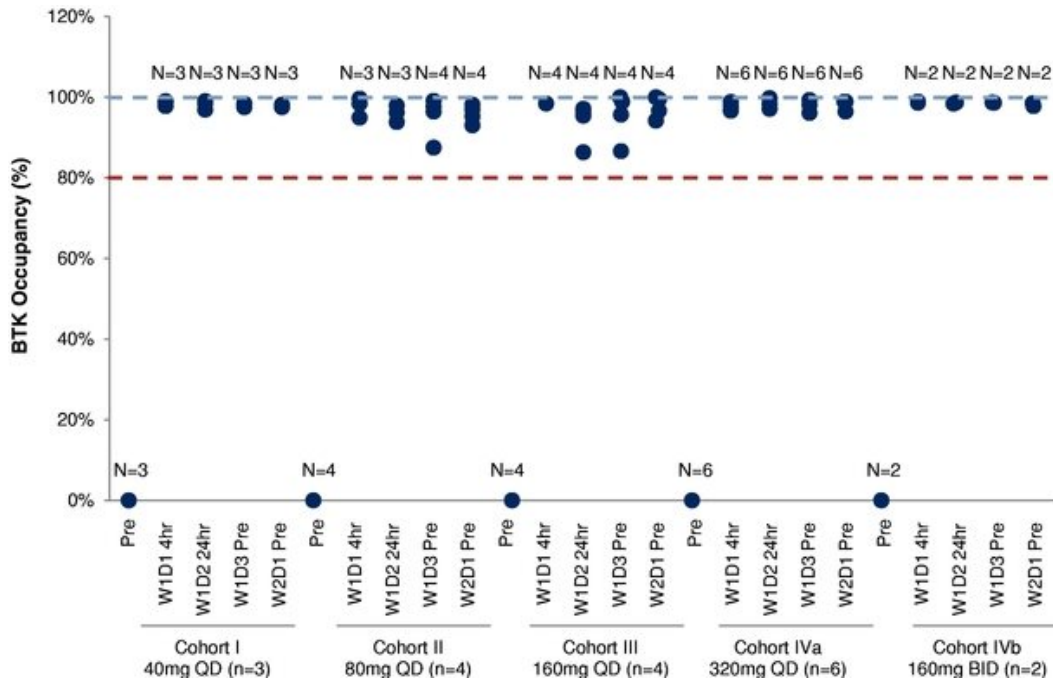
BGB-3111 has completed the dose-escalation phase of our multi-center, open-label clinical trial in Australia and is currently in the 100-patient expansion-cohort part of the trial. As of January 15, 2016, a total of 84 patients have been dosed in this trial.



The dose-escalation phase of our clinical trial for BGB-3111 started in August 2014. The trial, conducted in Australia, was designed to assess the safety, tolerability, pharmacokinetic properties and preliminary activity of BGB-3111 as a monotherapy. In the dose-escalation phase of our clinical trial, a total of 25 patients with relapsed or refractory non-Hodgkin's lymphoma and chronic lymphocytic leukemia with a median of two prior therapies were enrolled in five dose cohorts (40, 80, 160, and 320 mg QD; 160 mg BID). No dose-limiting toxicities have been encountered and the maximum tolerated dose was not reached. We determined the recommended dose for the dose-expansion phase of our clinical trial based on our pharmacokinetics, pharmacodynamics, safety and efficacy evaluation of BGB-3111. In April 2015, we initiated the multi-cohort dose-expansion phase of the ongoing clinical trial 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 and Waldenström's Macroglobulinemia.

The initial results of the dose-escalation phase and dose-expansion phase of our clinical trial are shown below. Consistent with BGB-3111's pharmacokinetic profile, as shown below, complete and sustained 24-hour BTK occupancy in the blood was demonstrated in all tested patients, starting at the lowest dose of 40 mg QD.

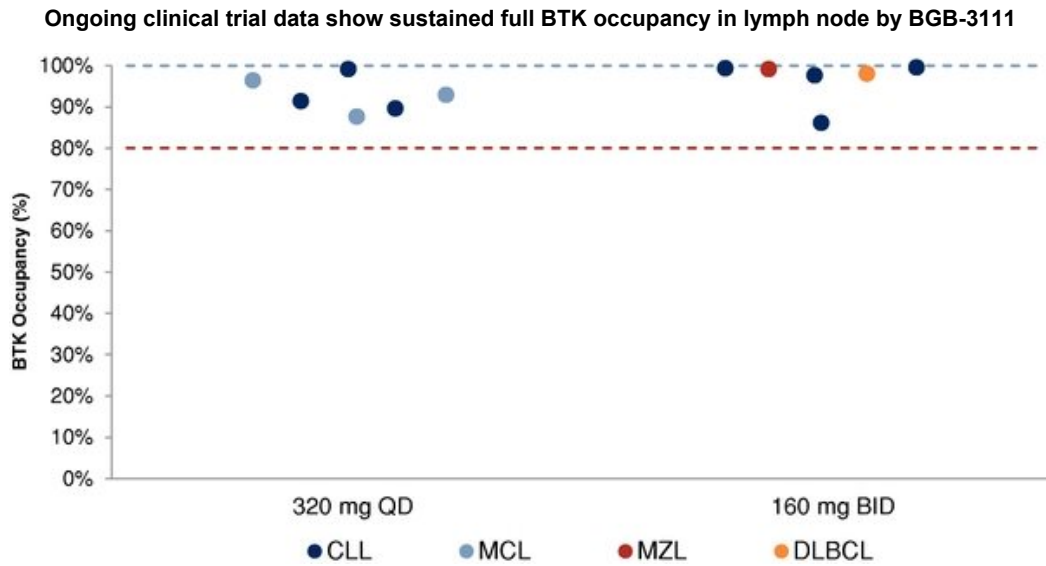
**Ongoing clinical trial data show sustained full BTK occupancy by BGB-3111**



Note: W1D1 stands for week 1 day 1; W1D2 stands for week 1 day 2; W1D3 stands for week 1 day 3; W2D1 stands for week 2 day 1. W1D2, W1D3 and W2D1 are all pre-dose samples.



In addition, sustained full BTK occupancy was achieved in the lymph node for both 320 mg QD and 160 mg BID dosing regimens.



*Note: Paired lymph node biopsies were collected during screening or pre-dose on day 3. BTK occupancy was measured 24 hours post-dose for QD patients and 12 hours post-dose for BID patients.*

The most recent analysis, which had a data cutoff date of October 19, 2015, included all 25 patients treated in the dose-escalation phase of our clinical trial and 14 patients treated in the dose-expansion phase who were enrolled before August 1, 2015. Eight patients discontinued BGB-3111 treatment, including six due to disease progression and two due to adverse events related to their underlying malignancy. Three patients died during the study as a result of disease progression or complications related to disease progression. There was no treatment discontinuation due to drug-related adverse events. No patients experienced drug-related serious adverse events. Of 19 patients with grade 3 or higher adverse events, four were assessed by investigators as possibly drug-related—all were self-limited neutropenia, not requiring special treatment discontinuation. Major hemorrhage, defined as a bleeding event grade 3 or higher or an intracranial bleeding event of any grade, was reported in one patient with mantle cell lymphoma that had lymphomatous involvement of the gastrointestinal tract, but was not considered to be drug-related. The bleeding event occurred during drug hold and resolved rapidly with re-initiation of BGB-3111 treatment. Six patients had a baseline history of atrial fibrillation/flutter, and no exacerbation or new event of atrial fibrillation/flutter was reported. Clinically significant events and adverse events that occurred in more than 15% of the patients, independent of causality, are summarized in the table below.

### Safety overview: clinically significant events

	Total		Drug-related**	
	n	% (n=39)	n	% (n=39)
Subjects reporting $\geq 1$ SAE(s)	9	23%	0	0
AEs leading drug discontinuation	2***	5%	0	0
Subjects reporting grade $\geq 3$ AE(s)	19	49%	4	10%
Atrial fibrillation	0	0	0	0
Major hemorrhage*	1	3%	0	0

\*Defined as bleeding event  $\geq$  grade 3 or intracranial bleeding event (any grade)

\*\*Assessed as possibly related to study drug by the investigator

\*\*\*Complications related to refractory underlying malignancy

### Adverse events: independent of causality, incidence $\geq 15\%$

	Grade 1–2		Grade 3–4		All Grade	
	n (pts)	% (n=39)	n (pts)	% (n=39)	n (pts)	% (n=39)
Minor bleeding*	13	33%	0	0	13	33%
Upper respiratory tract infection	11	28%	0	0	11	28%
Constipation	9	23%	0	0	9	23%
Diarrhea	8	21%	0	0	8	21%
Cough	8	21%	0	0	8	21%
Rash	6	15%	0	0	6	15%
Neutropenia	1	3%	6	15%	7	18%

\*petechiae, contusion, bruising

Note: Adverse events were reported pursuant to Common Terminology Criteria for Adverse Events v4.03 (patients with baseline cytopenias remained evaluable for neutropenia and thrombocytopenia).

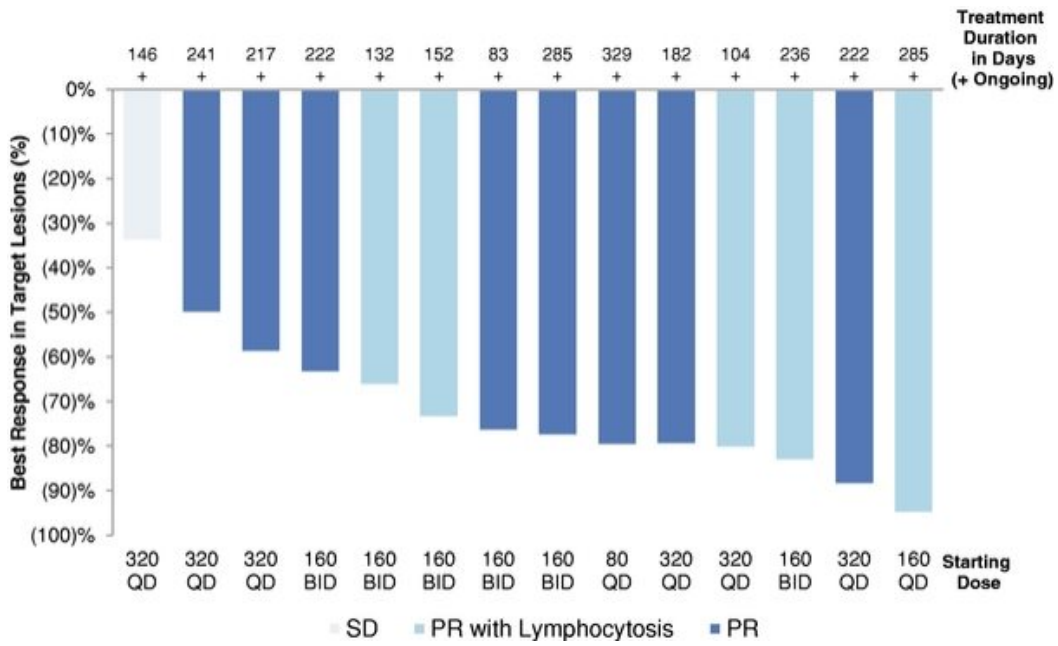
Subsequent to the last full data cutoff on October 19, 2015 for BGB-3111, a serious adverse event of grade 3 purpura (subcutaneous bleeding) was recently reported in one patient among a total of over 85 patients who had received BGB-3111 as of January 25, 2016, the date of the event. Subsequent to the event, the patient received a blood transfusion, and treatment with BGB-3111 has been temporarily suspended in this patient with treatment reinitiation planned after further recovery of the patient. This event was reported to be possibly drug-related and is still under evaluation.

Data from this most recent analysis indicate that BGB-3111 is a potent BTK inhibitor with objective anti-tumor activity observed in multiple types of B-cell malignancies starting at the lowest dose tested. As of October 19, 2015, the cutoff date for the most recent data analysis, preliminary data show that among 39 patients treated in either the dose-escalation phase or dose-expansion phase of our clinical trial enrolled before August 1, 2015, 29 patients had an objective response including three patients with a complete response and 26 patients with a partial response. By specific disease, the best responses are:

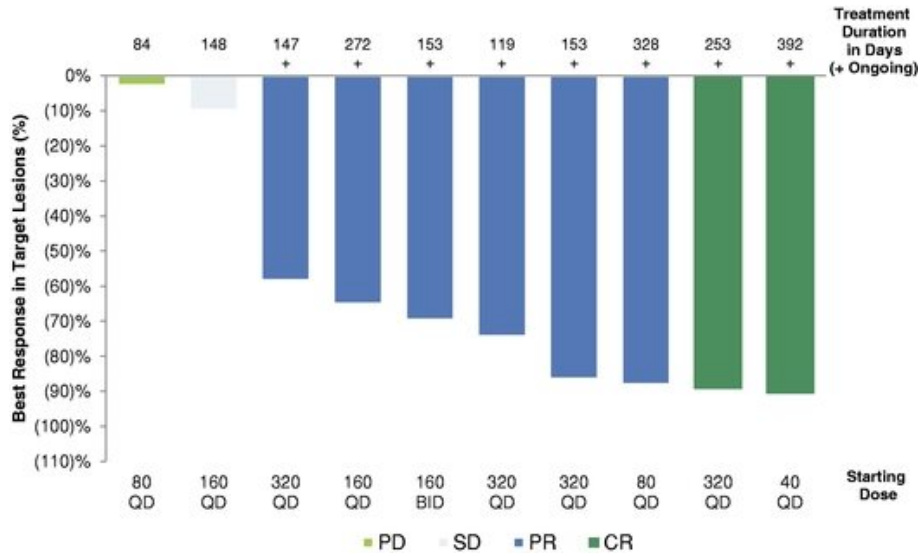
- Of the 14 chronic lymphocytic leukemia patients, 13 had a partial response, including five patients with lymphocytosis at the latest assessment, and one had stable disease. The median follow-up was 220 days, ranging from 83 to 329 days.
- Of the ten mantle cell lymphoma patients, two had a complete response, six had a partial response, one had stable disease and one had progressive disease. The median follow-up was 148 days, ranging from 84 to 392 days.
- Of the seven Waldenström's Macroglobulinemia patients, six had a partial response, including one with a very good partial response, and one had progressive disease. The median follow-up was 271 days, ranging from 11 to 398 days.
- Of the four diffuse large B-cell lymphoma patients, one had a complete response and three had progressive disease. The median follow-up was 29 days, ranging from 20 to 236 days.
- Of the two indolent non-Hodgkin's lymphoma patients, one with marginal zone lymphoma and one with follicular lymphoma, both had stable disease. The follow-up period was 215 and 250 days, respectively.
- An additional partial response was seen in a hairy cell leukemia patient. The follow-up period was 362 days.
- One Burkitt's-like lymphoma patient had progressive disease. The follow-up period was 84 days.

As of October 19, 2015, all 29 responders remained on BGB-3111 treatment with the duration of ongoing treatment ranging from three to 13 months. The best objective response in each patient with chronic lymphocytic leukemia and mantle cell lymphoma, and the serial serum immunoglobulin M, or IgM, and hemoglobin, or Hb, levels in each patient with Waldenström's Macroglobulinemia, is shown below. In summary, we believe our clinical data support our further investigation of BGB-3111 as a potentially safe, well-tolerated and highly active BTK inhibitor.

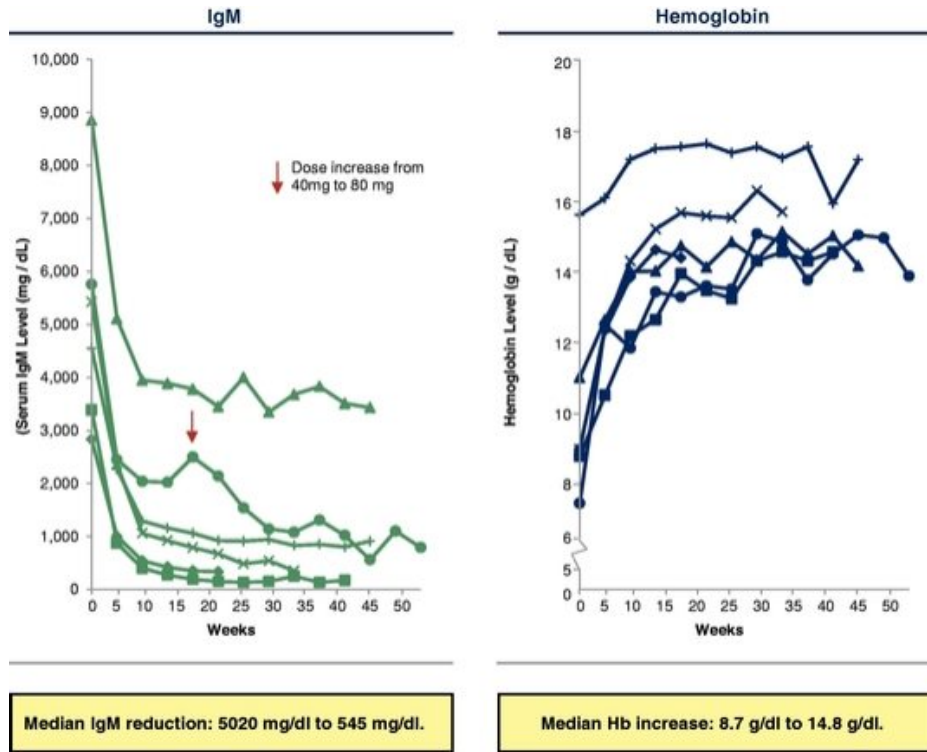
**Best response in chronic lymphocytic leukemia patients**



**Best response in mantle cell lymphoma patients**



**Serial serum IgM and hemoglobin levels in Waldenström's Macroglobulinemia patients**



*Note: Data for one patient (progression on day 11) not included. The degree of reduction in serum IgM level is the basis of response assessment in Waldenström's Macroglobulinemia: >25% – <50% = minor response; >50% – <90% = partial response; >90% – <100% = very good partial response; and absence of clonal IgM = complete response.*

Our IND of BGB-3111 is in effect with the FDA. We plan to pursue a full, global development of BGB-3111 with registration trials starting in 2016. In the coming months, we plan to finalize design of the registration programs following discussions with the FDA and EMA.

In January 2016, we initiated a combination trial of BGB-3111 with the CD20 antibody obinutuzumab in patients with chronic lymphocytic leukemia and other lymphomas. In addition, on the basis of the supportive preclinical combination data discussed below, we plan to explore the combination of BGB-3111 with our PD-1 antibody BGB-A317 in diseases such as diffuse large B-cell lymphoma and follicular lymphoma where accelerated development opportunities may be available. We are also evaluating later stage trials for various B-cell malignancies.

In China, we plan to start an abbreviated dose-escalation trial followed by potential single-arm trials in 2016 in chronic lymphocytic leukemia, mantle cell lymphoma and Waldenström's Macroglobulinemia. Because obinutuzumab is not approved in China, we plan to conduct a combination trial with the CD20 antibody rituximab in chronic lymphocytic leukemia and non-Hodgkin's lymphoma. In addition, we plan to start translational studies to take advantage of patient access in China to identify correlative biomarkers in diseases such as diffuse large B-cell lymphoma where BTK inhibitors have shown good activity in a sub-population of patients.

We plan to present additional data from the dose-escalation and dose-expansion phases of our monotherapy study with BGB-3111 in 2016. We plan to present the data from our combination trials with BGB-3111 in 2016 or 2017.

### **BGB-283, RAF Dimer Inhibitor**

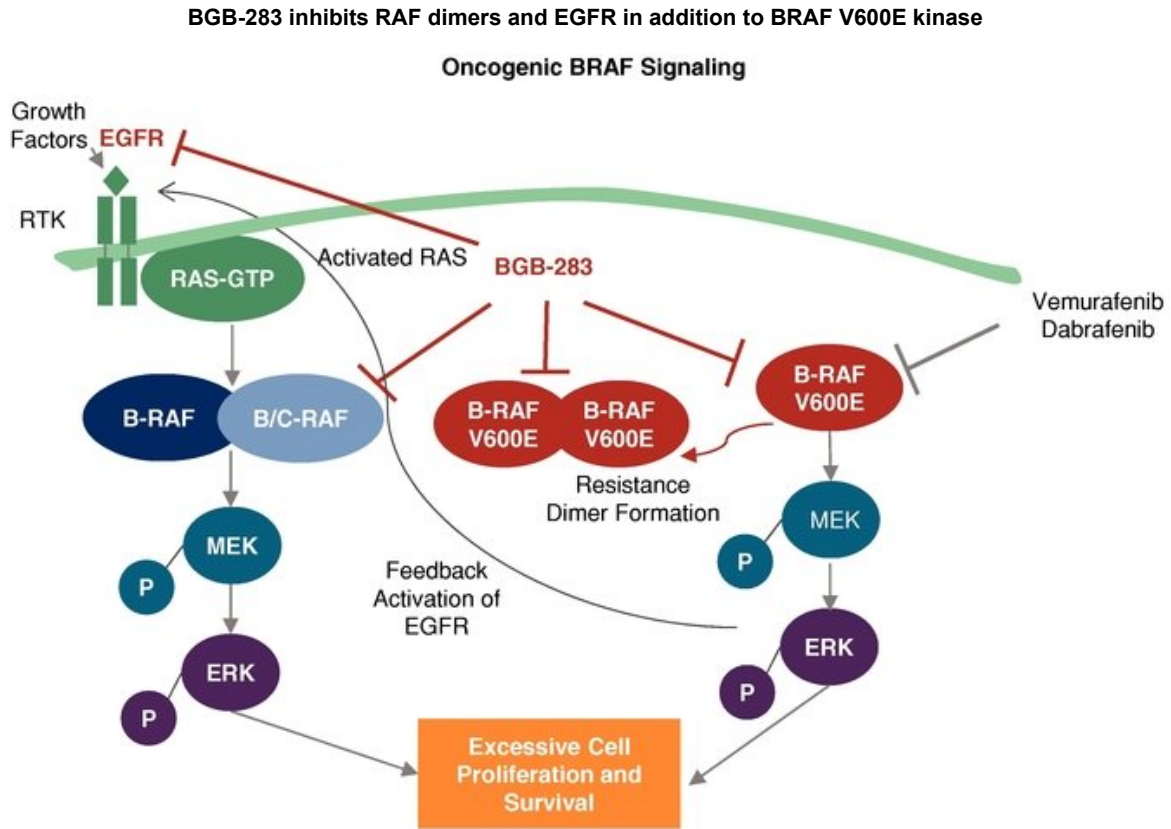
BGB-283 is a small molecule RAF inhibitor. We are currently developing BGB-283 as a monotherapy and in combination with other therapies for the treatment of cancers with aberrations in the MAPK pathway, including BRAF mutations and KRAS/NRAS mutations where first generation BRAF inhibitors are not effective. 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 32-patient dose-escalation phase, and we are currently conducting 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 an abbreviated dose-escalation trial in China. We have dosed a total of 129 patients in our trials in Australia, New Zealand, and China as of January 15, 2016. Initial analysis of data from these trials has shown BGB-283 to be well-tolerated with a favorable safety profile. We have achieved proof-of-concept in a range of cancers including those with KRAS and BRAF mutations. 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 titled "—Collaboration with Merck KGaA."

#### *Mechanism of Action*

The MAPK pathway is a chain of proteins that communicates a signal from a receptor on the surface of a cell to the DNA in the nucleus of the cell. The pathway includes a small G protein (RAS) and three protein kinases (RAF, MEK, and ERK). A kinase is an enzyme that catalyzes the transfer of a phosphate group from a donor molecule to an acceptor. This process often acts as an "on" or "off" switch to regulate cellular signaling. The MAPK pathway plays an essential role in regulating cell proliferation and survival. Activation of the RAS-RAF-MEK-ERK kinase cascade by external stimuli transduces signals from the plasma membrane into the cell nucleus to control gene expression and determine cell fate. Aberrant activation of the MAPK signal transduction pathway is frequently found in different types of cancers, contributing to increased cell division, suppressed apoptosis, and enhanced cell motility and invasion. In many cancers, a defect in the MAPK pathway leads to uncontrolled tumor growth. The two key components of the MAPK pathway, BRAF and RAS, are two of the most frequently mutated genes in human cancers. BRAF is one of the three kinases that belong to the RAF kinase family. There are three members: ARAF, BRAF and CRAF. BRAF is the most frequently mutated oncogene in this kinase superfamily. Mutated BRAF and RAS lead to activation of the MAPK pathway and promote tumor development and growth. Functions of BRAF in the MAPK pathway are key to cell proliferation and survival. Mutations that lead to activation of BRAF promote cell transformation and proliferation and thus positively correlate with tumor development and growth. The most frequent BRAF mutation, BRAF V600E, causes constitutive activation of the kinase as well as insensitivity to negative feedback mechanisms. The mutated BRAF signals as a monomer, independent of upstream growth stimuli. It has been found that RAF kinases can homo- and heterodimerize and form homodimer or heterodimer of RAF proteins. Dimerization has been reported to be one of the key mechanisms of resistance to first-generation BRAF inhibitors, such as vemurafenib and dabrafenib. The three most common

molecular mechanisms of acquired resistance of BRAF V600E melanomas to RAF inhibitors—NRAS mutation, splicing of BRAF V600E that produce a truncated BRAF kinase, and BRAF V600E overexpression due to gene amplification—all result in dimerization of BRAF V600E. First-generation BRAF inhibitors only inhibit the BRAF V600E monomer form at physiologically meaningful concentrations, as shown in the right pathway in the figure below. In contrast, BGB-283 has been shown to inhibit both BRAF V600E monomer and RAF dimer in BRAF inhibitor sensitive and resistant melanoma cell models, which is involved in signaling downstream from RAS, as shown in the left pathway in the figure below. We believe this feature of BGB-283 may help to address the drug resistance issues in BRAF mutated tumors and further expand its utility into RAS mutated patient populations.



Source: Adapted from Wan PTC, et al.

#### Market Opportunity

We believe BGB-283 has applications in both BRAF mutated cancers and RAS, including KRAS and NRAS, mutated cancers. The oncogenic BRAF V600E mutation was detected in approximately 8% of all human solid tumors, including approximately 45% of papillary thyroid cancers. Mutations in any one of the three RAS genes, HRAS, NRAS or KRAS, are among the most common events in human tumorigenesis. KRAS mutations are detected prominently in colorectal cancer, non-small cell lung carcinoma and pancreatic cancer. Additionally, notable KRAS or NRAS mutation rates have been reported in melanoma, ovarian cancer, endometrial cancer, bladder cancer, biliary cancer, thyroid cancer, leukemia and multiple myeloma.



The table below illustrates the limited activity of first-generation, FDA-approved BRAF inhibitors outside of melanoma, non-small cell lung cancer and thyroid cancers. The table also shows that these first-generation BRAF inhibitors do not exhibit activity against KRAS and NRAS mutations.

**Ability of BGB-283 to address numerous unmet medical needs for KRAS/NRAS and BRAF mutations**

Opportunities for 2nd-gen RAF dimer inhibitor						
Indication	Incidences		BRAF V600E (Opportunity for 1st-gen BRAF inhibitor)		KRAS / NRAS (New opportunities for 2nd-gen RAF dimer inhibitor)	
	US*	World**	Mutation %	Response to 1st-gen BRAF inhibitor	Mutation %	Response to 1st-gen BRAF inhibitor
Melanoma	76,100	232,100	50%	51–53%	22%	No
Colorectal	136,800	1,360,600	10%	5%	36%	No
NSCLC	188,000	1,551,000	1–3%	42%	23%	No
Thyroid	63,000	298,100	44%	29%	14%	No
Pancreatic	46,400	337,900	7%	Not reported	63%	No
Ovarian	22,000	238,700	11%	Not reported	18%	No
Endometrial	52,600	319,600	2%	Not reported	10–30%	No
AML	18,900	352,000	2%	Not reported	18%	No
Multiple Myeloma	24,100	114,300	2.8%	Not reported	39%	No

\* 2014 estimates; \*\* 2012 estimates; NSCLC: non-small cell lung carcinoma; AML: acute myeloid leukemia

**Current Therapies and Limitations**

Small molecules that selectively target mutant BRAF have shown considerable efficacy in melanoma patients with the BRAF V600E mutation. Vemurafenib and dabrafenib are first-generation BRAF inhibitors approved by the FDA to treat late-stage BRAF V600E mutant melanoma. The limitations of the first-generation BRAF inhibitors are listed below:

- **Limited activity towards RAF dimers.** Vemurafenib and dabrafenib have not demonstrated significant activity outside of melanoma, thyroid, and non-small cell lung cancers with BRAF V600E mutation. One potential explanation for the limited activity of these first-generation BRAF inhibitors beyond BRAF V600E mutant cancers is that they inhibit only the BRAF V600E monomer and do not inhibit the RAF dimers.
- **Limited activity in KRAS/NRAS mutated cancers.** To date, first-generation BRAF inhibitors have not demonstrated activity in RAS mutated cancers. Efforts in developing RAS-directed molecular therapeutics have been limited by the difficulty in selectively targeting the RAS GTPase family of enzymes with small-molecule inhibitors. A number of mitogen/extracellular signal-regulated kinase, or MEK, inhibitors have been developed and tested clinically but have very limited activity in patients with RAS mutated cancers.
- **Limited activity against EGFR.** A number of studies have suggested that feedback activation of EGFR and MAPK signaling upon BRAF inhibition may contribute to the poor response of colorectal cancer patients to the first generation BRAF inhibitors. First generation BRAF inhibitors do not have inhibitory activity against EGFR and as a result are not able to sequester the feedback activation of EGFR upon BRAF inhibition.



- *Rapid development of resistance.* Despite the success of first-generation BRAF inhibitors in treating metastatic melanoma patients, they are limited by the durability of response. For example, in previously treated metastatic melanoma patients with BRAF V600E mutation who were treated with vemurafenib, approximately 52% of the patients had an objective response, corresponding to significant tumor shrinkage but the median duration of response was only 6.5 months. Only rarely do tumors regress completely in the clinic, and for most patients the therapeutic effects are temporary as resistance to the therapies develops. Studies have shown that the majority of these resistance cases are caused by increased RAF dimer formation in response to treatment with first-generation BRAF inhibitors, resulting in the restoration of extracellular signal-regulated kinase, or ERK, signaling and insensitivity to drug treatment.

#### *Potential Advantages of BGB-283*

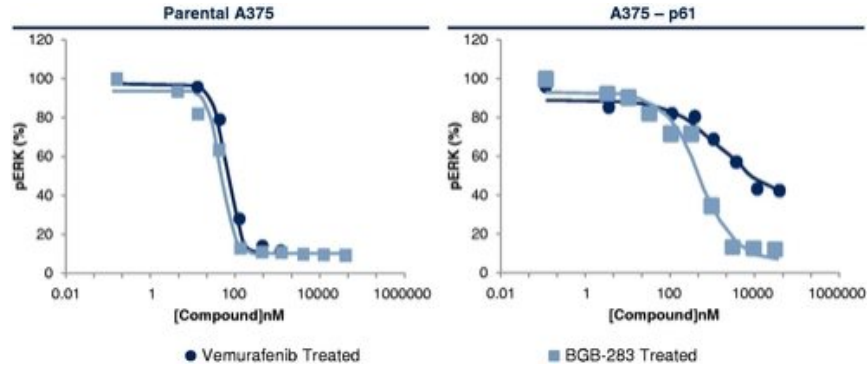
BGB-283 is a novel inhibitor of RAF, in both monomeric and dimeric forms. BGB-283 has demonstrated potent and reversible inhibitory activities against RAF family kinases, including wild-type ARAF, BRAF, CRAF and BRAF V600E, in biochemical assays. In addition, BGB-283 has shown potent inhibitory activity against EGFR in biochemical assays using EGFR kinases, cancer cell lines, and xenograft models. In BRAF wild-type cells that harbor the KRAS mutations, treatment with BGB-283 resulted in much reduced up-regulation of pERK, a phosphorylated form of ERK, compared with vemurafenib in cancer cell models.

In preclinical testing, BGB-283 also retained inhibitory activity in vemurafenib-resistant BRAF splicing isoform p61-BRAF V600E. Data generated in preclinical studies using biochemical, cell-based and animal studies suggest that BGB-283 could offer significant patient benefit in inhibiting tumors with aberrations in the RAF MAPK/ERK pathway, including BRAF mutations and KRAS/NRAS mutations as either monotherapy or in combination with other cancer therapies.

We believe BGB-283 has the potential to be differentiated from other drug candidates currently under development and from approved first-generation BRAF inhibitors due to the following:

- *Increased inhibitory activity against RAF dimers.* BGB-283's increased inhibitory activity against RAF dimers may potentially address resistances associated with increased RAF dimer formation in response to treatment with first-generation BRAF inhibitors. As noted above, most known molecular mechanisms of resistance to RAF inhibitors induce RAF dimerization. As such, BGB-283's ability to inhibit RAF dimers and target dysregulated MAPK pathways resistant to first-generation BRAF inhibitors could result in a clinically significant effect. In preclinical testing, we compared dimer inhibition activity of BGB-283 to vemurafenib in p61-BRAF V600E, which is resistant to vemurafenib. BGB-283 and vemurafenib are both active in melanoma cell line A375, resulting in the complete shutdown of the signaling as measured by pERK. However, in the mutant cell line A375-p61 containing RAF dimer, vemurafenib only led to partial blockage of the signaling pathway, whereas BGB-283 resulted in complete inhibition of pERK.

**Expression of p61-BRAF-V600E (dimer forming BRAF truncation mutant) result in resistance of A375 melanoma cells to vemurafenib while BGB-283 retains potent activity**



- **Increased activity in KRAS/NRAS mutated cancers.** We believe that BGB-283's RAF dimer activity could translate into anti-tumor activity in KRAS/NRAS mutated cancers. Anti-tumor activities were observed in preclinical KRAS/NRAS mutant cancer models *in vivo*. BGB-283 was shown to have activity in 15 KRAS mutant cancer mouse models including:
  - four different primary tumor derived colorectal cancer models (ranging from 67–93% tumor growth inhibition at day 14);
  - three different primary tumor derived lung cancer models (79–100+% tumor growth inhibition at day 14);
  - one primary tumor derived pancreatic cancer model (96% tumor growth inhibition at day 14); and
  - seven xenograft models including one colorectal (95% tumor growth inhibition at day 14), one lung (100+% tumor growth inhibition at day 14), and five endometrial (86–100+% tumor growth inhibition at day 14).
- **Increased inhibitory activity against EGFR.** BGB-283 has demonstrated inhibitory activity against EGFR. The reported response rate of vemurafenib in BRAF V600E colorectal cancer is only 5%. Two independent studies suggested that EGFR feedback activation could be one of the main mechanisms of the observed resistance to first-generation BRAF inhibitors. BGB-283 has demonstrated good EGFR inhibitory activity in both *in vitro* and *in vivo* preclinical models. BGB-283's activity against EGFR may help address the EGFR feedback activation observed in BRAF V600E colorectal cancer tumors.
- **Differentiated resistance profile.** BGB-283 has shown inhibitory activity against RAF dimers. An increase in RAF dimers has been observed to be a major resistance mechanism to first-generation BRAF inhibitors. A differentiated resistance profile has been observed in preclinical models for BGB-283.

**Summary of Clinical Results**

The dose-escalation phase of our multi-center, open-label clinical trial was completed in June 2015. This trial was designed to assess the safety, tolerability and pharmacokinetic properties of BGB-283 as a monotherapy. Thirty-two relapsed or refractory solid tumor patients with BRAF or KRAS/NRAS mutations were enrolled in the trial in seven dose cohorts across five sites in Australia and New Zealand.

To date, BGB-283 has been well-tolerated with a favorable safety profile. Dose-limiting toxicity was reversible, peripheral thrombocytopenia. Based on preliminary safety data (as of the last data

cutoff date June 30, 2015), most of the reported drug-related adverse events have been mild or moderate, with thrombocytopenia being the most frequent severe adverse event, reported in approximately 10% of the patients. The severe adverse events that were considered to be drug-related included two cases of fever, one case of fatigue, one case of dehydration and three cases of thrombocytopenia. Drug-related adverse events were observed in 3–39% of patients, including fatigue, rash, hand-foot syndrome, thrombocytopenia and anorexia. Cutaneous malignancies such as squamous cell carcinomas, which have been observed with the approved first-generation BRAF inhibitors, have not been observed in patients treated with BGB-283. Since the last data cutoff on June 30, 2015, investigators have reported two additional cases of thrombocytopenia, two additional cases of fever, and one case each of Drug Reaction with Eosinophilia and Systemic Symptoms syndrome, sepsis, hyponatraemia, febrile neutropenia, and constipation as drug-related serious adverse events.

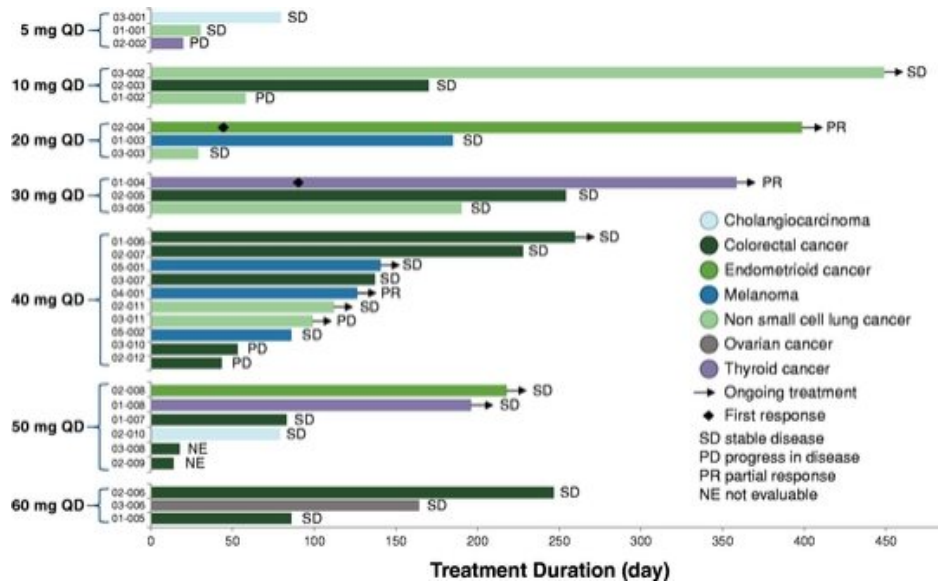
BGB-283 showed a dose dependent pharmacokinetic profile, and plasma concentrations of BGB-283 increased proportionally from 5 mg through 50 mg. The mean half-life of BGB-283 was approximately 110 hours.

In addition, in the 29 patients who are evaluable for efficacy, 24 patients achieved stable disease or better and significant anti-tumor activities were observed in four of those patients including:

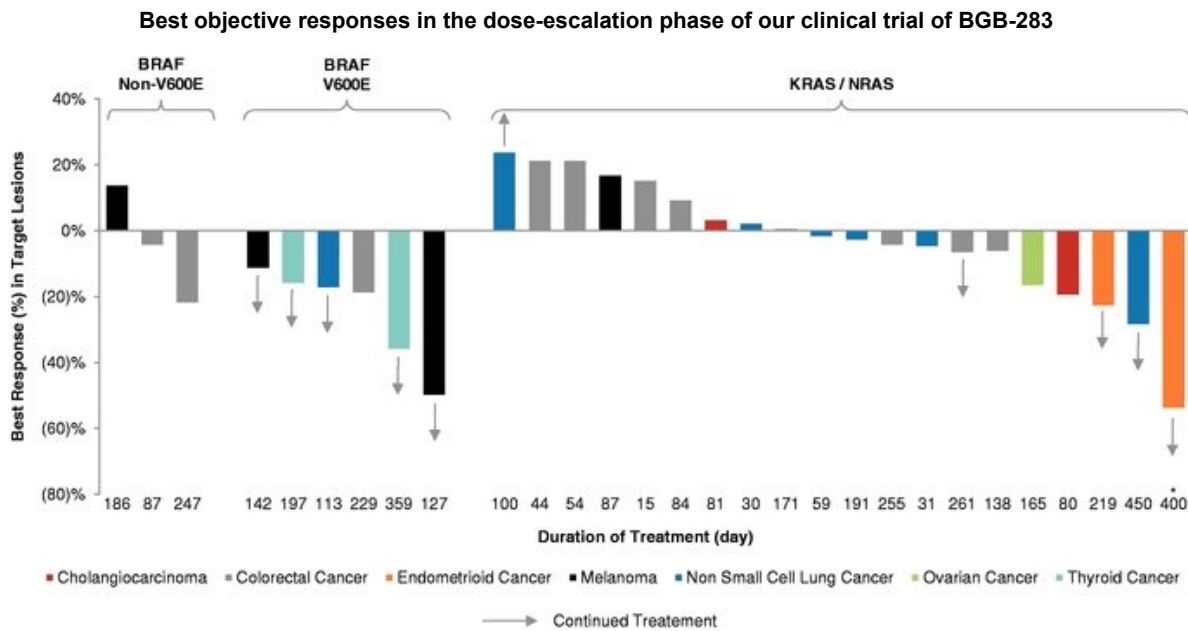
- one patient with a partial response in KRAS mutated endometrial cancer,
- one patient with KRAS mutated non-small cell lung cancer with a transient response; that patient has been on BGB-283 for over 475 days,
- one thyroid cancer patient with BRAF V600E mutation with a partial response, and
- one melanoma patient with BRAF V600E mutation with a partial response.

All of these four responders were on BGB-283 treatment as of last data cutoff date of June 30, 2015 with a duration of ongoing treatment of 13, 15, 12 and four months, respectively. Treatment response of all patients who could be evaluated is shown below, based on dose levels and tumor type.

**Treatment response and duration by dose and tumor type in dose-escalation phase of our clinical trial of BGB-283**



The chart below shows the best anti-tumor response for all evaluable patients as measured by change in the length of target lesions.



In July 2015, we initiated a multi-arm dose-expansion phase of our clinical trial in solid tumors with BRAF mutations and/or aberrations in the MAPK pathway, including thyroid cancer, colorectal cancer, non-small cell lung cancer and other non-V600E BRAF mutated cancers, and KRAS/NRAS mutated endometrial cancer, colorectal cancer, non-small cell lung cancer and other KRAS/NRAS mutated cancers. In addition, BGB-283 has shown immune sensitization and enhancement of T-cell function in preclinical studies, supporting its combination with cancer immunotherapies such as agents targeting PD-1. We have also planned trials that combine BGB-283 and BGB-A317, our PD-1 antibody. We are also exploring alternative dosing schedules, for example, one week of dosing followed by one week without dosing.

In China, we have obtained approval of our Clinical Trial Application for BGB-283. We have initiated an abbreviated dose-escalation trial in China, which we anticipate will be followed by larger studies in BRAF V600E thyroid cancer, BRAF V600E melanoma and potentially other indications where objective responses have been observed in the international dose-expansion trials. Among the 24 patients treated in China as of January 15, 2016, there were three treatment-related serious adverse effects, including one case of grade 3 and two cases of grade 4 thrombocytopenia. Because the number of enrolled melanoma patients reached the targeted accrual range, and there have been more frequent observations of grade 3/4 thrombocytopenia in the China trial (reported in seven out of 24 patients, including three cases reported to date as serious adverse events) compared to the Australia / New Zealand trial (reported in eight out of 105 patients), we voluntarily decided to temporarily suspend new patient accrual to this trial to allow evaluation of pharmacokinetics, safety and efficacy while dosing in already-enrolled patients continues.

We plan to present the data from the dose-escalation phase of our clinical trial at a medical conference in 2016. We also plan to present data from the dose-expansion phase of our clinical trial starting in 2016.

**BGB-290, PARP Inhibitor**

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 repair mechanism making these cancers particularly sensitive to PARP inhibitors. On February 2, 2016, we initiated a trial with BGB-290 in combination with BGB-A317 for the treatment of cancers with mutations in the breast cancer susceptibility gene (BRCA) or deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal, and pancreatic cancers, as well as platinum-sensitive ovarian cancer. We plan to initiate combination trials with chemotherapies for the treatment of gastric cancer, small cell lung cancers, and glioblastoma. 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 are evaluating BGB-290 in the ongoing dose-escalation phase of our clinical trial in Australia. We have dosed a total of 40 patients as of January 15, 2016. Initial analysis of data from this trial has shown BGB-290 to be well-tolerated. Proof-of-concept has also been established, with anti-tumor activity seen starting at the lowest tested dose and data suggestive of a wide therapeutic window.

#### *Mechanism of Action*

PARP family members PARP1 and PARP2 are involved in DNA replication and transcriptional regulation and play essential roles in cell survival in response to DNA damage. PARP1 and PARP2 are key base-excision-repair proteins that function as DNA damage sensors by binding rapidly to the site of damaged DNA and modulating a variety of proteins in DNA repair processes. Inhibition of PARPs prevents the repair of common single-strand DNA breaks which leads to formation of double-strand breaks during DNA replication. Double-strand breaks in normal cells are repaired by homologous recombination, and normal cells are relatively tolerant of PARP inhibition. On the other hand, cancer cells with mutations in BRCA1/2 genes, key players in homologous recombination, are highly sensitive to PARP inhibition, a phenomenon called "synthetic lethality" that is the foundation of the therapeutic utility of PARP inhibitors as a monotherapy for BRCA mutant cancers. In addition to hereditary BRCA1/2 mutations, the synthetic lethal concept has been broadened to include sporadic tumors that display a so-called "BRCAness" profile, a gene expression profile that resembles that of a BRCA deficient tumor. BRCAness can stem from somatic mutation of BRCA1/2, epigenetic silencing of BRCA genes or genetic or epigenetic loss of function of other genes in homologous recombination DNA damage repair pathways.

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

#### *Market Opportunity*

- *Glioblastoma multiforme.* This is one of the frequently occurring tumors in the central nervous system. More than 10,000 cases are diagnosed annually in the United States. Despite aggressive treatment, glioblastoma multiforme still has a dismal prognosis: the five-year survival rate of newly diagnosed patients with glioblastoma multiforme, who have received standard concurrent and adjuvant temozolomide, is less than 10%. BGB-290 has shown positive combination activity with temozolomide in both temozolomide sensitive and resistant tumor models.
- *BRCA mutant and BRCAness tumors.* Based on a recent population-based cohort of Australian ovarian cancer patients, BRCA1/2 mutations are found in approximately 14% of ovarian cancer patients and approximately 17% of patients diagnosed with high-grade serous ovarian cancers. Further, in the United States, BRCA1/2 mutations are found in

approximately 5–10% of breast cancers. The BRCAness profile has been observed in up to 50% of high-grade serous ovarian cancers and in 66–69% of breast cancer patients with the triple-negative subtype (approximately 15–20% of breast cancer cases).

- **Small cell lung cancer.** Small cell lung cancer is an aggressive malignancy accounting for approximately 15–18% of all lung cancers. Approximately 31,000 patients are diagnosed annually with small cell lung cancer in the United States. Although newly diagnosed patients often achieve objective responses with first-line cytotoxic treatments, such as platinum-etoposide based chemotherapy combined with early thoracic radiotherapy, early relapses are common. In addition, tumor metastasis to the brain is frequent among small cell lung cancer patients. In our preclinical human patient biopsy-derived tumor models, BGB-290 has shown superior combination activity with the standard first-line cytotoxic treatments, platinum plus etoposide.
- **Gastric cancer.** Gastric cancer is the fifth most common cancer worldwide, with over 40% of new cases coming from China. In China, the incidence rate for gastric cancer was 23.7 per 100,000 in 2014, corresponding to over 300,000 new cases annually. At the time of diagnosis of gastric cancer, the rate of metastasis is close to 50%. The cornerstone of therapy is surgery with adjuvant chemotherapy or chemoradiation when applicable. However, treatment of advanced or metastatic gastric cancer has not recently progressed, and the median survival rate is less than one year. ATM is a serine/threonine protein kinase that plays a critical role in response to DNA damage. It regulates the signaling and the initiation of cell cycle checkpoint in response to DNA-damaging agents such as ionizing radiation. In ATM-low gastric cancer patients, which account for 13–22% of the gastric cancer patient population, a paclitaxel-plus-olaparib combination significantly prolonged patient overall survival in a Phase 2 study.

#### *Current Therapies and Limitations*

There are several PARP inhibitors that are either approved (olaparib) or are in advanced clinical development, including veliparib, rucaparib, niraparib, and talazoparib.

- **Safety and tolerability.** Current PARP inhibitors have shown significant toxicities in various areas. High frequency of myelosuppression, including anemia, neutropenia, and thrombocytopenia, has been reported with several PARP inhibitors in the clinic, including talazoparib, niraparib, and olaparib. Only rucaparib has reported a high incidence of elevation of liver enzymes associated with the drug treatment.
- **Limited DNA-trapping activity.** Veliparib has reported a lower response rate in BRCA mutated cancer patients. Veliparib's lower response rate is believed to be related to its weak reported DNA-trapping activity, which is the ability of a compound to trap PARP proteins at damaged DNA sites and lead to enhanced cytotoxicity to the tumor cells.
- **Formulation/oral availability.** Formulation for certain PARP inhibitors has proven to be challenging, potentially requiring the need for a significant number of capsules to achieve desired dosing levels. As a related issue, certain PARP inhibitors, such as olaparib, have poor bioavailability.

#### *Potential Advantages of BGB-290*

BGB-290 is a highly potent and selective PARP inhibitor with favorable drug metabolism and pharmacokinetic properties. BGB-290 has shown favorable PARP1 and PARP2 selectivity in biochemical assays and has demonstrated improved specificity compared to other PARP inhibitors, such as olaparib, in cell line proliferation screens. Enhanced selectivity could potentially translate into a better safety and tolerability profile over existing PARP inhibitors. We believe a favorable safety and tolerability profile could be particularly advantageous for the combined use of BGB-290 with immune checkpoint inhibitors or chemotherapeutic agents.

- **Brain penetration.** BGB-290 has shown significant brain penetration in preclinical models. The brain/plasma ratio in mice after oral dosing of 10 mg/kg BGB-290 was approximately 18%, as shown in the following table. We believe the only other PARP inhibitor currently in development that has shown significant brain penetration is veliparib, which appears to be significantly less potent compared to other PARP inhibitors and has minimal DNA-trapping activity.

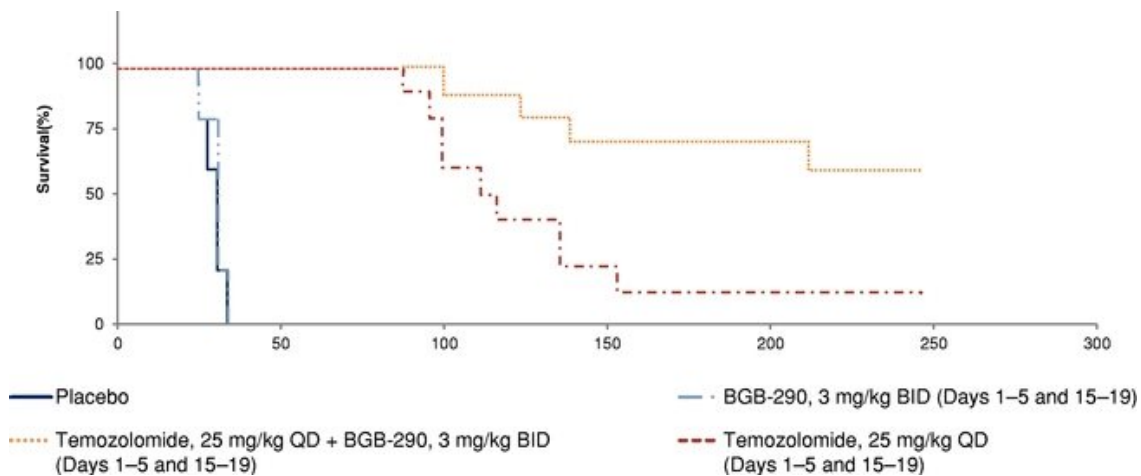
**Brain penetration of PARP inhibitors in mice**

<b>Compound</b>	<b>Brain / Plasma (%)</b>
BGB-290 10 mg/kg p.o.	18%
Niraparib 50 mg/kg p.o.	9%
Olaparib 50 mg/kg p.o.	2%
Talazoparib 3 mg/kg p.o.	2%
Veliparib 50 mg/kg p.o.	38%

*Note: Due to lack of oral availability of rucaparib in our experiment, its brain penetration was not studied in mice.*

As shown in the figure below, BGB-290 demonstrated strong synergistic anti-tumor effects with temozolomide in treating intracranially implanted glioblastoma multiforme, consistent with its ability to cross the blood-brain barrier. In patient-derived small cell lung cancer xenograft models, BGB-290 significantly enhanced the anti-tumor activity of chemotherapy (etoposide plus carboplatin) during the concomitant treatment stage and kept animals in a tumor-free condition throughout their maintenance treatment. One of the major risk factors for small cell lung cancer patients is the high risk of brain metastases. Due to BGB-290's ability to penetrate the blood-brain barrier, we believe BGB-290 could provide a clear advantage over other PARP inhibitors in treating small cell lung cancer patients.

**BGB-290 enhanced temozolomide's effect in intracranial glioblastoma multiforme model**



- **Greater selectivity potentially leading to improved safety and tolerability.** BGB-290 is a highly active and selective PARP1 and PARP2 inhibitor in biochemical and cellular assays. Based on the preliminary data reported by investigators in the ongoing dose-escalation phase of our clinical trial of BGB-290 the only drug-related adverse events that occurred in over 10% of patients are nausea (38%), fatigue (28%), vomiting (14%) and diarrhea (10%). Drug-related adverse events are summarized below.



## Drug-related adverse events in the ongoing dose-escalation phase of our clinical trial of BGB-290. (Data as of June 30, 2015.)

Description	All Grade		Grade 3-4		Patient number in each cohort						
	n(pts)	%(N=29)	n(pts)	%(N=29)	2.5mg BID n=4	5mg BID n=3	10mg BID n=3	20mg BID n=3	40mg BID n=6	60 mg BID n=6	80mg BID n=4
<b>Gastrointestinal disorders</b>											
Nausea	11	38%	0		2			1	4	3	1
Vomiting	4	14%	0		1				2	1	
Diarrhea	3	10%	0			1			2		
Dry mouth	1	3%	0				1				
<b>General disorders and administration site conditions</b>											
Fatigue	8	28%	0		1	1		2	2	1	1
<b>Nervous system disorders</b>											
Lethargy	2	7%	0					1		1	
Dysgeusia	1	3%	0					1			
Hypoesthesia	1	3%	0			1					
<b>Blood and lymphatic system disorders</b>											
Neutropenia	2	7%	1	3%					1		1
Anemia	1	3%	1	3%					1		
Thrombocytopenia	1	3%	0						1		
<b>Metabolism and nutrition disorders</b>											
Hypophosphatemia	1	3%	1	3%					1		
Hypokalemia	1	3%	1	3%				1			
Decreased appetite	1	3%	0							1	
<b>Vascular disorders</b>											
Hot flush	1	3%	0					1			

- **Strong DNA-trapping activity.** BGB-290 also demonstrates potent DNA-trapping activity. PARP inhibitors are reported to trap PARP protein at damaged DNA sites, creating more cytotoxic DNA lesions. The potency of DNA-trapping for PARP inhibitors is shown to be better correlated with tumor cell growth-inhibition than inhibition of PARP enzyme activity. BGB-290 has demonstrated potent activity across multiple assays: DNA-trapping, enzymatic and cellular inhibition of PARP and tumor cell growth inhibition.

## DNA-trapping activity of PARP inhibitors correlates with inhibition of tumor cell growth in BRCA mutant MDA-MB-436 cells

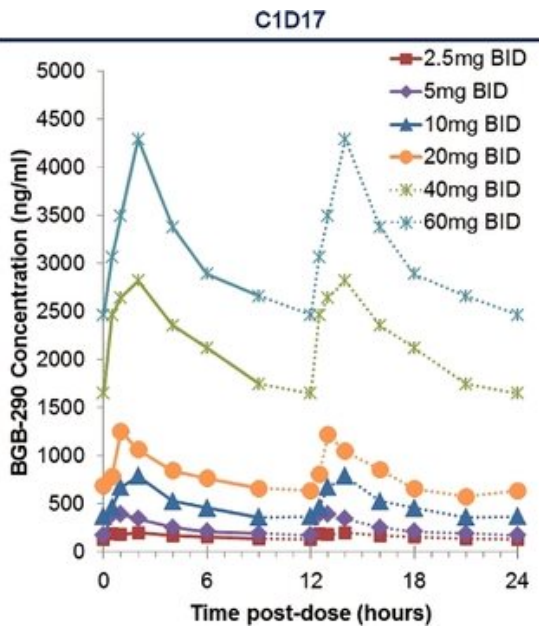
Compound	DNA Trapping FP Assay IC <sub>50</sub> (nM)	PARP1 Enzymatic IC <sub>50</sub> (nM)	Cellular PARylation IC <sub>50</sub> (nM)	Anti-proliferation (MDA-MB-436) EC <sub>50</sub> (nM)
BGB-290	13	1.3	0.24	41
Olaparib	16	1.9	0.47	21
Veliparib	400	5.4	2.7	820
Rucaparib	24	2.2	0.41	27
Niraparib	387	5.9	3.9	84
Talazoparib	3.2	3.3	0.13	0.5

Note: DNA trapping fluorescent polarization assay measures the ability of a compound to trap PARP1 protein on nicked DNA. PARP1 Enzymatic assay measures the inhibition of catalytic activity of PARP1. Cellular PARylation assay measures the inhibition of the increase of cellular poly ADP ribose level after stimulation by hydrogen peroxide. Anti-proliferation assay measures the inhibition of cellular growth in MDA-MB-436 cells.

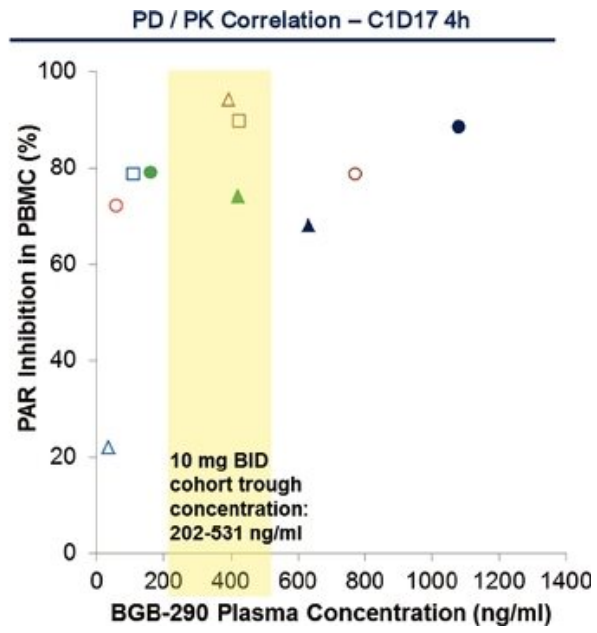
- **Good oral bioavailability and potent target inhibition.** In preclinical animal models, BGB-290 shows good oral bioavailability. BGB-290 has demonstrated bioavailability of 71–76% in animal studies. In the ongoing dose-escalation phase of our clinical trial, we observed a linear and dose-dependent pharmacokinetic profile for BGB-290 with approximately two-fold accumulation at steady state, as shown in the figure below. BGB-290 induced robust poly ADP ribose, or PAR, inhibition in PBMCs even at the first dose level and sustained PAR inhibition in PBMC was expected at a steady state dose of 10 mg BID or greater.



**Pharmacokinetics and pharmacodynamics in the dose-escalation phase of our clinical trial of BGB-290**



Note: C1D17 stands for cycle 1 day 17.



Note: C1D17 stands for cycle 1 day 17. Each symbol represents one patient.

**Summary of Clinical Results**

BGB-290 is being evaluated in an ongoing dose-escalation phase of our multi-center, open-label clinical trial, which was initiated in July 2014. As of June 30, 2015, the cutoff date for the most recent data analysis, this trial conducted at three sites in Australia, had enrolled 29 relapsed or refractory solid tumor patients in seven cohorts receiving monotherapy BGB-290 in doses ranging from 2.5 mg BID to 80 mg BID. One patient receiving 40 mg BGB-290 BID experienced a dose-limiting toxicity of persistent grade 2 nausea, although the maximum tolerated dose had not been reached. Since the last data cutoff on June 30, 2015, eight additional patients have been treated, including five patients dosed at 120 mg BID where dose-limiting toxicity was observed in two patients, one with persistent grade 2 nausea and anorexia; and another one with persistent grade 2 nausea, grade 3 fatigue and peripheral neuropathy. Thus, 80 mg was determined to be the maximum tolerated dose, and additional patients are being enrolled to confirm the safety of an 80 mg BID dose as a potential recommended Phase 2 dose. Drug-related serious adverse events reported by investigators include three cases of grade 3 anemia and one case of shortness of breath.

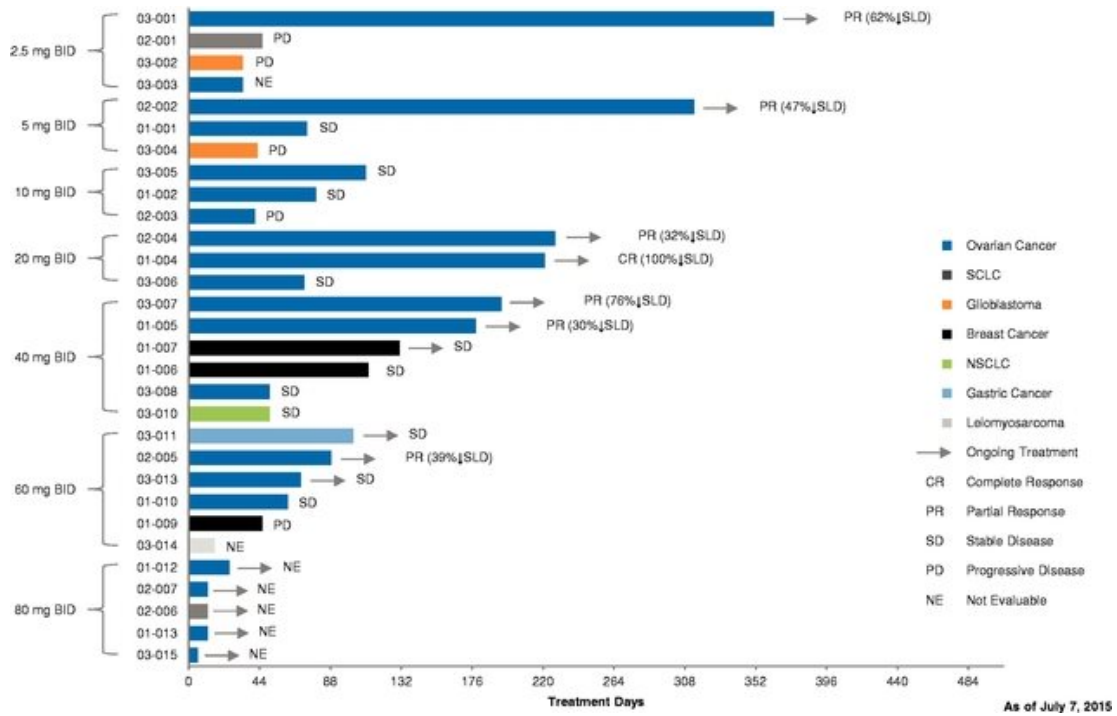
Among the 19 ovarian cancer patients treated, 14 patients were evaluated as of June 30, 2015. Three patients have not yet been evaluated for response; one patient withdrew from the trial prior to the first disease assessment, and one patient was not evaluable due to lack of measurable disease.

- Of the 14 evaluated patients with ovarian cancer, seven had an objective response, including six with a partial response and one with a complete response. All seven responders remained on BGB-290 treatment as of June 30, 2015 with the duration of ongoing treatment ranging from three to 12 months.

- Of the ten ovarian cancer patients evaluated with germ-line BRCA mutation, five had an objective response.
- Of the three ovarian cancer patients evaluated with germ-line BRCA wild-type, two had an objective response.

Treatment duration and response of all patients is shown below, based on dose levels and tumor type.

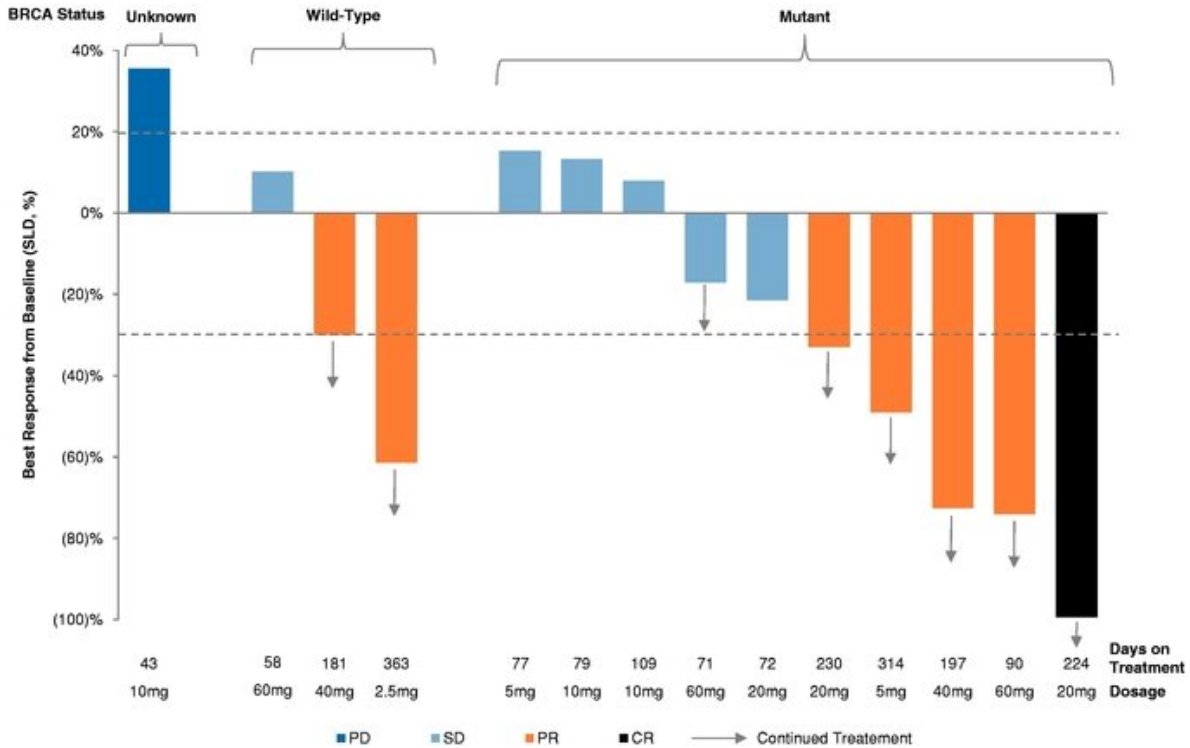
**Treatment response and duration by dose and by tumor response in the dose-escalation phase of our clinical trial of BGB-290**



Note: Best response is listed next to each bar graph.

The treatment response of ovarian cancer patients based on BRCA status is shown below.

**Best response in all evaluable ovarian cancer patients (as defined by % change in sum of longest diameter)**



We will continue to confirm clinical activities of BGB-290 in BRCA mutant ovarian cancer and other indications with homologous recombination deficiency in the dose-expansion trial. We also plan to explore emerging indications with homologous recombination deficiency, such as prostate cancer or cancers with high frequency of brain metastasis given the potential brain penetration advantage.

On February 2, 2016, we initiated a Phase 1 clinical trial with BGB-290 in combination with BGB-A317 for the treatment of cancers with mutations in the breast cancer susceptibility gene (BRCA) or deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal, and pancreatic cancers, as well as platinum-sensitive ovarian cancer. The Phase 1 multi-center, dose-escalation and dose-expansion clinical trial of BGB-A317 with BGB-290 is the first combination study exclusively based on drug candidates from our internal portfolio. Key objectives in the trial include determining maximum tolerated dose, recommended Phase 2 dose, pharmacokinetics, and preliminary anti-tumor activity of the BGB-A317 and BGB-290 combination. We also plan to commence a combination trial with temozolomide in glioblastoma multiforme.

In China, we plan to pursue monotherapy approval in BRCA mutant ovarian cancer and breast cancer, two cancers whose unmet medical needs have not been addressed and therefore may provide accelerated development opportunity. We also plan to explore combination trials with paclitaxel in gastric cancer and platinum/etoposide in small cell lung cancers.

## **BGB-A317, PD-1 Antibody**

BGB-A317 is a 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 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 are evaluating BGB-A317 in the ongoing dose-escalation phase of our clinical trial in relapsed or refractory solid tumor patients in Australia. As of January 15, 2016, we have dosed a total of 73 patients. BGB-A317 is the first drug candidate produced from our immuno-oncology biologic programs, and we believe it could serve as one of the cornerstones for our immuno-oncology combination platform.

### *Mechanism of Action*

Cells called cytotoxic T-cells provide humans an important self-defense mechanism against cancer, patrolling the body, recognizing cancer cells due to immunogenic features that differ from normal cells, and killing cancer cells by injecting poisonous proteins into them. T-cells have various mechanisms built into them that prevent them from damaging normal cells, among which is a protein called PD-1 receptor, which is expressed on the surface of T-cells. The most important signaling protein that could engage PD-1 is called PD-L1, which binds the PD-1 receptor and sends an inhibitory signal inside the T-cell, stopping it from making more poisonous proteins and killing the cells sending the signal via PD-L1 and other cells nearby. Many types of cancer cells have hijacked the PD-L1 expression system that normally exists in healthy cells. By expressing PD-L1, cancer cells protect themselves from being killed by cytotoxic T-cells. BGB-A317 is a monoclonal antibody designed to specifically bind to PD-1, thereby preventing PD-L1 from engaging PD-1. Therefore, we believe BGB-A317 has the potential to restore the cytotoxic T-cell's ability to kill cancer cells. BGB-A317 belongs to a class of agents known as immune checkpoint inhibitors which are currently the most important part of a new type of anti-cancer treatment called immuno-oncology therapy.

### *Market Opportunity*

Forecasts of the market for monotherapy PD-1 and PD-L1 antibodies have increased as new tumor types responding to these antibodies have been identified and data has accumulated regarding their potential efficacy. It is estimated that these inhibitors will reach sales of approximately \$13 billion by 2023 across seven major markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan).

Tumor types that have been shown to be responsive to a PD-1 antibody include several types that are common in China. These include lung, gastric and liver cancers, for which an estimated 37%, 45% and 53% of the worldwide annual incidence in 2012, respectively, was in China, according to the World Health Organization. To our knowledge, BGB-A317 is the first PD-1 antibody developed in China to enter clinical trials. Due to a distinct regulatory pathway for drug candidates manufactured in China, we believe that BGB-A317 will become an important participant in China's PD-1 antibody and immuno-oncology market.

### *Current Therapies and Limitations*

Clinical trials of several monotherapy PD-1 and PD-L1 inhibitory antibodies have shown a signal of efficacy in a wide spectrum of cancers, including melanoma, lung cancer, kidney cancer,

head and neck cancer, bladder cancer, gastric cancer, ovarian cancer, Hodgkin's lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, a subtype of breast cancer known as triple-negative breast cancer, and a subtype of colorectal and other cancers having mismatch repair deficiency. Two such PD-1 monotherapy antibodies, nivolumab and pembrolizumab, have been approved by the FDA for treating certain patients with metastatic melanoma and, in the case of nivolumab, non-small cell lung cancer.

Monotherapy PD-1 and PD-L1 antibodies have demonstrated objective responses against these tumors that can be rapid and in most cases durable. In addition, these agents can be effective against large tumors. In some tumors, including squamous and non-squamous non-small cell lung cancer, renal cell carcinoma and melanoma, randomized Phase 3 trials conducted by third parties have demonstrated superior overall survival of PD-1 antibodies compared to standard care including chemotherapy. Although some distinct toxicities associated with PD-1 and PD-L1 antibodies, overall, they have been remarkably well-tolerated.

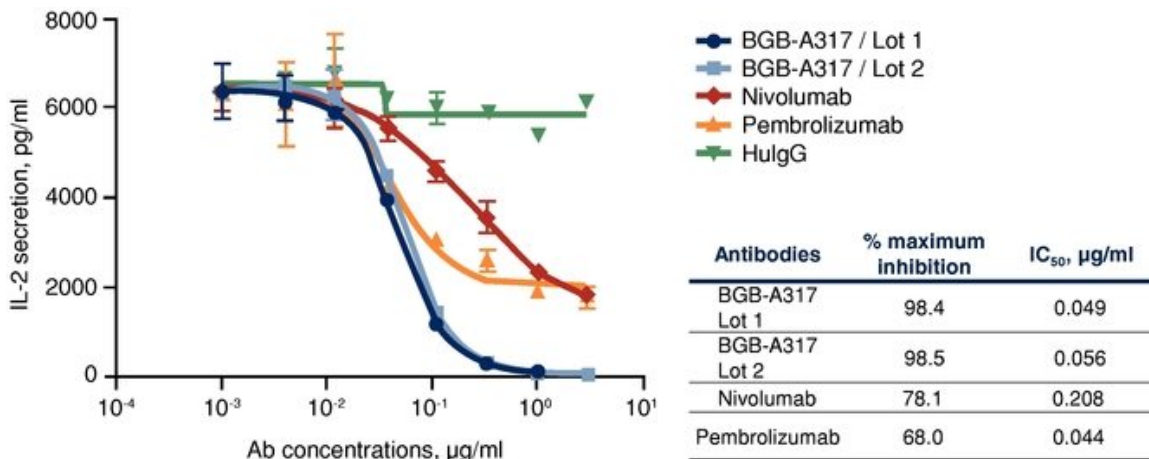
Objective responses to monotherapy PD-1 antibodies have only been seen in a minority of patients in nearly all tumor types tested with the exception of a small population of blood cancer patients with Hodgkin's lymphoma and a selected subpopulation of solid tumor patients with mismatch repair deficiency. Combination therapy with a PD-1 or PD-L1 antibody as a backbone is being explored with a wide variety of agents by the industry and clinical investigators.

*Potential Advantages of BGB-A317*

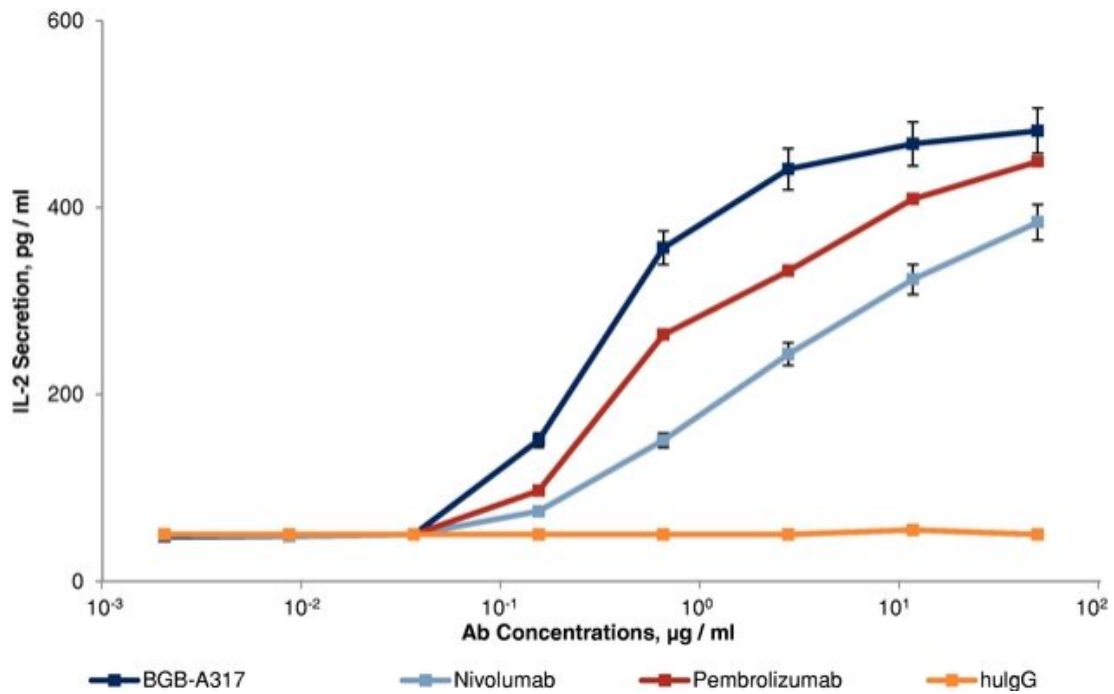
We believe that having BGB-A317 in addition to our multiple clinical-stage drug candidates puts us in a strong competitive position. Based on our preclinical data, we believe a strong rationale exists for combining BGB-A317 with our drug candidates BGB-3111, BGB-283 and BGB-290. In addition, we are developing several immuno-oncology candidates that we intend to combine with BGB-A317.

We believe BGB-A317 is differentiated from the currently approved PD-1 antibodies with the ability to bind Fc  $\gamma$  RI, 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. BGB-A317 showed better cellular functional activities in blocking PD-1 mediated reverse signal transduction and in activating human T-cells and primary PBMCs, as shown in the figures below.

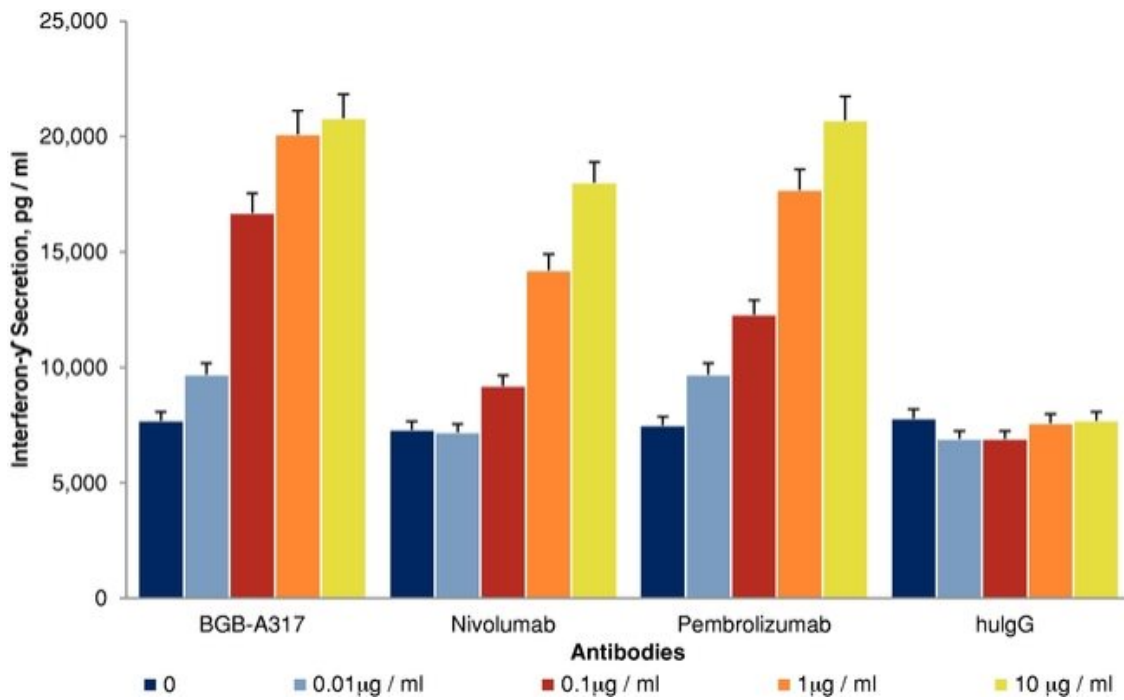
**BGB-A317 showed differential inhibition to PD-1 signaling in co-culture assays using engineered human T-cell line as the signal-sensing cell**



**BGB-A317 activates human T-cells in presence of signal-initiating cells in the co-culture assay as measured by IL-2 secretion**



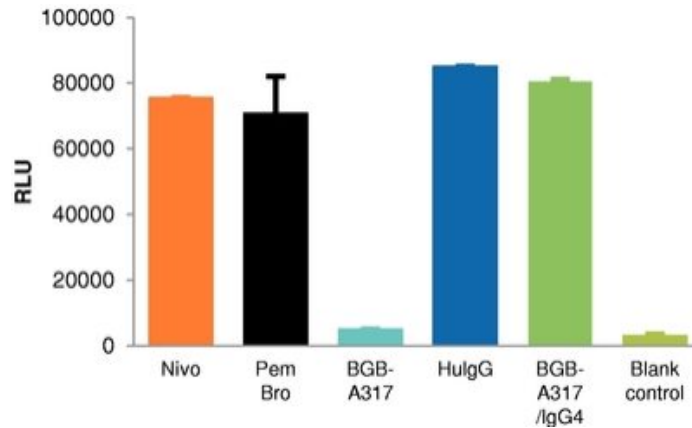
**BGB-A317 activates human PBMCs in presence of signal-initiating cells in the co-culture assay as measured by IFN-γ secretion**



BGB-A317 has displayed significant differentiation in CDR sequences and key binding epitopes on PD-1. BGB-A317 has also displayed cell biology differentiation in lack of Fc receptor

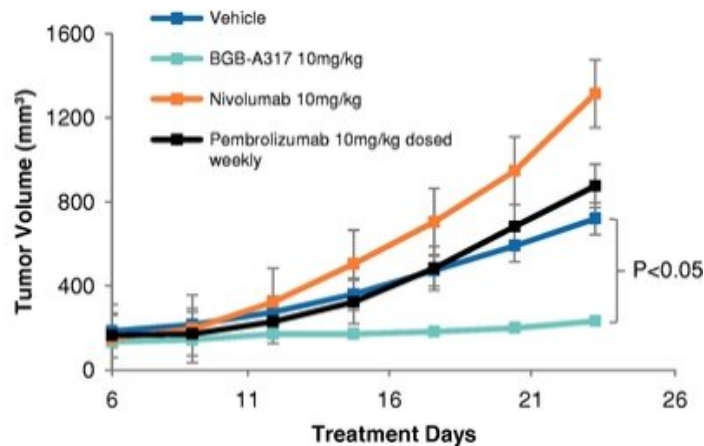
binding, which was recently shown to have a negative effect on the activity of PD-1 antibodies. BGB-A317 is differentiated from the currently approved PD-1 antibodies, nivolumab and pembrolizumab, in Fc  $\gamma$  RI mediated effector function. The human IgG4 antibody is well-known to bind the high-affinity Fc  $\gamma$  RI. As shown in the figure below, both nivolumab and pembrolizumab bind to Fc  $\gamma$  RI expressed on HEK293 cells that are easily detected by fluorescent antibody. In contrast, BGB-A317 has no binding to Fc  $\gamma$  RI. When the constant region of BGB-A317 was switched to the same IgG4S228P antibody as that of nivolumab and pembrolizumab, the resulting BGB-A317/IgG4S228P binds to Fc  $\gamma$  RI equally as well as nivolumab and pembrolizumab. A recent paper as well as our unpublished data show that in preclinical models Fc  $\gamma$  RI binding may compromise the activity of PD-1 antibodies.

**Comparison of Fc  $\gamma$  RI-binding activities by different PD-1 antibodies assayed by cell-based binding followed by fluorescent signal detection**



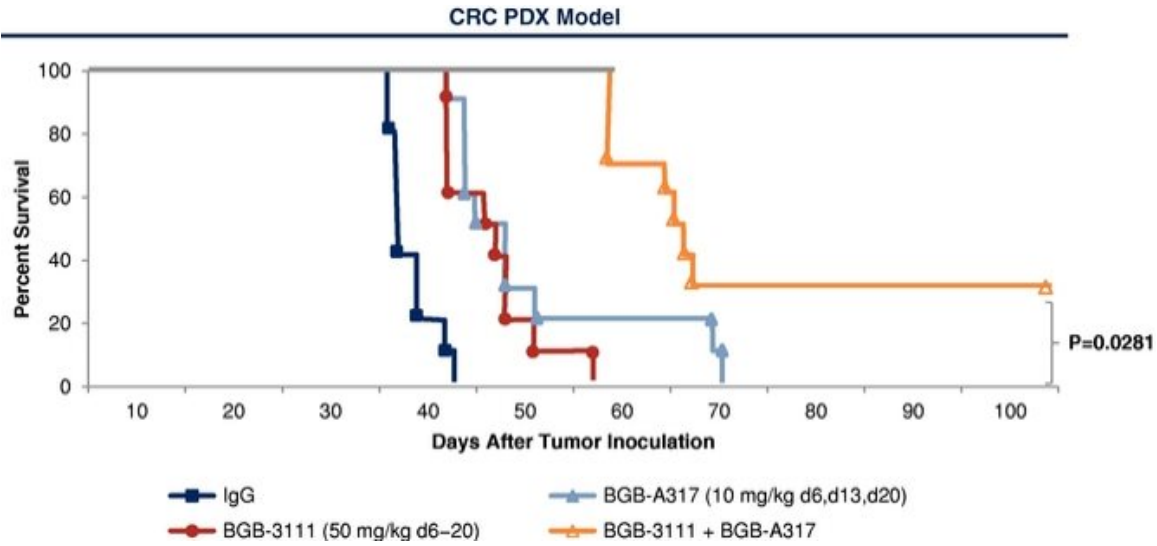
We compared the anti-cancer activity of BGB-A317 with other PD-1 antibodies in an *in vivo* mouse cancer model in which the mice bearing human cancer cells A431 and PBMCs were treated with BGB-A317, nivolumab, pembrolizumab or a vehicle using the same dose regimen. The results demonstrated that BGB-A317 significantly inhibited the tumor growth, while nivolumab and pembrolizumab did not reduce tumor growth in this model as shown in the following figure.

**Comparison preclinical efficacy of BGB-A317 with currently approved PD-1 antibodies in an *in vivo* mouse tumor model**



Combination with BGB-3111

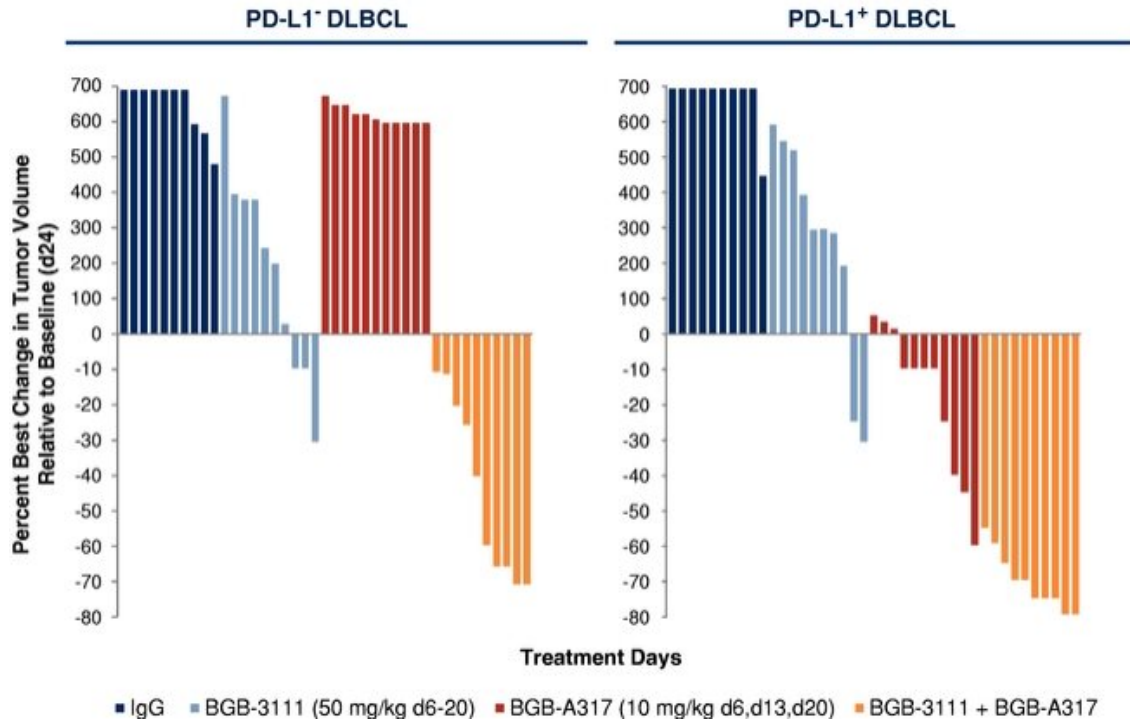
We have explored the combination activity of BGB-3111 and BGB-A317 in both solid tumor and blood tumor preclinical models. In these models, human primary tumor fragments and immune cells from the same donor were co-injected into immune-deficient mice. The mice were then treated with BGB-3111 and BGB-A317 and their tumor growth and survival were followed. In the colorectal primary tumor model, shown in the figure below, the combination of BGB-3111 and BGB-A317 significantly prolonged survival.



We also explored the combination of BGB-3111 and BGB-A317 in two diffuse large B-cell lymphoma primary tumor models. In both models, BGB-3111 showed weak monotherapy activity. When used as a monotherapy BGB-A317 was only active in the PD-L1 positive tumor. However, the combination of BGB-3111 and BGB-A317 was highly active, better than either monotherapy, and induced tumor regression in both PD-L1 positive and PD-L1 negative models.



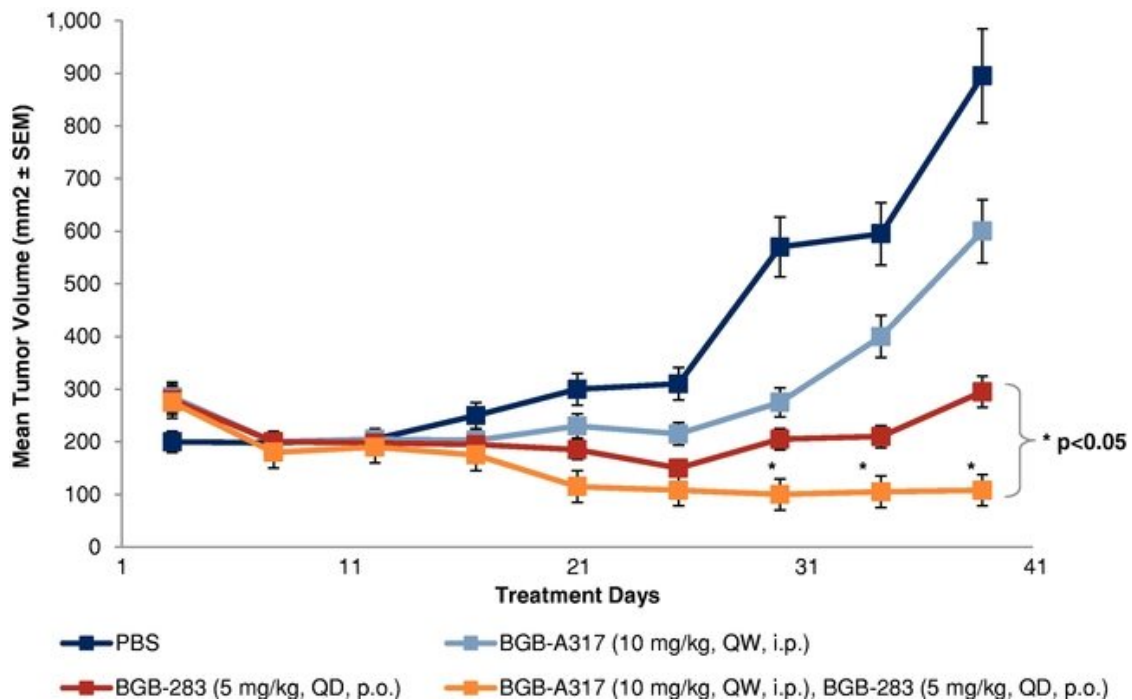
Improved activity for the combination of BGB-A317 and BGB-3111 in diffuse large B-cell lymphoma models



Combination with BGB-283

We tested the combination activity of BGB-283 and BGB-A317 in a mouse cancer model in which a human lung cancer cell line with KRAS mutation was engrafted. As shown in the figure below, the synergistic efficacy of BGB-283 and BGB-A317 is clearly demonstrated by the tumor growth curves. The tumor in the combination-treated group is significantly smaller than either of the monotherapy treatment.

## Improved activity for the combination of BGB-317 and BGB-283 in a KRAS lung cancer model



## Summary of Clinical Trials

In June 2015, BGB-A317 entered the dose-escalation phase of our multi-center, open-label trial for safety and toxicology evaluation in patients with advanced solid tumors. Clinical sites are active or being established in Australia and New Zealand, and we intend to open at least one site in the United States now that we have an IND in effect with the FDA. The Safety Monitoring Committee of the trial has cleared for testing each of the four initial dose levels (0.5, 2, 5 and 10 mg/kg every two weeks), and the 2 and 5 mg/kg every-two-week or every-three-week dose cohorts, or schedule-expansion cohorts, are being expanded with 10 to 20 patients each. We have dosed a total of 73 patients as of January 15, 2016 in four dose-escalation cohorts at 0.5, 2, 5 and 10 mg/kg dosing levels and in schedule-expansion cohorts at 2 and 5 mg/kg dosing levels, and we are rapidly enrolling new patients. To date, BGB-A317 has been well-tolerated with a favorable safety profile. One patient receiving the 5 mg/kg dose developed grade 3 immune-related colitis which was considered a dose-limiting toxicity and a drug-related serious adverse event. As of January 15, 2016, investigators have reported six drug-related serious adverse events, including two cases of grade 3 immune-related colitis (including the patient with dose-limiting toxicity noted above), one case of grade 3 autoimmune diabetes and one case of grade 3 diabetic ketoacidosis (occurring in the same patient), one case of grade 3 hypotension, and one case of grade 2 infusion reaction. The enrolled patient population included patients with a wide range of tumor types (more than 20) and a majority of the patients have cancers that have not been shown to respond to PD-1 or PD-L1 antibodies. There were no patients with melanoma or lung cancer, two of the indications for which PD-1 antibodies have received approvals, and patients with renal cell carcinoma, the third approved indication for PD-1 antibodies, represented a small portion (approximately 10%) of the enrolled patients. In addition, efficacy assessment is early with a large number of patients who have not had a computerized tomography scan. While efficacy data are preliminary, signals of BGB-A317's activity have been observed with significant objective tumor shrinkage qualifying for unconfirmed partial responses or confirmed partial responses based on the RECIST 1.1 criteria reported by investigators for a small number of patients. We plan to enroll approximately 84

patients in the dose-escalation phase of the trial, including schedule-expansion cohorts at 2 and 5 mg/kg dosing levels and potentially dose up to 200 patients in the dose-expansion phase of our clinical trial to reach proof-of-concept in tumor types known to respond to PD-1 antibodies and to explore potential differentiation in tumor types that, to date, have been insensitive or resistant to PD-1 blockade.

Once we have established a favorable safety profile of BGB-A317 in the clinic, we plan to combine BGB-A317 with our other drug candidates, including BGB-3111, BGB-283 and BGB-290, in targeted tumors and patient populations. These targets include RAF/RAS mutated cancer such as colorectal cancers, pancreatic cancer and non-small cell lung cancer for the BGB-283 combination and B-cell malignancies and select solid tumors for the BGB-3111 combination. On February 2, 2016, we initiated a Phase 1 clinical trial with BGB-290 in combination with BGB-A317 for the treatment of cancers with mutations in the breast cancer susceptibility gene (BRCA) or deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal, and pancreatic cancers, as well as platinum-sensitive ovarian cancer.

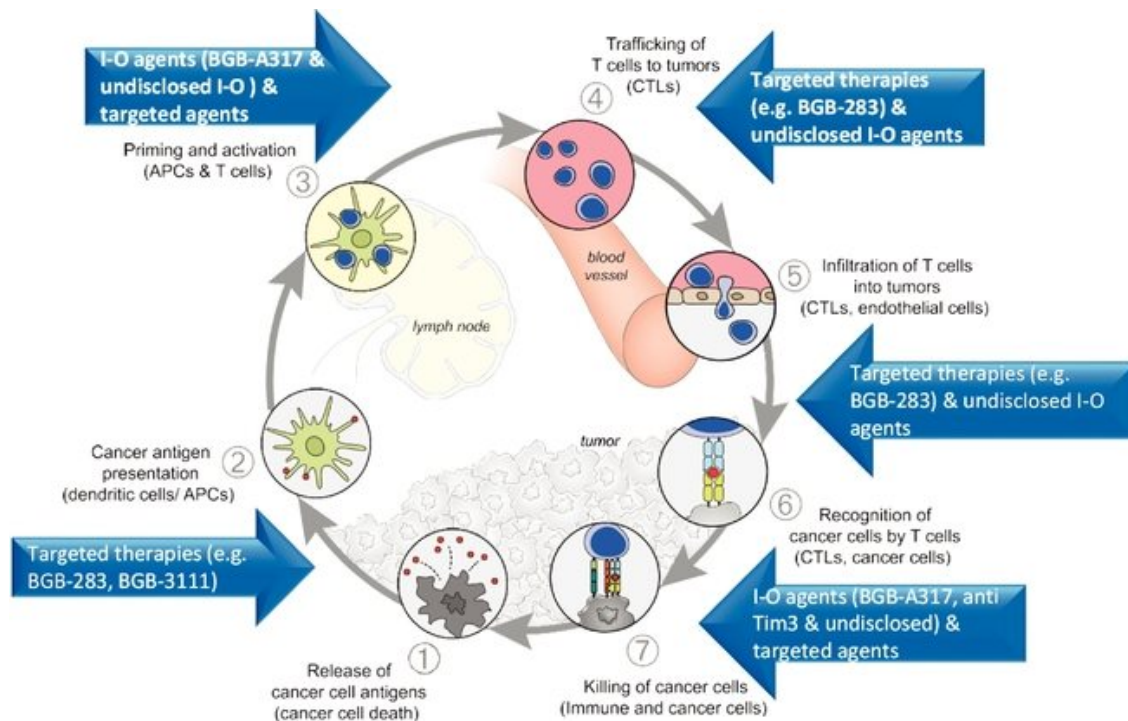
We plan to focus development programs on Asia-prevalent tumors including liver, gastric, esophageal, and lung cancers. In China, we believe we have the opportunity to supplement global enrollment in high-incidence cancers in China. In addition, we believe we have opportunities for an accelerated registration path in China given the high unmet needs.

We plan to present the data from the dose-escalation phase of our clinical trial at a medical conference in 2016. We also plan to present data from the dose-expansion phase of our clinical trial potentially starting in 2016. We plan to initiate our combination trials in 2016.

### ***Preclinical Assets***

Our preclinical pipeline currently consists of targeted therapies and immuno-oncology agents including a PD-L1 monoclonal antibody, an additional RAF dimer inhibitor, a TIM-3 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 18 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. We also seek to develop companion diagnostics that will help identify patients that are most likely to benefit from the use of our drug candidates.

**Combination opportunities with our pipeline portfolio to target the cancer immunity cycle**



Source: Adapted from Chen & Mellman, *Immunity* (2013)

**Intellectual Property**

The proprietary nature of, and protection for, our drug candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. We have obtained a U.S. patent and filed patent applications in the United States and other countries relating to certain of our drug candidates, and are pursuing additional patent protection for them and for other of our drug candidates and technologies. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection including our manufacturing processes.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for our product candidates and other commercially important products, technologies, inventions and know-how, as well as on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and support our development programs.

As of December 31, 2015, we own two issued U.S. patents and ten pending U.S. patent applications as well as corresponding patents and patent applications internationally. In addition, we own six 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. For example, in the United States, we can apply for a patent term extension of up to five years for one of the patents covering a product once the

product is approved by the FDA. The exact duration of the extension depends on the time we spend in clinical studies as well as getting a new drug application approval from the FDA. The patent portfolios for our four leading product candidates as of December 31, 2015 are summarized below.

**BGB-3111**

We own three pending U.S. patent applications and corresponding patent applications in other jurisdictions directed to BGB-3111, a small molecule BTK inhibitor, and its use for the treatment of hematological malignancies. Any patents that may issue from the currently pending U.S. patent applications would be expected to expire in 2034. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries

**BGB-283**

We own one pending U.S. patent application and one pending PCT application directed to BGB-283, a small molecule BRAF inhibitor, and its use for the treatment of cancer, including BRAF mutated cancers. We also own pending patent applications in other jurisdictions corresponding to the U.S. patent application. In addition, we plan to file nationally in the U.S. and other jurisdictions based on the pending PCT application. Any patent that may issue from the currently pending U.S. patent application would be expected to expire in 2031. If a U.S. application is filed based on the pending PCT application, a patent issuing from that application, if any, would be expected to expire in 2035. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

**BGB-290**

We own one pending U.S. patent application and one pending PCT application directed to BGB-290, a small molecule PARP1/2 inhibitor, and its use for the treatment of cancer, including glioblastomas and breast cancer. We also own the corresponding pending patent applications in other jurisdictions. Any patent that may issue from the currently pending U.S. patent application would be expected to expire in 2031. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

**BGB-A317**

We are the owner of one issued U.S. patent, one pending U.S. application, and corresponding pending patent applications in other jurisdictions directed to BGB-A317, a humanized monoclonal antibody against PD-1, and its use for the treatment of cancer. The expected expiration for the issued U.S. patent is 2033, excluding any additional term for patent term extensions. Any patent that may issue from the currently pending U.S. patent application would be expected to expire in 2033. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file including the United States, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. However, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval.

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

Furthermore, the patent positions of biotechnology and pharmaceutical products and processes like those we intend to develop and commercialize are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date in the United States. The scope of patent protection outside the United States is even more uncertain. Changes in the patent laws or in interpretations of patent laws in the United States and other countries may diminish our ability to protect our inventions, and enforce our intellectual property rights and more generally, could affect the value of intellectual property.

Additionally, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in patents owned by others. Substantial scientific and commercial research has been conducted for many years in the areas in which we have focused our development efforts, which has resulted in other parties having a number of issued patents and pending patent applications relating to such areas. Patent applications in the United States and elsewhere are generally published only after 18 months from the priority date, and the publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patents and patent applications relating to drugs similar to our current drug candidates and any future drugs, discoveries or technologies we might develop may have already issued or been filed, which could prohibit us from commercializing our product candidates. Specifically, we are aware of certain U.S. patents owned by Ono Pharmaceutical Co. and licensed to Bristol-Myers Squibb Co., that are relevant to our BGB-A317 drug candidate. We are also aware of a U.S. patent owned by Pharmacyclics, Inc., which was acquired by AbbVie Inc., that is relevant to our BGB-3111 drug candidate, and certain U.S. patents owned or licensed by KuDOS Pharmaceuticals, Ltd., which was acquired by AstraZeneca PLC, that are relevant to our BGB-290 drug candidate. For more information, see "Risk Factors—Risks Related to Our Intellectual Property."

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drug candidates and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from others will result in the issuance of any patents. The issued patents that we own or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

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

systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of other parties. The issuance of any patent by others with claims covering or related to aspects of our product candidates would require us to alter our development or commercial strategies, redesign our drug candidates or processes, obtain licenses or cease certain activities. Such licenses may not be available on reasonable commercial terms or at all, which could require us to cease development or commercialization of our product candidates. In addition, our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our drug candidates would have a material adverse impact on us. If others have prepared and filed patent applications in the United States that also claim technology to which we have filed patent applications, we may have to participate in interference, derivation or other proceedings in the USPTO to determine issues such as priority of claimed invention or validity of such patent applications as well as our own patent applications and issued patent.

For more information on these and other risks related to intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Additionally, we currently use a number of unregistered trademarks and are seeking trademark protection in jurisdictions where available and appropriate. We currently have applications pending in China for BeiGene, and our corporate logo.

## **Collaboration with Merck KGaA**

### ***BGB-283***

On May 24, 2013, we entered into license agreements with Merck KGaA, which we amended and restated on December 10, 2013 and which we refer to respectively as the Ex-PRC BRAF Agreement and PRC BRAF Agreement. On October 1, 2015 and December 3, 2015, we further amended the Ex-PRC BRAF Agreement. Pursuant to the Ex-PRC BRAF Agreement and PRC BRAF Agreement (a) we granted to Merck KGaA an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA exercises its Continuation Option (described below), to commercialize and manufacture our compound BGB-283, and any other compound covered by the same existing patent rights with primary activity to inhibit wildtype or certain mutant BRAF, or the Licensed BRAF Inhibitors, in all countries of the world excluding The People's Republic of China, which we refer to as the Ex-PRC Territory, and (b) Merck KGaA granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the Licensed BRAF Inhibitors in The People's Republic of China, which we refer to as the PRC Territory, subject to the non-compete restrictions discussed below.

Under the Ex-PRC BRAF Agreement, Merck KGaA has the option to continue such agreement and obtain the exclusive commercialization rights described above in the Ex-PRC Territory, which we refer to as the Continuation Option, by notifying us of such election within 60 days (depending on whether we choose to conduct certain pre-specified Phase 1 clinical trials outside of China) following Merck KGaA's receipt of the final results reports for the last of certain pre-specified Phase 1 clinical trials that we have retained the responsibility to perform. If Merck KGaA exercises its Continuation Option, it will pay us a continuation fee based on the costs of conducting the relevant trials, subject to a certain cap. If Merck KGaA does not exercise its Continuation Option, the Ex-PRC BRAF Agreement will terminate in its entirety except for certain provisions that will survive the termination. We have agreed to use commercially reasonable efforts to conduct certain pre-specified Phase 1 clinical trials.



Further, pursuant to the PRC BRAF Agreement, Merck KGaA has an exclusive right of first negotiation to expand its exclusive rights granted under the Ex-PRC BRAF Agreement to include the PRC Territory on terms to be mutually agreed in the event we seek to license our intellectual property rights to a third party therein. In addition, if we undergo a change of control and the Ex-PRC BRAF Agreement is still in effect, Merck KGaA has the right to do the same in exchange for pre-specified additional milestone payments for certain clinical events in the PRC Territory, but with other financial terms to be mutually agreed.

Under the Ex-PRC and PRC BRAF Agreements, we received \$13 million in non-refundable payments in December 2013 following their execution. As of September 30, 2015, we have received \$5 million in milestone payments. We are additionally eligible to receive up to \$32 million, \$33 million and \$145 million, respectively, in payments upon the successful achievement of pre-specified clinical, regulatory and commercial milestones in the Ex-PRC Territory, and another \$18 million in payments upon the successful achievement of pre-specified clinical milestones in the PRC Territory. Merck KGaA also is required to pay us tiered royalties ranging from the mid single-digit to the low-teens, on a country-by-country and Licensed BRAF Inhibitor-by-Licensed BRAF Inhibitor basis, on aggregate net sales of Licensed BRAF Inhibitors in the Ex-PRC Territory.

In consideration for the licenses Merck KGaA grants to us under the PRC BRAF Agreement, we are required to pay Merck KGaA a high single-digit royalty on aggregate net sales of Licensed BRAF Inhibitors in the PRC Territory.

During the term of the Ex-PRC BRAF Agreement, we and our affiliates have agreed not to, alone or with a third-party partner, develop, manufacture, use or sell (i) a product containing a Licensed BRAF Inhibitor in the Ex-PRC Territory or (ii) a product containing a Licensed BRAF Inhibitor other than BGB-283 in the PRC Territory. For clarity, we have retained the rights to develop, manufacture, use or sell any product containing BGB-283 in the PRC Territory. In addition to the rights we have retained for BGB-283 in the PRC Territory (subject to the above Merck KGaA rights), we and our affiliates have retained the ability to develop and commercialize anywhere in the world any compounds that are not the Licensed BRAF Inhibitors, for any use including as inhibitors of wildtype or mutant BRAF.

The term of the Ex-PRC BRAF Agreement continues on a country-by-country and product-by-product basis until the last to expire of Merck KGaA's payment obligations to us, unless terminated earlier by either party, and the PRC BRAF Agreement continues unless terminated as permitted by either party. Under each agreement, Merck KGaA has the right to terminate due to our uncured breach or voluntarily upon prior written notice, and Merck KGaA also has a right of first refusal to purchase our interest in the Licensed BRAF Inhibitors (and solely related intellectual property rights) in case of our insolvency and a third party has made an offer to acquire the same. We have the right to terminate these agreements due to Merck KGaA's uncured breach or for any challenge brought against our licensed patent rights.

#### **BGB-290**

On October 28, 2013, we entered into license agreements with Merck KGaA, which we refer to respectively as the Ex-PRC PARP Agreement and the PRC PARP Agreement, pursuant to which (a) we granted to Merck KGaA an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA exercises a certain continuation option, to commercialize and manufacture our compound BGB-290 and any other compound covered by the same existing patent rights with primary activity to inhibit PARP 1, 2 or 3 enzymes, or the Licensed PARP Inhibitors, in the Ex-PRC Territory, and (b) Merck KGaA granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the Licensed PARP Inhibitors in the PRC Territory. On October 1, 2015, pursuant to a purchase of rights agreement, we repurchased all of Merck KGaA's rights under the Ex-PRC PARP Agreement, in



consideration for, among other things, a one-time payment of \$10 million and reduction of future milestone payments we are eligible for under the PRC PARP Agreement. In connection with such repurchase, we also agreed to provide Merck KGaA with global access to our clinical PARP supplies, including BGB-290, for its combination trials, during the certain option period. The Ex-PRC PARP Agreement was terminated, except for certain provisions therein that are needed to effectuate the continuation of the PRC PARP Agreement, including those provisions that are required in the event that Merck KGaA exercises its PRC Commercialization Option (described below).

Pursuant to the PRC PARP Agreement, if we fail to achieve national priority project status in the PRC Territory under its 12<sup>th</sup> or 13<sup>th</sup> five-year plan with respect to our BGB-290 PARP program in the PRC Territory by July 28, 2017, Merck KGaA can exercise its option to acquire exclusive commercialization rights under the BGB-290 PARP program in the PRC Territory, which we refer to as the PRC Commercialization Option. If, however, we do achieve such event by such time, Merck KGaA only has a right of first negotiation to acquire exclusive commercialization rights under the BGB-290 PARP program in the PRC Territory in the event we seek to license our intellectual property rights to a third party therein.

Under the Ex-PRC and PRC PARP Agreements, we received \$6 million in non-refundable payments in November 2013 following their execution and \$9 million in milestone payments in 2014. We are eligible to receive up to \$7 million and \$2.5 million, respectively, in payments upon the successful achievement of pre-specified clinical and regulatory milestones in the PRC Territory. In addition, if Merck KGaA exercises the PRC Commercialization Option, Merck KGaA is required to pay us a \$50 million non-refundable payment upon such exercise, and we are eligible for a \$12.5 million milestone payment upon the successful achievement of a certain additional regulatory event in the PRC Territory.

Under the PRC PARP Agreement, in consideration for the licenses granted to us, we are required to pay Merck KGaA a high single-digit royalty on aggregate net sales of Licensed PARP Inhibitors in the PRC Territory.

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

### **Competition**

Our industry is highly competitive and subject to rapid and significant change. While we believe that our development and commercialization experience, scientific knowledge and industry relationships provide us with competitive advantages, we face competition from pharmaceutical, medical device and biotechnology companies, including specialty pharmaceutical companies, and generic drug companies, academic institutions, government agencies and research institutions.

#### ***BGB-3111 Competition***

We are developing BGB-3111, a highly selective small molecule covalent BTK inhibitor, for a variety of B-cell malignancies, either as a monotherapy or in combination with other therapies.

Janssen/AbbVie's ibrutinib (IBRUVICA) is one of the currently approved drugs used for the treatment of B-cell malignancies, including patients with mantle cell lymphoma who have received at least one prior therapy, patients with chronic lymphocytic leukemia who have received at least one prior therapy, and chronic lymphocytic leukemia patients with 17p deletion. It has also recently been approved by the FDA for the treatment of Waldenström's Macroglobulinemia.

There are multiple ongoing Phase 3 trials for ibrutinib as a monotherapy or in combination with chemotherapeutics or target therapeutics in various B-cell malignancies, including chronic

lymphocytic leukemia, mantle cell lymphoma, Waldenström's Macroglobulinemia, follicular lymphoma, diffuse large B-cell lymphoma and marginal zone lymphoma. In addition, we are aware of other BTK inhibitors in clinical development for oncology indications, including Celgene's CC-292 currently in Phase 2 trials, Ono/Gilead's Ono-4059 currently in Phase 1 trials, and Acerta's ACP-196 currently in Phase 3 trials.

#### ***BGB-283 Competition***

We are developing BGB-283 as either a monotherapy or in combination with other cancer therapies for the treatment of cancers with aberrations in the MAPK pathway including BRAF mutations and KRAS/NRAS mutations. We intend to develop BGB-283 in various malignancies, including melanoma, papillary thyroid carcinoma, colorectal cancers and non-small-cell lung carcinoma.

Roche's vemurafenib (Zelboraf) and Novartis' dabrafenib (Tafinlar) are two of the currently approved BRAF inhibitors for treating late-stage BRAF V600E/K mutant melanoma. In addition, the combination of dabrafenib and GSK's trametinib (Mekinist), an MEK inhibitor, is approved in patients with BRAF V600E/K mutation-positive metastatic melanoma. We are aware of several other BRAF inhibitors in clinical development targeting BRAF V600E/K mutated cancers including melanoma, non-small-cell lung cancer, hairy cell leukemia and thyroid cancer. These BRAF inhibitors include Array Biopharma's encorafenib (LGX818), currently in Phase 3 trials, and Takeda MLN-2480 (BIIB-024) and Eli Lilly's LY3009120, both in Phase 1 trials.

#### ***BGB-290 Competition***

AstraZeneca's Olaparib (LYNPARZA) is approved by the FDA for treating patients with deleterious or suspected deleterious germline BRCA mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. It is approved by the EMA as a maintenance treatment for patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response or partial response to platinum-based chemotherapy.

There are a number of companies with ongoing clinical trials, including AstraZeneca, Abbott, Clovis Oncology, Tesaro and BioMarin. AstraZeneca's olaparib has been approved in gBRCAm ovarian cancer and is currently in Phase 3 trials for treatment of gBRCAm breast cancer, gastric cancer, gBRCAm pancreatic cancer and other cancers with sBRCAm or homologous recombinant repair associated genetic mutations. Abbott's veliparib, in combination with other compound(s), is currently in Phase 3 trials for treatment of non-small-cell lung cancer, breast, ovarian cancers and glioblastoma multiforme. Clovis Oncology's rucaparib is currently in Phase 3 trials as a maintenance treatment in patients with platinum-sensitive, high-grade serous or endometrioid epithelial ovarian, primary peritoneal or fallopian tube cancer, Tesaro's niraparib is currently in Phase 3 trials for platinum-sensitive ovarian cancer and gBRCAm breast cancer, and BioMarin's talazoparib is currently in Phase 3 trials for BRCAm breast cancer.

#### ***BGB-A317 Competition***

Two anti-PD-1 monoclonal antibody drugs, Merck's pembrolizumab (Keytruda) and BMS's nivolumab (Opdivo), have been recently approved by the FDA for advanced melanoma patients who have failed other treatment, including ipilimumab and vemurafenib. Nivolumab has also been approved for advanced non-small-cell lung cancer patients.

There are a number of companies with ongoing clinical trials involving an anti-PD-1 or anti-PD-L1. Three anti-PD-L1 antibody drugs, Roche's Atezolizumab, AstraZeneca/Celgene's MEDI4736 and Pfizer/Merck Serono's Avelumab, together with anti-PD-1 antibodies, Merck's pembrolizumab, Bristol-Myers Squibb's nivolumab and Medivation/CureTech pidilizumab, are currently engaged in a

number of Phase 2/3 trials, for treatment of multiple cancers, including non-small-cell lung cancer, head and neck squamous cell carcinoma, bladder cancer, triple-negative breast cancer, non-Hodgkin's lymphoma and melanoma. Several new anti-PD-1 antibodies have started Phase 1 trials, including AstraZeneca's MEDI0680, Regeneron's REGN2810 and Novartis' PDR001.

Many of our competitors have significantly greater financial, technical and human resources than we have. Mergers and acquisitions in the pharmaceutical, medical device and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future drug candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our drug candidates. Our success will be based in part on our ability to identify, develop and manage a portfolio of drug candidates that are safer and more effective than competing products.

## **Government Regulation**

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing and export and import of drug products, such as those we are developing. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, disbarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

## **U.S. Regulation**

### ***U.S. Government Regulation and Product Approval***

Government authorities in the United States at the federal, state and local level extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of drug and biological products such as those we are developing. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and biologics under the FDCA, its implementing regulations, and the Public Health Service Act, or PHSA, and its implementing regulations.

### ***U.S. Drug Development Process***

The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product

development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practice, or GCP, to establish the safety and efficacy of the proposed product for its intended use;
- preparation and submission to the FDA of a New Drug Application, or NDA, for a drug, or a Biologics License Application, or BLA, for a biologic;
- a determination by the FDA within 60 days of its receipt of a NDA or BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP; and
- FDA review and approval of the NDA or BLA.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product drug is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or noncompliance, and may be imposed on all products within a certain class of products. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals

participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- **Phase 1.** The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- **Phase 2.** Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- **Phase 3.** Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labelling.

We refer to our Phase 1 program as dose-escalation and dose-expansion trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product drug. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product drug and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product drug does not undergo unacceptable deterioration over its shelf life.

### **U.S. Review and Approval Processes**

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed

labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug or a BLA for a biologic, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of a substantial user fee; although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use, and a BLA to determine whether the biologic is safe, pure, and potent for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA or BLA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA or BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical trials, to further assess a product's safety and effectiveness after NDA or BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA could also approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

## **Regulation of Combination Products in the United States**

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-drug combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

### ***Expedited Programs***

#### ***Fast Track Designation***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs, including biologics, that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug may request the FDA to designate the drug as a Fast Track product concurrently with, or at any time after, submission of an IND, and the FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

In addition to other benefits, such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a Fast Track drug's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA

approves, a schedule for the submission of each portion of the NDA or BLA and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

#### *Accelerated Approval*

Under FDA's accelerated approval regulations, the FDA may approve a drug, including a biologic, for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a marker, such as a measurement of laboratory or clinical signs of a disease or condition that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trials sometimes referred to as Phase 4 trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

#### *Breakthrough Designation*

The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require the FDA to expedite the development and review of a breakthrough therapy. A drug or biologic product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

#### *Priority Review*

Based on results of the Phase 3 clinical trial(s) submitted in a NDA or BLA, upon the request of an applicant, the FDA may grant the NDA or BLA a priority review designation, which sets the target date for FDA action on the application at six months after the FDA accepts the application for filing. Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.



### ***Post-Approval Requirements***

Any products for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. Moreover, each component of a combination product retains their regulatory status (as a drug or biologic, for example) and is subject to the requirements established by the FDA for that type of component. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory requirements, and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our drug candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, untitled or warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

### ***Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review

process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that this review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if available, we intend to apply for restorations of patent term for some of our currently owned patents beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA; however, there can be no assurance that any such extension will be granted to us.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity or patent period, may be granted based on the voluntary completion of a pediatric clinical trial in accordance with an FDA-issued "Written Request" for such a clinical trial.

### ***Biosimilars and Exclusivity***

The Patient Protection and Affordable Care Act signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

### ***Orphan Drugs***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs, including biologics, intended to treat a rare disease or condition—generally a disease or condition that affects 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. Orphan drug designation must be requested before submitting an NDA or BLA.

After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease or condition with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

During the exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease or condition, except in limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product to the product with orphan drug exclusivity through a demonstration of superior safety, superior efficacy, or a major contribution to patient care. "Same drug" means a drug that contains the same identity of the active moiety if it is a drug composed of small molecules, or of the principal molecular structural features if it is composed of macromolecules and is intended for the same use as a previously approved drug, except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug. Drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

### ***Pediatric Information***

Under the Pediatric Research Equity Act of 2003, NDAs, BLAs or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDASIA amended the FDCA to require that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting

information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of FDA-regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

***Pharmaceutical Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list which might not include all of the FDA-approved products for a particular indication. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our drug candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

#### ***Other Healthcare Laws and Compliance Requirements***

If we obtain regulatory approval of our products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. 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, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing 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 executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the federal Physician Payment Sunshine Act, which is part of the Affordable Care Act, that requires applicable manufacturers of covered drugs and biologics to disclose payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific

intent to violate it in order to have committed a violation. In addition, 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 civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

### ***Patient Protection and Affordable Health Care Act***

In March 2010, the Affordable Care Act was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of average manufacturer price, or AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits. The Centers for Medicare & Medicaid Services, or CMS, have proposed to expand Medicaid rebate liability to the territories of the United States as well. In addition, the Affordable Care Act provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this

requirement by the CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.

- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.
- Effective in 2011, the Affordable Care Act imposed a requirement on manufacturers of branded drugs to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the "donut hole").
- Effective in 2011, the Affordable Care Act imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- The Affordable Care Act required pharmaceutical and biologics manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers were required to begin tracking this information in 2013 and to report this information to CMS beginning in 2014. The reported information was made publicly available in a searchable format on a CMS website beginning in September 2014.
- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the Affordable Care Act to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- The Affordable Care Act created the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- The Affordable Care Act established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

## **PRC Regulation**

In the PRC, we operate in an increasingly complex legal and regulatory environment. We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This

section summarizes the principal PRC laws, rules and regulations relevant to our business and operations.

### ***General Regulations on China Food and Drug Administration***

In the PRC, the China Food and Drug Administration, or CFDA, monitors and supervises the administration of pharmaceutical products, as well as medical devices and equipment. The CFDA's primary responsibility includes evaluating, registering and approving new drugs, generic drugs, imported drugs and traditional Chinese medicines; approving and issuing permits for the manufacture, export and import of pharmaceutical products and medical appliances; approving the establishment of enterprises for pharmaceutical manufacture and distribution; formulating administrative rules and policies concerning the supervision and administration of food, cosmetics and pharmaceuticals; and handling significant accidents involving these products. The local provincial drug administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions.

The PRC Drug Administration Law promulgated by the Standing Committee of the National People's Congress in 1984 and the Implementing Measures of the PRC Drug Administration Law promulgated by the Ministry of Health, or the MOH, in 1989 set forth the legal framework for the administration of pharmaceutical products, including the research, development and manufacturing of drugs.

The PRC Drug Administration Law was revised in December 2001 and again in April 2015. The purpose of the revisions was to strengthen the supervision and administration of pharmaceutical products and to ensure the quality and safety of those products for human use. The revised PRC Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products. It regulates and prescribes a framework for the administration of pharmaceutical preparations of medical institutions and for the development, research, manufacturing, distribution, packaging, pricing and advertisement of pharmaceutical products. Revised Implementing Measures of the PRC Drug Administration Law promulgated by the State Council took effect in September 2002, providing detailed implementing regulations for the revised PRC Drug Administration Law.

Under these regulations, we need to follow related regulations for preclinical research, clinical trials and production of new drugs.

### ***Good Laboratories Practice Certification for Preclinical Research***

To improve the quality of preclinical research, the CFDA promulgated the Administrative Measures for Good Laboratories Practice of Preclinical Laboratory in 2003 and began to conduct the certification program of Good Laboratories Practice, or the GLP. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice, or CFDA Circular 214, providing that the CFDA is responsible for certification of preclinical research institutions. Under CFDA Circular 214, the CFDA decides whether an institution is qualified for undertaking pharmaceutical preclinical research upon the evaluation of the institution's organizational administration, its research personnel, its equipment and facilities and its operation and management of preclinical pharmaceutical projects. If all requirements are met, a GLP Certification will be issued by the CFDA and the result will be published on the CFDA's website.

Currently for all our ongoing projects, we cooperated with CFDA certified GLP laboratories operated by Wuxi AppTec (Suzhou) Co., Ltd. and JOINN Laboratories (Beijing) to conduct the studies following GLP based on CFDA requirements.



## **Approval for Clinical Trials and Production of New Drugs**

According to the Provisions for Drug Registration promulgated by the CFDA in 2007, Drug Administration Law promulgated and amended by the Standing Committee of the National People's Congress in 2015, Circular on Regulations for Special Approval on New Drug Registration issued by the CFDA in 2009, and Circular on Information Publish Platform for Pharmaceutical Clinical Trials issued by the CFDA in 2013, we must comply with the following procedures and obtain several approvals for clinical trials and production of new drugs.

### *Clinical Trial Application*

Upon completion of its preclinical research, a research institution must apply for approval of a Clinical Trial Application before conducting clinical trials.

### *Special Examination and Approval for Domestic Category 1 Pharmaceutical Products*

#### Domestic Category 1 New Drugs Are Eligible for Special Examination and Approval

According to Provisions for Drug Registration promulgated by the CFDA in 2007, drug registration applications are divided into three different types, namely Domestic New Drug Application, Domestic Generic Drug Application, and Imported Drug Application. Drugs fall into one of three categories, namely chemical medicine, biological product, or traditional Chinese or natural medicine. A Category 1 drug is a new drug that has never been marketed in any country. All of our clinical-stage drug candidates qualify as domestic Category 1 new drugs.

According to Provisions on the Administration of Special Examination and Approval of Registration of New Drugs, or the Special Examination and Approval Provisions promulgated by the CFDA in July 2009, the CFDA conducts special examination and approval for new drugs registration application when:

- (1) the chemical raw material medicines as well as the preparations and biological products thereof haven't been approved for marketing home and abroad;
- (2) the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinic treatment; or
- (3) the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval Provisions provide that the applicant may file for special examination and approval at the stage of Clinical Trial Application if the drug candidate falls within item (1). The provisions provide that for drug candidates that fall within items (2) or (3), the application for special examination and approval must be made when filing for production.

We believe that BGB-3111, BGB-283, BGB 290 and BGB-A317 fall within items (1) and (2) above. Therefore, we may file an application for special examination and approval at the Clinical Trial Application stage, which may enable us to pursue a more expedited path to approval in China and bring therapies to patients more quickly.

#### The Advantages of Category 1 New Drugs over Category 3 Drugs

Category 3 drugs are new drugs which have already been marketed abroad by multinational companies, but are not yet approved in China. Compared with the application for Category 3 drugs, the application for Category 1 domestic new drugs has a more straight-forward registration pathway. According to Provisions for Drug Registration, where a special examination and approval treatment is granted, the application for clinical trial and manufacturing will be handled with priority and with enhanced communication with the Center for Drug Evaluation of the CFDA, or the CDA, which will establish a working mechanism for communicating with the applicants. If it becomes necessary to revise the clinical trial scheme or make other major alterations during the clinical trial,

the applicant may file an application for communication. When an application for communication is approved, the CDA will arrange the communication with the applicant within one month.

In comparison, according to Provisions for Drug Registration, the registration pathway for Category 3 drugs is complicated and evolving. Category 3 drug applications may only be submitted after a company obtains an NDA approval and receive the CPP granted by a major regulatory authority, such as the FDA or the EMA. Multinational companies may need to apply for conducting MRCTs, which means that companies do not have the flexibility to design the clinical trials to fit the Chinese patients and standard-of-care. Category 3 drug candidates may not qualify to benefit from fast track review with priority at the Clinical Trial Application stage. Moreover, a requirement to further conduct local clinical trials can potentially delay market access by several years from its international NDA approval. Further, according to *Opinions on reforming the review and approval process for pharmaceutical products and medical devices* issued by the Chinese State Council, or the State Council, in August 2015, which is a guideline for future legislation and CFDA examination, the drugs which have already been marketed abroad may no longer be categorized as new drugs under the PRC law in the future, and therefore may not be able to enjoy any preferential treatment for new drugs.

Our drug candidates are all new therapeutic agents and we expect that all of our current drug candidates fall under the Category 1 application process. In July 2015 the CFDA approved our Clinical Trial Application including all phases of clinical trials for BGB-283. We have filed similar Clinical Trial Applications for BGB-3111, BGB-290, and BGB-A317.

#### *Changes to the Review and Approval Process*

In August 2015, the 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, orphan diseases and 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 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; (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; (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.

The CFDA is soliciting public opinions on detailed policies regarding such abovementioned fast track clinical trial approval and drug registration pathway, and 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.

#### ***Subsidies and Preferential Tax Treatment for "12-5 Major New Drugs Development Projects"***

In 2012, the State Council adopted a "12-5 Major New Drugs Development Projects," according to which a special fund was established by the government to encourage the development of new drugs. Our BGB-283 drug candidate and another BRAF preclinical research project have been recognized as "12-5 Major New Drugs Development Projects" and received government subsidies of RMB 6,554,600 during the period from January 1, 2013 to September 30, 2015.

#### ***PRC Enterprise Income Tax Law and Its Implementation***

The PRC Enterprise Income Tax Law, or EIT Law, and its implementation rules permit certain High and New Technologies Enterprises, or HNTes, to enjoy preferential enterprise income tax rates subject to these HNTes meeting certain qualification criteria. One of our PRC subsidiaries enjoys such preferential tax treatment.

Pursuant to the Temporary Regulations on Business Tax, which were promulgated by the State Council on December 13, 1993 and effective January 1, 1994, as amended on November 10, 2008 and effective January 1, 2009, any entity or individual conducting business in a service industry is generally required to pay business tax at the rate of 5% on the revenues generated from providing such services. However, if the services provided are related to technological development and transfer, such business tax may be exempted subject to approval by the relevant tax authorities.

In November 2011, the Ministry of Finance and the State Administration of Taxation, or SAT, promulgated the Pilot Plan for Imposition of Value-Added Tax to Replace Business Tax, or the Pilot Plan. Since January 2012, the SAT has been implementing the Pilot Plan, which imposes value-added tax, or VAT, in lieu of business tax for certain industries in Shanghai. The Pilot Plan was expanded to other regions, including Beijing, in September 2012, and was further expanded nationwide beginning August 1, 2013. VAT is applicable at a rate of 6% in lieu of business taxes for certain services and 17% for the sale of goods and provision of tangible property lease services. VAT payable on goods sold or taxable services provided by a general VAT taxpayer for a taxable period is the net balance of the output VAT for the period after crediting the input VAT for the period.

#### ***Four Phases of Clinical Trials***

A clinical development program consists of Phases 1, 2, 3 and 4. Phase 1 refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase 2 refers to the preliminary evaluation of a drug candidate's therapeutic effectiveness and safety for particular indication(s) in patients, provide evidence and support for the design of Phase 3 clinical trial, and settle the administrative dose regimen. Phase 3 refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase 3 is used to further verify the drug's therapeutic effectiveness and safety on patients with target indication(s), to evaluate overall benefit-risk relationships of the drug,

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and ultimately to provide sufficient evidence for the review of drug registration application. Phase 4 refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among general population or specific groups, and to adjust the administration dose, etc.

### *New Drug Application*

When Phase 1, 2 and 3 of the clinical trials have been completed, the applicant must apply to the CFDA for approval of a new drug application. The CFDA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the CFDA. We have obtained approval of our Clinical Trial Application for BGB-283 in the PRC, and clinical trials are expected to be initiated. We must obtain approval of a new drug application before our drugs can be manufactured and sold in the PRC market.

### *Good Manufacturing Practice*

All facilities and techniques used in the manufacture of products for clinical use or for sale in the PRC must be operated in conformity with cGMP guidelines as established by the CFDA. Failure to comply with applicable requirements could result in the termination of manufacturing and significant fines.

### *Animal Test Permits*

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

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

We obtained a Certificate for Use of Laboratory Animals in 2012 regarding the scope of rats and mice.

## ***Regulations Relating to Intellectual Property Rights***

### *Patent*

#### General

Pursuant to the Patent Law of the PRC and its implementation rules, patents in the PRC fall into three categories, namely invention patent, utility model and design patent. Invention patent refers to a new technical solution proposed in respect of a product, method or its improvement;

utility model refers to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product; and design patent refers to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the Patent Law of the PRC, the term of patent protection starts from the date the patent was filed. Patents relating to utility-models and designs are effective for ten years from the initial date the patent application was filed. The Patent Law of the PRC adopts the principle of "first to file," which means where more than one person files a patent application for the same invention, a patent will be granted to the person who first filed the application.

Existing patents can become invalid or unenforceable due to a number of factors, including known or unknown prior art, deficiencies in patent application and lack of novelty in technology. In the PRC, a patent must have novelty, innovation and practical application. Under the Patent Law of PRC, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in the PRC or abroad or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is published after the filing date. Patents in the PRC are filed with the State Intellectual Property Office, or SIPO. Normally, the SIPO publishes an application for a pharmaceutical invention 18 months after the application is filed, which may be shortened upon request by the applicant. The applicant must apply to the SIPO for a substantive examination within three years from the date the application is filed.

Article 20 of the Patent Law of the PRC provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the subject invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies who conduct research and development activities in the PRC or outsource research and development activities to service providers in the PRC. Currently we have three invention patents published by SIPO and one invention patent under the application process.

#### Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other infringement acts against patent rights, will subject the infringers to tortious liabilities. Serious offences may be subject to criminal penalties.

When a dispute arises as a result of infringement of the patent owner's patent right, PRC law requires that the parties first attempt to settle the dispute through consultation between them. However, if the dispute cannot be settled through consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority under the SIPO. A PRC court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as either the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. As in other jurisdictions, with one notable exception, the patent owner in the PRC has the burden of proving that the patent is being infringed. However, if the owner of a manufacturing process patent alleges infringement of its patent, the alleged infringer has the burden of proving that it has not infringed. To our knowledge, there are no disputes as to our infringement of any third party's patent.

### Medical Patent Compulsory License

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

### Exemptions for Unlicensed Manufacture, Use and Import of Patented Drugs

According to the Patent Law of the PRC, any person may manufacture, use or import patented drugs for the purpose of providing information required for administrative examination and approval without authorization granted by the patent owner.

### *Trade Secrets*

According to the Anti-Unfair Competition Law of the PRC, the term "trade secrets" refers to technical information and business information that is unknown to the public, that has utility and may create business interest or profit for its legal owners or holders, and that is maintained as a secret by its legal owners or holders.

Under this law, business persons are prohibited from employing the following methods to infringe trade secrets: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as stealing, solicitation or coercion; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; or (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB 10,000–200,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a PRC court for loss and damages caused by the misappropriation.

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

### ***Regulations Relating to Foreign Exchange and Dividend Distribution***

#### *Foreign Exchange Regulation*

The Foreign Exchange Administration Regulations, most recently amended in August 2008, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities is required when Renminbi is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, or SAFE Circular 142, regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into Renminbi by restricting how the converted

Renminbi may be used. In addition, SAFE promulgated Notice on Issues concerning Further Clarifying and Regulating the Foreign Exchange Administration under Some Capital Accounts, or Circular 45, on November 9, 2011 to clarify the application of SAFE Circular 142. Under SAFE Circular 142 and Circular 45, Renminbi capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC. In addition, SAFE strengthened its oversight of the flow and use of the Renminbi capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such Renminbi capital may not be changed without SAFE's approval, and such Renminbi capital may not, in any case, be used to repay Renminbi loans whose proceeds were not used. Furthermore, SAFE promulgated Notice on Issues Concerning Strengthening Administration of Foreign Exchange Services in November 2010, which tightens the regulation over settlement of net proceeds from overseas offerings, such as our initial public offering, and requires, among other things, the authenticity of settlement of net proceeds from offshore offerings to be closely examined and the net proceeds to be settled in the manner described in our prospectus or otherwise approved by our board of directors. Violations of these SAFE regulations may result in severe monetary or other penalties, including confiscation of earnings derived from such violation activities, a fine of up to 30% of the RMB funds converted from the foreign invested funds or in the case of a severe violation, a fine ranging from 30% to 100% of the Renminbi funds converted from the foreign-invested funds.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment, which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of Renminbi proceeds by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, and multiple capital accounts for the same entity may be opened in different provinces, which was not previously possible. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by the SAFE or its local branches over direct investment by foreign investors in the PRC will be conducted by way of registration, and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

Under the Circular of the SAFE on Further Improving and Adjusting the Policies for Foreign Exchange Administration under Capital Accounts promulgated by the SAFE on January 10, 2014 and effective from February 10, 2014, administration over the outflow of the profits by domestic institutions has been further simplified. In principle, a bank is no longer required to examine transaction documents when handling the outflow of profits of no more than the equivalent of \$50,000 by a domestic institution. When handling the outflow of profits exceeding the equivalent of \$50,000, the bank, in principle, is no longer required to examine the financial audit report and capital verification report of the domestic institution, provided that it must examine, according to the principle of transaction authenticity, the profit distribution resolution of the board of directors (or the profit distribution resolution of the partners) relating to this profit outflow and the original copy of its tax record-filing form. After each profit outflow, the bank must affix its seal to and endorsements on the original copy of the relevant tax record-filing form to indicate the actual amount of the profit outflow and the date of the outflow.

On March 30, 2015, SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or SAFE

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Circular 19, which became effective on June 1, 2015. According to SAFE Circular 19, the foreign exchange capital of foreign-invested enterprises may be settled on a discretionary basis, meaning that the foreign exchange capital in the capital account of a foreign-invested enterprise for which the rights and interests of monetary contribution has been confirmed by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operational needs of the foreign-invested enterprise. The proportion of such discretionary settlement is temporarily determined as 100%. The Renminbi converted from the foreign exchange capital will be kept in a designated account, and if a foreign-invested enterprise needs to make further payment from such account, it still must provide supporting documents and go through the review process with the banks.

Furthermore, SAFE Circular 19 stipulates that the use of capital by foreign-invested enterprises must adhere to the principles of authenticity and self-use within the business scope of enterprises. The capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes:

1. directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations;
2. directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations;
3. directly or indirectly used for granting the entrusted loans in RMB, unless permitted by the scope of business, repaying the inter-enterprise borrowing (including advances by the third party), or repaying the bank loans in RMB that have been sub-lent to the third party; and/or
4. paying the expenses related to the purchase of real estate that is not for self-use, except for the foreign-invested real estate enterprises.

Our PRC subsidiaries' distributions to the offshore parent and carrying out cross-border foreign exchange activities shall comply with the various SAFE registration requirements described above.

### *Share Option Rules*

Under the Administration Measures on Individual Foreign Exchange Control issued by the People's Bank of China on December 25, 2006, all foreign exchange matters involved in employee share ownership plans and share option plans in which PRC citizens participate require approval from SAFE or its authorized branch. In addition, under the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly-Listed Companies, or Share Option Rules, issued by the SAFE on February 15, 2012, PRC residents who are granted shares or share options by companies listed on overseas stock exchanges under share incentive plans are required to (1) register with the SAFE or its local branches; (2) retain a qualified PRC agent, which may be a PRC subsidiary of the overseas listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the share incentive plans on behalf of the participants; and (3) retain an overseas institution to handle matters in connection with their exercise of share options, purchase and sale of shares or interests and funds transfers. We will make efforts to comply with these requirements upon completion of our initial public offering.

### *Regulation of Dividend Distribution*

The principal laws, rules and regulations governing dividend distribution by foreign-invested enterprises in the PRC are the Company Law of the PRC, as amended, the Wholly Foreign-owned Enterprise Law and its implementation regulations, and the Equity Joint Venture Law and its



implementation regulations. Under these laws, rules and regulations, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. Both PRC domestic companies and wholly-foreign owned PRC enterprises are required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

### **Labor Laws and Social Insurance**

Pursuant to the PRC Labor Law and the PRC Labor Contract Law, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

In addition, according to the PRC Social Insurance Law, employers like our PRC subsidiaries in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance, and housing funds.

### **Rest of the World Regulation**

For other countries outside of the United States and the PRC, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### **Manufacturing and Supply**

We 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. In addition, we expect to lease a 9,000 square meter manufacturing facility in Suzhou, PRC. At the Suzhou manufacturing facility, we intend to produce drug candidates for clinical or, in the future, commercial use. We expect this facility to consist of one oral-solid-dosage production line for small molecule drug products and one pilot plant for monoclonal antibodies. We also outsource to a limited number of external service providers the production of some drug substances and drug products, and we expect to continue to do so to meet the preclinical and clinical requirements of our drug candidates. For example, cell line and process development for BGB-A317 was completed by Boehringer Ingelheim, and it is currently manufacturing BGB-A317 in China. We do not have a long-term agreement with these third parties. We have framework agreements with most of our external service providers, under which they generally provide services to us on a short-term, project-by-project basis.

Currently, we obtain drug raw materials for our manufacturing activities from multiple suppliers who we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, a risk exists that an interruption supplies would materially harm our business. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements governing record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our manufacturing facilities and the contract manufacturing organizations we use to manufacture our drug candidates operate under cGMP conditions. cGMP are regulatory requirements for the production of pharmaceuticals that will be used in humans. For most of our manufacturing processes a back-up cGMP manufacturer is in place or can easily be identified.

### **Employees**

As of December 31, 2015, we had 192 full-time employees and two part-time employees. Of these, 149 are engaged in full-time research and development and laboratory operations and 43 are engaged in full-time general and administrative functions. As of December 31, 2015, 187 of our employees were located in the PRC, six were located in the United States, and one was located in Australia. We have also engaged and may continue to engage independent contractors to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment related work stoppages, and we consider our relations with our employees to be good.

### **Facilities**

Our research and development center is located in Changping, Beijing, PRC, where we lease approximately 6,000 square meters of office, laboratory and manufacturing space. The lease for this facility expires in 2021. Our 9,000 square meter manufacturing facility is expected to be located in Suzhou, PRC. Our clinical development office is located in downtown Beijing, PRC. We also have offices in the Greater Boston area and New Jersey, United States. We lease all of our facilities and believe our current facilities are sufficient to meet our needs.

### **Legal Proceedings**

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**MANAGEMENT****Directors and Executive Officers**

Our executive officers and directors and their respective ages and positions as of January 27, 2016:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
John V. Oyler	47	Founder, Chief Executive Officer and Chairman
Howard Liang, Ph.D.	52	Chief Financial Officer and Chief Strategy Officer
RuiRong Yuan, M.D.	55	Chief Medical Officer and President of Global Clinical Research and Development
Jason Yang, M.D., Ph.D.	51	Senior Vice President, Head of Clinical Development
Wendy Yan	50	Senior Vice President, Head of Regulatory Affairs
<i>Non-Management Directors:</i>		
Michael Goller(1)	40	Director
Donald W. Glazer(1)	71	Director
Ranjeev Krishana(2)	41	Director
Ji Li*	47	Director
Ke Tang(3)	35	Director
Qingqing Yi(2)(3)	43	Director
Thomas Malley(3)	47	Director
Xiaodong Wang, Ph.D.	52	Director Nominee

\* Mr. Li resigned from our board of directors prior to the effectiveness of the registration statement.

(1) Member of the Nominating and Corporate Governance Committee.

(2) Member of the Compensation Committee.

(3) Member of the Audit Committee.

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

**Executive Officers**

**John V. Oyler** is our Founder and has served as our principal executive officer and a member of our board of directors since 2010. From 2005 to 2009, Mr. Oyler served as President and Chief Executive Officer of BioDuro, LLC, a drug discovery outsourcing company, which was acquired by Pharmaceutical Product Development Inc. in 2010. From 2002 to 2004, Mr. Oyler served as Chief Executive Officer of Galenea Corp., a biopharmaceutical company dedicated to the discovery of novel therapies for central nervous system diseases, which initially were developed at Massachusetts Institute of Technology. From 1997 to 2002, Mr. Oyler was a Founder and the President of Telephia, Inc. which was sold to The Nielsen Company in 2007. From 1997 to 1998, Mr. Oyler served as Co-Chief Executive Officer of Genta Incorporated (NASDAQ: GNTA), an oncology-focused biopharmaceutical company. Mr. Oyler began his career as a management consultant at McKinsey & Company. Mr. Oyler received his B.S. from Massachusetts Institute of Technology and MBA from Stanford University. Mr. Oyler's qualifications to sit on our board of directors include his extensive leadership, executive, managerial, business and pharmaceutical and biotechnology company experience, along with his years of industry experience in the development and commercialization of pharmaceutical products.

**Howard Liang, Ph.D.** joined our company in July 2015 as our Chief Financial Officer and Chief Strategy Officer. Dr. Liang has more than 20 years of combined experience on Wall Street as an analyst covering the biotechnology and pharmaceutical sectors and as a scientist in the biopharmaceutical industry. Prior to joining us, from 2005 to 2015, Dr. Liang was at Leerink

Partners LLC, a leading investment bank specializing in the healthcare industry, where he served as a Managing Director and Head of Biotechnology Equity Research. Dr. Liang served as a Senior Biotechnology Analyst at two full-service investment banks: A.G. Edwards Inc., from 2004 to 2005, and JMP Securities, from 2003 to 2004. From 2000 to 2003, Dr. Liang served as an Associate Analyst at Prudential Securities, where he covered major and specialty pharmaceuticals. Before joining Wall Street, from 1992 to 2000, Dr. Liang was with Abbott Laboratories, where he was a Senior Scientist and a member of one of the pharmaceutical industry's leading structure-based discovery teams. During his career as a scientist, Dr. Liang authored a review and 13 papers including six in *Nature*, *Science*, and *Proceedings of the National Academy of Sciences*. Dr. Liang received his B.S. in Chemistry from Peking University and both his MBA and Ph.D. in Biochemistry and Molecular Biology from the University of Chicago.

**RuiRong Yuan, M.D.** joined our company in November 2015 as our Chief Medical Officer and President of Global Clinical Research and Development. Dr. Yuan has extensive international clinical experience having worked across the United States, Europe and Asia. Prior to joining us, from 2014 to 2015, Dr. Yuan served as Chief Medical Officer and Head of Americas Oncology Medical Research & Strategy at Eisai Inc., a global oncology company seeking innovative solutions in disease treatment and prevention. From 2010 to 2014, Dr. Yuan served as Executive Director/Head of Oncology and other therapeutic areas at Daiichi Sankyo, Inc.—a pharmaceutical company focused on developing therapies for cardiovascular, oncology and metabolic diseases—where she was responsible for early- and late-stage clinical programs in the United States. Prior to this, Dr. Yuan served as a Senior Global Clinical Leader at Novartis AG from 2007 to 2010 where she led global teams conducting registrational studies for Afinitor and supported its successful regulatory approval in patients with renal cell carcinoma. From 2003 to the present, Dr. Yuan has served as an attending physician at VA New Jersey Health Care System. Dr. Yuan is also a founding member of the Chinese American Hematologist and Oncologist Network (CAHON), where she previously served as both President and Chairman of the Board of Directors. She earned her medical doctor degree from Shandong Medical University, received her postgraduate training in clinical medical oncology and tumor immunology at the Chinese Academy of Medical Sciences and in molecular biology at The University of Bern, and received her post-doctoral fellowship in immunology from the Albert Einstein College of Medicine (AECOM). Dr. Yuan was U.S. board-certified in both internal medicine and medical oncology after her internal medicine residency at AECOM and clinical oncology and hematology fellowships at Cancer Hospital of Peking Union Medical College and Memorial Sloan Kettering Cancer Center.

**Jason Yang, M.D., Ph.D.** has served as our Senior Vice President, Head of Clinical Development since July 2014. Prior to joining us, Dr. Yang served as an Oncology Medical Director in Clinical Development and other roles at Covance Inc. from 2011 to 2014. Prior to his time at Covance, Dr. Yang served as a Senior Principal Scientist in cancer biomarker at Pfizer, Inc. for seven years since 2004, and as a research scientist in cancer genomics at Tularik Inc. (acquired by Amgen Inc. in 2004) for six years since 1998. Dr. Yang was a post-doctoral fellow at The Howard Hughes Medical Institute in Chemical Biology with Dr. Stuart Schreiber at Harvard University. Dr. Yang received his Ph.D. in Biochemistry and Molecular Genetics from the University of Texas Southwestern Medical Center while conducting cutting-edge research on cholesterol transcription regulation with Nobel Laureates Drs. Michael Brown and Joseph Goldstein. Dr. Yang received his M.S. in Medicine from Nanjing Medical University, and his M.D. from Hubei Medical College, Xianning.

**Wendy Yan** has served as our Senior Vice President, Head of Regulatory Affairs since August 2014. Prior to joining us, Ms. Yan served in various positions, including Director, Head of Regulatory Affairs for China, and Global Regulatory Strategist, at Bayer HealthCare AG from 2008 to 2014. Prior to that, Ms. Yan served at GlaxoSmithKline Pharmaceutical China as both a director and Head of Regulatory Affairs. Ms. Yan also served as a Senior Regulatory Affair Manager at AstraZeneca plc.

previously. Ms. Yan received her M.B.A. from Staffordshire University. She began her career at the Beijing Drug Control Institute and is a licensed pharmacist, having received her Bachelor of Medicine from Beijing Traditional Medicine University.

#### **Non-Employee Directors**

**Michael Goller** has served as a member of our board of directors since April 2015. Mr. Goller has been with Baker Bros. Advisors LP since 2005 and currently serves as a Managing Director. Prior to joining Baker Bros., Mr. Goller served as an Associate of JPMorgan Partners, LLC where he focused on venture investments in the life sciences sector from 1999 to 2003. Mr. Goller began his career as an investment banker with Merrill Lynch and Co. from 1997 to 1999. Mr. Goller holds a B.S. in Molecular and Cell Biology from The Pennsylvania State University and Masters degrees in each of Biotechnology (School of Engineered and Applied Sciences) and Business Administration (Wharton School) from the University of Pennsylvania. We believe that Mr. Goller is qualified to serve on our board of directors based on his experience in the life sciences industry and for his knowledge in financial and corporate development matters.

**Donald W. Glazer** has served as a member of our board of directors since February 2013. Mr. Glazer has served as a member of the Board of Trustees of GMO Trust, a mutual fund group, since 2000 and as the Chairman of the Board since 2005. Mr. Glazer was a Co-Founder and Secretary, and from 2002 until 2010, Vice Chairman, of Provant, Inc., a provider of performance improvement training solutions. From 1992 to 1995 Mr. Glazer was President of Mugar/Glazer Holdings and from 1992 to 1993 served as Vice Chairman—Finance of New England Television Corp and WHDH-TV, Inc. From 1997 to the present, Mr. Glazer has served as Advisory Counsel to Goodwin Procter LLP. From 1970 to 1978 Mr. Glazer was an associate and from 1978 to 1992 a partner at Ropes & Gray LLP, a Boston law firm. At Ropes & Gray, Mr. Glazer chaired the firm's Emerging Companies Group. Mr. Glazer was also a Lecturer in Law at Harvard Law School, from 1978 to 1991 teaching a course called The Business Lawyer. Mr. Glazer is a former member of the boards of directors of Environics Inc.; Kronos Incorporated; Reflective Technologies, Inc.; and Teleco Oilfield Services Inc. Mr. Glazer received his A.B. from Dartmouth College; J.D. from Harvard Law School, where he was an editor of the Harvard Law Review; and L.L.M. from the University of Pennsylvania Law School. Additionally, Mr. Glazer is a co-author of both *Glazer and FitzGibbon on Legal Opinions, Third Edition* (Aspen Publishers) and *Massachusetts Corporation Law & Practice, Second Edition* (Aspen Publishers). Mr. Glazer's qualifications to sit on our board of directors include his extensive leadership, executive, managerial, business, and corporate legal experience.

**Ranjeev Krishana** has served as a member of our board of directors since October 2014. Mr. Krishana has worked at Baker Bros. Advisors LP from 2011 to the present and currently serves as Head of International Investments. Prior to joining Baker Bros., Mr. Krishana held a series of commercial, strategy, and business development leadership roles for Pfizer, Inc.'s pharmaceutical business across a variety of international regions and markets, including Asia, Eastern Europe, and Latin America. Mr. Krishana was at Pfizer from 2003 to 2007 and from 2008 to 2011. From 2008 to 2010, Mr. Krishana was based in Beijing, China, where he served as a Senior Director and a member of the Pfizer China Leadership Team. Mr. Krishana began his career as a strategy consultant at Accenture plc. Mr. Krishana holds a B.A. in Economics and Political Science from Brown University, and a Masters of Public Policy from Harvard University. We believe Mr. Krishana's knowledge of the healthcare sector across international markets qualifies him to serve on our board of directors.

**Ji Li** served as a member of our board of directors from January 2015 to February 2, 2016. Mr. Li resigned from our board of directors prior to the effectiveness of the registration statement. Mr. Li has served as Vice President of Business Development and Licensing at Merck Sharp & Dohme Corp. since December 2013. Mr. Li is responsible for the search, scientific evaluation and

due diligence for late-stage inbound and outbound opportunities sponsored by Merck Research Laboratories, or MRL. He also leads the coordination of MRL input into Merck's Global Human Health Business Development—and Corporate Development—sponsored activities to ensure appropriate alignment. Mr. Li also serves as a key member of the Global Clinical Development Leadership Team. From August 2010 to August 2013, Mr. 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. We believe Mr. Li's experience in the healthcare sector qualifies him to serve on our board of directors.

**Ke Tang** has served as a member of our board of directors since October 2014. Mr. Tang has been a Vice President at CITIC PE Private Equity Funds Management Co., Ltd. since 2013. Mr. Tang has also served as an Executive Director of Changsheng Medial, a medical service company focusing on renal diseases from July 2014. From 2012 to 2013, Mr. Tang served as Investment Manager at the Principal Investment Department at Goldman Sachs Group, responsible for private equity investments in China. Before that, Mr. Tang served as an Associate and Executive Director at the investment banking division of Goldman Sachs Asia from 2008 to 2012. Mr. Tang holds a B.A. from Southeast University and an MBA from Kellogg School of Management at Northwestern University. We believe Mr. Tang's knowledge of the healthcare sector, along with his extensive experience in capital markets, qualifies him to serve on our board of directors.

**Qingqing Yi** has served as a member of our board of directors since October 2014. Mr. Yi is a Principal at Hillhouse Capital Group, or Hillhouse. He has worked with Hillhouse since the inception of the firm in 2005. Prior to joining Hillhouse, Mr. Yi was an Equity Research Analyst at China International Capital Corporation. Mr. Yi's work at Hillhouse includes investments in the healthcare and consumer sectors in both its public and private equity portfolios. He received a B.S. in Engineering from Shanghai Maritime University, as well as an MBA from University of Southern California. We believe Mr. Yi's extensive experience in capital markets and knowledge of the healthcare sector qualifies him to serve on our board of directors.

**Thomas Malley** has served as a member of our board of directors since January 2016. Mr. Malley has served as President of Mossrock Capital, LLC, a private investment firm, since May 2007. Mr. Malley worked for Janus Mutual Funds in positions of increasing responsibility from April 1991 to May 2007. From January 1999 to May 2007, Mr. Malley served as the portfolio manager of the Janus Global Life Sciences Fund and also led the Janus Healthcare team of analysts. From 1991 to 1998, Mr. Malley served as an equity analyst for Janus covering, among others, healthcare and biotechnology stocks. Mr. Malley has been a director of OvaScience, Inc. since October 2012, and a director of Kura Oncology, Inc. since 2015. Previously, he served as a director of Synageva BioPharma Corp., a public biopharmaceutical company, from 2006 to 2015, until its acquisition by Alexion Pharmaceuticals, Inc., Puma Biotechnology, Inc., a public biopharmaceutical company, from 2011 to 2015, and Cougar Biotechnology, Inc., a public biopharmaceutical company, from 2007 to 2009, until its acquisition by Johnson and Johnson. Mr. Malley holds a B.S. in Biology from Stanford University. Our board of directors believes that Mr. Malley's experience in the biopharmaceutical industry, including serving on other boards of directors, and his executive experience qualify him to serve on our board of directors.

**Xiaodong Wang, Ph.D.** is our Founder and has served as the Chairman of our scientific advisory board since 2011. Dr. Wang will become a member of our board of directors upon the completion of this offering. Dr. Wang has served as the founding Director of the National Institute of Biological Sciences in Beijing since 2003 and became its Director and Investigator in 2010. Previously, he was a Howard Hughes Medical Institute Investigator from 1997 to 2010 and held the position of the George L. MacGregor Distinguished Chair Professor in Biomedical Sciences at the University of Texas Southwestern Medical Center in Dallas, Texas from 2001 to 2010. In 2004,

Dr. Wang founded Joyant Pharmaceuticals, Inc., a venture capital-backed biotechnology company focused on the development of small molecule therapeutics for cancer. Dr. Wang received his Ph.D. in Biochemistry from the University of Texas Southwestern Medical Center and B.S. in Biology from Beijing Normal University. Dr. Wang has been a member of the National Academy of Science, USA since 2004 and a foreign associate of the Chinese Academy of Sciences since 2013. We believe that Dr. Wang's extensive experience in cancer drug research, combined with his experience in the biotech industry, qualify him to serve as a member of our board of directors.

### **Composition of Our Board of Directors**

Our board of directors currently consists of eight members, all of whom were elected pursuant to the board composition provisions of our voting agreement, which is described under "Certain Relationships and Related Party Transactions—Agreements with Our Shareholders" in this prospectus. These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and governance committee and board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity and is not limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our shareholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our amended and restated articles of association that will become effective immediately prior to the completion of this offering also provide that our directors may be removed in the manner provided for in the amended and restated articles of association by the affirmative vote of the holders of at least two-thirds of the votes cast at a shareholder meeting, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

**Director independence.** Our board of directors has determined that all members of the board of directors, except John V. Oyler and Xiaodong Wang, are independent, as determined in accordance with the rules of the NASDAQ Stock Market. In making such independence determination, our board of directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our share capital by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our share capital. Upon the closing of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of the NASDAQ Stock Market and the rules and regulations of the U.S. Securities and Exchange Commission, or SEC. There are no family relationships among any of our directors or executive officers.

**Staggered board.** In accordance with the terms of our amended and restated memorandum and articles of association that will become effective immediately prior to the completion of this offering, our board of directors will be divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of

directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of shareholders in the year in which their term expires.

- Our Class I directors will be John V. Oyler and Ke Tang;
- Our Class II directors will be Donald W. Glazer, Michael Goller and Thomas Malley; and
- Our Class III directors will be Qingqing Yi, Xiaodong Wang and Ranjeev Krishana.

Our amended and restated memorandum and articles of association that will become effective immediately prior to the completion of this offering provide that the authorized number of directors may be changed only by ordinary resolution of the shareholders. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent shareholder efforts to effect a change of our management or a change in control.

### **Board's Role in Risk Oversight**

Our board of directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our board of directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our board of directors addresses the primary risks associated with those operations and corporate functions. In addition, our board of directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of our risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer reports to the audit committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our audit committee meets privately with representatives from our independent registered public accounting firm and our Chief Financial Officer. The audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our board of directors regarding these activities.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a separate charter adopted by our board of directors. The composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the NASDAQ Stock Market and SEC rules and regulations.

#### ***Audit Committee***

Ke Tang, Qingqing Yi and Thomas Malley currently serve on the audit committee, which is chaired by Ke Tang. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable rules of the NASDAQ Stock Market. Our board of directors has designated



each of Ke Tang and Thomas Malley as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the internal audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and the independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by the SEC rules to be included in our annual proxy statement;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing earnings releases.

#### ***Compensation Committee***

Qingqing Yi and Ranjeev Krishana currently serve on the compensation committee, which is chaired by Qingqing Yi. Our board of directors has determined that each member of the compensation committee is "independent" as that term is defined in the applicable rules of the NASDAQ Stock Market. The compensation committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer and Chief Financial Officer;
- evaluating the performance of our Chief Executive Officer and Chief Financial Officer in light of such corporate goals and objectives and determining the compensation of our Chief Executive Officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential current compensation advisors in accordance with the independence standards identified in the applicable rules of the NASDAQ Stock Market;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;

- reviewing and making recommendations to the board of directors with respect to director compensation;
- preparing the compensation committee report required by the SEC rules to be included in our annual proxy statement;
- reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K; and
- reviewing and discussing with the board of directors corporate succession plans for the Chief Executive Officer and other key officers.

#### **Nominating and Corporate Governance Committee**

Donald W. Glazer and Michael Goller currently serve on the nominating and corporate governance committee, which is chaired by Donald W. Glazer. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as that term is defined in the applicable rules of the NASDAQ Stock Market. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by shareholders;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a set of corporate governance guidelines; and
- overseeing the evaluation of the board of directors and management.

Our board of directors may establish other committees from time to time.

#### **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

#### **Corporate Governance**

We adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the completion of this offering, a current copy of the code will be posted on the Corporate Governance section of our website, which is located at [www.beigene.com](http://www.beigene.com). If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

#### **Limitation of Liability**

Insofar as indemnification for liabilities arising under the U.S. Securities Act of 1933, as amended may be permitted to our directors, officers or controlling persons, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**EXECUTIVE COMPENSATION**

**Executive Compensation Overview**

Historically, our executive compensation program has reflected our growth and development-oriented corporate culture. To date, the compensation of John V. Oyler, our Chief Executive Officer and Chairman, and the other executive officers identified in the summary compensation table below, who we refer to as the named executive officers, has consisted of a combination of base salary, bonuses and long-term incentive compensation in the form of share options. Our executive officers and all salaried employees are also eligible to receive health and welfare benefits.

As we transition from a private company to a publicly-traded company, we will evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require. At a minimum, we expect to review executive compensation annually with input from a compensation consultant if and when determined appropriate by the compensation committee. As part of this review process, we expect the board of directors and the compensation committee to apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive. We will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

**Compensation Tables**

**Summary Compensation Table—2015**

The following table presents information regarding the total compensation awarded to, earned by, and paid to our Chief Executive Officer and the two most highly-compensated executive officers (other than the Chief Executive Officer) who were serving as executive officers of our company at the end of the last completed fiscal year for services rendered in all capacities to us for the year ended December 31, 2015, and in the case of our Chief Executive Officer for the year ended December 31, 2014. These individuals are our named executive officers for 2015.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
<b>John V. Oyler</b>	2015	344,705 <sup>(2)</sup> <sup>(3)</sup>	—	3,890,991	11,898 <sup>(4)</sup>	4,247,594
<i>Founder, Chief Executive Officer and Chairman</i>	2014	97,664 <sup>(5)</sup> <sup>(6)</sup>	1,272,073 <sup>(7)</sup>	—	13,751 <sup>(8)</sup>	1,383,488 <sup>(9)</sup>
<b>Howard Liang</b>	2015	160,417 <sup>(10)</sup>	—	1,622,880	—	1,783,297
<i>Chief Financial Officer and Chief Strategy Officer</i>						
<b>RuiRong Yuan</b>	2015	66,667 <sup>(11)</sup>	—	2,266,619	—	2,333,286
<i>Chief Medical Officer and President of Global Clinical Research and Development</i>						

(1) Amounts represent the aggregate grant date fair value, including any incremental fair value, of option awards granted to our named executive officers in 2015 computed in accordance with FASB ASC Topic 718. The assumptions used in the valuation of these awards are consistent with the valuation methodologies specified in the notes to our consolidated financial statements and discussions in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. The amounts above reflect our aggregate accounting expense for these awards and do not necessarily correspond to the actual value that will be recognized by the named executive officers.

- (2) Payment in Renminbi was translated into dollars based on the noon buying rate of the Federal Reserve Bank of New York for Renminbi of ¥1.00=\$0.1544 at December 31, 2015.
- (3) Represents base salary earned by Mr. Oyler for services as our Chief Executive Officer and Chairman during 2015.
- (4) Mr. Oyler is entitled to living expense assistance in connection with his commuting to our offices in Beijing, China. This amount represents \$11,898 attributable to the use of a company car.
- (5) Represents base salary earned by Mr. Oyler for services as our Chief Executive Officer and Chairman during 2014. Mr. Oyler's annual base salary starting October 1, 2014 was \$350,000.
- (6) Payment in Renminbi was translated into dollars based on the noon buying rate of the Federal Reserve Bank of New York for Renminbi of ¥1.00=\$0.1612 at December 31, 2014.
- (7) The bonus amount of \$1,272,073 paid to Mr. Oyler in 2014 was awarded by the board of directors after our Series A preferred share financing in recognition of Mr. Oyler's leadership and contributions to our company and his substantially below market compensation from our founding in 2010 through the Series A preferred share financing. The size of this bonus is not indicative of future bonus awards to Mr. Oyler.
- (8) Mr. Oyler is entitled to living expense assistance in connection with his commuting to our offices in Beijing, China. This amount represents \$13,751 attributable to the use of a company car.
- (9) 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 entered into with Merck Sharp & Dohme Research GmbH, including a 20% conversion discount after a qualified financing. On October 7, 2014, pursuant to the terms of the loan agreements, \$7,360,000 outstanding balance of such indebtedness converted into 13,629,629 Series A preferred shares, which included \$1,840,000 in conversion discount. Under FASB ASC Topic 718, the conversion discount is considered a compensation expense to our company as opposed to a loan repayment to Mr. Oyler. This amount does not include the \$1,840,000 discount. See "Certain Relationships and Related Party Transactions" for further information.
- (10) Represents base salary earned by Dr. Liang for services as our Chief Financial Officer and Chief Strategy Officer during 2015. Dr. Liang's annual base salary during this period was \$350,000.
- (11) Represents base salary earned by Dr. Yuan for services as our Chief Medical Officer and President of Global Clinical Research and Development during 2015. Dr. Yuan's annual base salary during this period was \$400,000.

#### **Employment Agreements with Our Executive Officers**

After this offering, we intend to enter into an employment agreement with our Chief Executive Officer. We have entered into employment agreements with each of our other executive officers.

**Howard Liang, Ph.D.** On July 13, 2015, we entered into an employment agreement with Dr. Liang for the position of Chief Financial and Chief Strategy Officer. Dr. Liang currently receives a base salary of \$350,000, which is subject to review and adjustment in accordance with company policy. Dr. Liang is eligible for an annual merit bonus of up to \$105,000, based on performance as

determined by our compensation committee. Dr. Liang was also granted an option to purchase up to 4,900,000 ordinary shares, which vests over four years. Dr. Liang is eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. Dr. Liang's employment has no specified term, but can be terminated at will by either party. Dr. Liang may be terminated with cause, in certain cases upon 30 days' written notice, in which event he would then be entitled to certain accrued obligations. Dr. Liang may also be terminated without cause, and if so he would receive his base salary during a nine-month severance period and other benefits including partial option vesting acceleration and health and dental insurance payments, unless Dr. Liang breaches his confidentiality obligations. Dr. Liang may terminate his employment with good reason upon 30 days' written notice received within 60 days of the occurrence of the event. If we do not cure the action identified in Dr. Liang's notice, he is entitled to the same benefits as if we terminated him without cause, subject to his execution of a release of claims and unless he breaches his confidentiality obligations. Dr. Liang may also terminate his employment without good reason upon 90 days' written notice and would then only be entitled to certain accrued obligations.

**RuiRong Yuan, M.D.** Under an employment agreement that became effective on November 1, 2015, Dr. Yuan has served as our Chief Medical Officer and President of Global Clinical Research and Development. Dr. Yuan currently receives a base salary of \$400,000 which will increase by four percent per year for the first three years of Dr. Yuan's employment. Dr. Yuan is eligible for an annual merit bonus of at least 40% of her base salary based on performance as determined by our compensation committee. Dr. Yuan will also receive a special cash bonus of \$200,000 on each of the first three annual anniversaries of the beginning of her employment with us. Dr. Yuan was granted an option to purchase up to 3,000,000 ordinary shares, which vest over three years. Dr. Yuan is eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. Dr. Yuan's employment has no specified term, but can be terminated at will by either party. Dr. Yuan may be terminated with cause, in certain cases upon 30 days' written notice, in which event she would then be entitled to certain accrued obligations. Dr. Yuan may also be terminated without cause, and if so she would receive her base salary during a severance period which lasts until November 1, 2018 and other benefits including health and dental insurance payments, unless Dr. Yuan breaches her confidentiality obligations. Dr. Yuan may terminate her employment with good reason upon 30 days' written notice received within 60 days of the occurrence of the event. If we do not cure the action identified in Dr. Yuan's notice, she is entitled to the same benefits as if we terminated her without cause, subject to her execution of a release of claims and unless she breaches her confidentiality obligations. Dr. Yuan may also terminate her employment without good reason upon 90 days' written notice and would then only be entitled to certain accrued obligations.

**Jason Yang, M.D., Ph.D.** On July 7, 2014, we entered into an employment contract with Dr. Yang for the position of Senior Vice President, Head of Clinical Development. Dr. Yang's employment contract has a three-year term that expires on July 6, 2017. Dr. Yang currently receives a base salary of \$20,000 per month, which is subject to annual review and adjustment in accordance with company policy. Dr. Yang is also eligible for an annual merit bonus of up to 20% of his annual base salary, payable at our discretion. Dr. Yang is eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. Dr. Yang is entitled to living expense assistance, including reimbursement of health insurance premiums and housing allowance. Dr. Yang may be terminated for cause without notice and terminated without cause upon the occurrence of specified conditions with 30 days' prior written notice. Where severance pay is mandated by law, Dr. Yang may be entitled to such severance pay in the amount mandated by law when his employment is terminated.

**Wendy Yan.** Under an employment agreement that became effective on August 1, 2014, Ms. Yan has served as our Senior Vice President, Head of Regulatory Affairs. Ms. Yan's employment contract has a three-year term that expires on July 31, 2017. Ms. Yan currently receives a base salary of ¥85,000 per month, which is subject to annual review and adjustment in accordance with company policy. Ms. Yan is also eligible for a merit bonus, in an amount at our discretion. Ms. Yan is eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. Ms. Yan is entitled to living expense assistance in connection with her commuting to our offices in Beijing, China. Ms. Yan may be terminated for cause without notice and terminated without cause upon the occurrence of specified conditions with 30 days' prior written notice. Where severance pay is mandated by law, Mr. Yan may be entitled to such severance pay in the amount mandated by law when her employment is terminated.

**Outstanding Equity Awards at Fiscal Year-End Table—2015**

The following table summarizes, for each of our named executive officers, the number of ordinary shares underlying outstanding share options held as of December 31, 2015.

Name	Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
John V. Oyler	—	11,400,500(1)	—	0.5	7/19/2025
Howard Liang	—	4,900,000(2)	—	0.5	7/1/2025
RuiRong Yuan	—	3,000,000(3)	—	0.5	7/1/2025

- (1) 20% of our ordinary shares subject to this option become exercisable on July 19, 2016, and the balance becomes exercisable in 48 successive equal monthly installments, subject to continued service.
- (2) 25% of our ordinary shares subject to this option become exercisable on July 15, 2016, and the balance becomes exercisable in 36 successive equal monthly installments, subject to continued service. All unvested shares subject to this option are subject to accelerated vesting upon a sale event or certain termination events.
- (3) 33% of our ordinary shares subject to this option become exercisable on November 1, 2016, and the balance becomes exercisable in 24 successive equal monthly installments, subject to continued service.

**Non-Employee Director Compensation**

In 2015, we did not pay the non-employee members of our board of directors for their service as a director other than for reimbursement of expenses. Our policy has been and will continue to be to reimburse any non-employee directors who are not affiliated with an institutional investor of the company for travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of the board of directors. In 2016, we granted options to a non-employee director who is not affiliated with an institutional investor of the company.

## **Compensation Risk Assessment**

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

## **Indemnification of Officers and Directors**

We have agreed to indemnify our directors and officers in certain circumstances. See "Certain Relationships and Related Party Transactions—Indemnification Agreements."

## **Equity Compensation Plans and Other Benefit Plans**

The two equity incentive plans described in this section are the BeiGene, Ltd. 2011 Option Plan, or the 2011 Plan, and the BeiGene, Ltd. 2016 Share Option and Incentive Plan, or the 2016 Plan. Prior to this offering, we granted awards to eligible participants under the 2011 Plan. Following this offering, we expect to grant awards to eligible participants only under the 2016 Plan.

### **2011 Plan**

The 2011 Plan was approved by our board of directors on April 15, 2011 and was most recently amended on April 17, 2015. Under the 2011 Plan, 43,560,432 ordinary shares have been reserved for issuance in the form of share options.

The shares issuable pursuant to awards granted under the 2011 Plan are authorized but unissued shares. The shares underlying any awards that are forfeited, cancelled, or otherwise terminated (other than by exercise), and the shares withheld upon exercise of an option to cover the exercise price or tax withholding are added to the pool for issuance under the 2011 Plan.

The 2011 Plan is administered by our board of directors or, at the discretion of our board of directors, a board committee, which, in either case, has full power, among other things, to select the individuals to whom awards will be granted; determine the timing of grants; the number of shares issuable upon exercise of an option and the exercise price of options; accelerate the exercisability of all or any portion of an option; impose limitations on options (including limitations on transfer), impose repurchase provisions on options and the shares issuable under the options, and to exercise repurchase rights; extend the period in which an option may be exercised; and adopt, alter and repeal rules and practices for administration of the plan, interpret the terms of the 2011 Plan and options issued under the 2011 Plan, and to make decisions and resolve disputes regarding the 2011 Plan, in each case subject to the provisions of the 2011 Plan.

The option exercise price of each option granted under the 2011 Plan is determined by our board of directors or board committee and may not be less than the fair market value of an ordinary share on the date of grant or the par value of the shares issuable thereunder. The board of directors or committee may fix the term of each option, up to a maximum of 10 years from the grant date, and determine at what time or times each option may be exercised when granting an option.

Options under the 2011 Plan are not transferable by the holder except by will or intestacy, and the shares issuable under the 2011 Plan may only be transferred in compliance with the 2011 Plan, the holder's option agreement, and applicable securities laws. We have the right to repurchase any shares that a holder wishes to sell or otherwise transfer. Upon termination of a holder's service

relationship, we also have the right to repurchase all of such holder's shares at fair market value within 120 days following such termination. We may request a person holding options or shares issued upon the exercise of the options to enter into a lockup agreement in connection with a public offering of our shares.

The 2011 Plan provides that it and all outstanding options shall terminate upon a sale event, which includes a merger or a sale of substantially all of our ordinary shares, unless assumed or continued by the successor entity. However, each holder of options may exercise all options that are exercisable or will become exercisable as of the effective time of such sale event within a period of time prior to the consummation of the sale event specified by the board or board committee. We also have the right to provide for a cash payment to each holder in exchange for the cancellation of options in an amount equal to the per share sale event consideration times the number of exercisable options cancelled, minus the aggregate exercise price of all such options.

Our board of directors may amend or discontinue the 2011 Plan, and a board committee may amend or cancel any outstanding options to satisfy changes in the law or for any other lawful purpose, but no such action may adversely affect the rights of an award holder without that holder's consent.

As of December 31, 2015, options to purchase 28,909,324 ordinary shares were outstanding under the 2011 Plan. Our board of directors has determined not to make any further awards under the 2011 Plan following the effectiveness of our 2016 Plan. Ordinary shares that were originally reserved for issuance under our 2011 Plan but were not issued or subject to awards under the 2011 Plan on the effective date of our 2016 Plan, and shares subject to outstanding options or forfeiture restrictions under our 2011 Plan on the effective date of our 2016 Plan that are subsequently forfeited or terminated for any reason before being exercised, will become available for awards under our 2016 Plan.

### **2016 Plan**

On January 14, 2016, our board of directors adopted and our shareholders approved our 2016 Plan to replace the 2011 Plan. Our 2016 Plan provides us flexibility to use various equity-based incentive and other awards as compensation tools to motivate our workforce. These tools include share options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, performance share awards, cash-based awards and dividend equivalent rights. The 2016 Plan will become effective immediately prior to the pricing of this offering.

We have initially reserved 65,029,595 ordinary shares for the issuance of awards under the 2016 Plan plus any shares available under the 2011 Plan and not subject to any outstanding options as of the effective date of the 2016 Plan. The 2016 Plan provides that the number of ordinary shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2017, by 5% of the outstanding number of ordinary shares on the immediately preceding December 31 or such lesser number of ordinary shares as determined by our compensation committee. This number is subject to adjustment in the event of a share split, share dividend or other change in our capitalization. In addition, shares not needed to fulfill any obligations under the 2011 Plan will also be available for issuance under the 2016 Plan.

The ordinary shares we issue pursuant to awards granted under the 2016 Plan will be authorized but unissued ordinary shares or ordinary shares that we reacquire. The ordinary shares underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of ordinary shares, expire or are otherwise terminated (other than by exercise) under the 2016 Plan and the 2011 Plan will be added back to the ordinary shares available for issuance under the 2016 Plan.



The 2016 Plan will be administered by the compensation committee. The compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2016 Plan. Full and part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee will be eligible to participate in the 2016 Plan.

The 2016 Plan permits the granting of options to purchase ordinary shares that are not intended to qualify as incentive share options under Section 422 of the Internal Revenue Code, as amended, or the Code. The exercise price of each share option will be determined by the compensation committee but may not be less than 100% of the fair market value of our ordinary shares on the date of grant to a grantee who is subject to U.S. tax. The term of each share option will be fixed by the compensation committee and may not exceed 10 years from the date of grant. The compensation committee will determine at what time or times each option may be exercised.

The compensation committee may award share appreciation rights subject to such conditions and restrictions as it may determine. Share appreciation rights entitle the recipient to ordinary shares, or cash, equal to the value of the appreciation in our share price over the exercise price. The exercise price of each share appreciation right may not be less than 100% of fair market value of the shares on the date of grant.

The compensation committee may award restricted shares or restricted share units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or service with us through a specified vesting period. The compensation committee may also grant cash-based awards to participants subject to such conditions and restrictions as it may determine. The compensation committee may also grant ordinary shares that are free from any restrictions under the 2016 Plan. Unrestricted ordinary shares may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient held a specified number of ordinary shares.

The compensation committee may grant cash bonuses under the 2016 Plan to participants, subject to the achievement of certain performance goals.

The 2016 Plan provides that, upon the effectiveness, of a "sale event," as defined in the 2016 Plan, the successor entity may assume, continue or substitute for outstanding awards, as appropriately adjusted. To the extent that awards are not assumed or continued or substituted by the successor entity, all awards granted under the 2016 Plan shall terminate. In addition, in connection with the termination of the 2016 Plan upon a sale event, we may make or provide for a cash payment to participants holding options and share appreciation rights, equal to the difference between the per share cash consideration payable to shareholders in the sale event and the exercise price of the options or share appreciation rights and we may make or provide for a similar payment to participants under other awards.

Our board of directors may amend or discontinue the 2016 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, including option repricing, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2016 Plan may require the approval of our shareholders.

No awards may be granted under the 2016 Plan after the date that is ten years from the date of shareholder approval of the 2016 Plan. No awards under the 2016 Plan have been made prior to the date hereof.

***Senior Executive Cash Incentive Bonus Plan***

In January 2016, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our compensation committee may select corporate performance goals from among the following: achievement of certain milestones (including, but not limited to, clinical, regulatory and commercial milestones); cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of the ADSs; economic value-added; acquisitions or strategic transactions; operating income (loss); return on capital, assets, equity, or investment; shareholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of the ADSs; sales or market share; number of customers, number of new customers or customer references; operating income and/or net annual recurring revenue; employee satisfaction, employee turnover or other employee based metrics, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, measured against the market as a whole or any applicable market indices, measured on a pre-tax or post-tax basis (as applicable), or as compared to another company or companies or to results of a peer group.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

**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.

Compensation arrangements for our directors and named executive officers are described elsewhere in this prospectus.

**Sales and Purchases of Securities*****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.

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.

<b>Name</b>	<b>Series A Preferred Shares</b>	<b>Aggregate Purchase Price Paid</b>
Entities affiliated with Baker Bros. Advisors LP(1)	49,537,036	\$ 33,437,500.00
Merck Sharp & Dohme Research GmbH(2)	18,518,519	\$ 10,000,000.00
Hillhouse BGN Holdings Limited(3)	14,814,814	\$ 10,000,000.00
CB Biotech Investment Limited(4)	14,814,814	\$ 10,000,000.00
John V. Oyler(5)	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, Vice President of Business Development and Licensing at Merck Sharp & Dohme Corp., of which Merck Sharp & Dohme Research GmbH is an affiliate, is a member of our board of directors.
- (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.

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.

<u>Name</u>	<u>Series A-2 Preferred Shares</u>	<u>Aggregate Purchase Price Paid</u>
Entities affiliated with Baker Bros. Advisors LP(1)	28,205,128	\$ 32,999,999.76
Merck Sharp & Dohme Research GmbH(2)	5,128,205	\$ 5,999,999.85
Hillhouse BGN Holdings Limited(3)	15,811,965	\$ 18,499,999.05
CB Biotech Investment Limited(4)	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 and Ranjeev Krishana, Head of International Investments at Baker Bros. Advisors LP, is a member of our board of directors.
- (2) Ji Li, Vice President of Business Development and Licensing at Merck Sharp & Dohme Corp., of which Merck Sharp & Dohme Research GmbH is an affiliate, is a member of our board of directors.
- (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 will be fully vested in 2016. 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, director nominee and principal shareholder, has been providing scientific and strategic advisory services to us. Dr. Wang currently receives an annual fixed fee of \$100,000. 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.

## **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. In addition, if this offering occurs on or prior to May 2, 2016, subject to certain limitations, the outstanding unpaid principal and interest of this note as of the effectiveness date of this registration statement, or the Exchanged Balance, will be automatically exchanged, effective immediately prior to the closing of this offering, into up to a number of our ordinary shares equal to the quotient of (1) the Exchanged Balance divided by (2) the per ordinary share public offering price in this offering. On February 2, 2011 and November 16, 2011, we issued a subordinated convertible promissory note to MSD for an aggregate principal amount of \$10 million, which converted into 18,518,519 Series A preferred shares on October 7, 2014. 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.

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. The warrants exercisable for 57,777 Series A Preferred Shares issued to Mr. Oyler in connection with the convertible promissory notes remain outstanding.

## **Employment Agreements**

For more information regarding employment agreements with certain of our executive officers, see "Executive Compensation—Employment Agreements with Our Executive Officers."

## **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 to be effective upon the completion of this offering 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 and intend to enter into new agreements to indemnify our directors and executive officers. These agreements will, 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. Our investors' rights agreement, or Investors' Rights Agreement, provides those certain holders of our preferred shares with the right to demand that we file a registration statement, subject to certain limitations, and to request that their share capital be covered by a registration statement that we are otherwise filing. See "Description of Share Capital—Registration Rights" for additional information.

The right of first refusal and co-sale agreement, or Co-Sale Agreement, provides for rights of first refusal and co-sale rights with respect to sales of securities by certain holders of our ordinary shares. The rights of first refusal, co-sale rights and participation rights under the Co-Sale Agreement and Investors' Right Agreement do not apply to this offering. The Investors' Rights Agreement further provides certain holders of our preferred shares and ordinary shares with a participation right to purchase their pro rata share of new securities that we may propose to sell and issue, subject to specified exceptions. The voting agreement contains provisions with respect to the election of our board of directors and its composition.

The primary rights under each of the (1) Investors' Rights Agreement, (2) the Co-Sale Agreement and (3) the voting agreement will terminate upon the closing of this offering, other than certain registration rights for certain holders of our preferred shares and ordinary shares.

In connection with the issuance of notes to MSD, we entered into a securityholder's agreement with MSD, pursuant to which MSD has right to designate a director, information right and right of first offer at a company sale event. These rights will terminate immediately prior to the completion of this offering.

### **Other Transactions**

We have granted share options to our executive officers. For a description of these share options, see "Executive Compensation."

### **Policies for Approval of Related Party Transactions**

Following the closing of this offering, the audit committee of our board of directors will have the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director or greater than 5% beneficial owner of our voting securities, in each case since the beginning of the most recently completed year, and their immediate family members. Our audit committee charter will provide that the audit committee shall review and approve or disapprove any related party transactions. In connection with this offering, we have adopted a written related party transactions policy that such transactions must be approved by our audit committee.

All of the transactions described above were entered into prior to the adoption of this policy. Accordingly, each was approved by disinterested members of our board of directors after making a determination that the transaction was executed on terms no less favorable than those that could have been obtained from an unrelated third party.

## PRINCIPAL SHAREHOLDERS

The following table sets forth certain information known to us regarding beneficial ownership of our share capital as of December 31, 2015 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 and director nominee; and
- all of our executive officers, directors and director nominee as a group.

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 \$63 million of our ADSs in this offering at the initial 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 316,164,735 ordinary shares outstanding as of December 31, 2015, which includes 199,990,641 ordinary shares resulting from the conversion of all outstanding preferred shares upon the closing of this offering, as if this conversion had occurred as of December 31, 2015 and includes 44,444 issued but unvested restricted shares, and also lists applicable percentage ownership based on 409,723,027 ordinary shares assumed to be outstanding after the closing of this offering assuming the underwriters do not exercise their option to purchase additional ADSs. These amounts assume (1) the conversion of all of our outstanding preferred shares into ordinary shares, which will occur immediately prior to the closing of this offering, and (2) the exchange of the outstanding balance of the senior promissory note as of September 30, 2015 into 7,758,292 ordinary shares upon the closing of this offering, computed at the initial public offering price of \$24.00 per ADS. Options or warrants to purchase ordinary shares that are exercisable within 60 days of December 31, 2015 are deemed to be beneficially owned by the persons holding these options or warrants 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.

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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 KY1-1108, Cayman Islands.

Name and Address of Beneficial Owner	Number of Ordinary Shares Beneficially Owned Prior to this Offering	Percentage of Ordinary Shares Beneficially Owned	
		Prior to this Offering	After this Offering
<b>5% or Greater Shareholders</b>			
Entities affiliated with Baker Bros. Advisors LP(1)	80,334,757	25.2%	19.5%
Hillhouse BGN Holdings Limited(2)	30,626,779	9.7	7.5
Merck Sharp & Dohme Research GmbH(3)	23,646,724	7.5	7.7
CB Biotech Investment Limited(4)	19,601,138	6.2	4.8
<b>Named Executive Officers, Directors and Director Nominee</b>			
John V. Oyler(5)	77,882,537	24.6	19.0
Howard Liang	—	—	—
RuiRong Yuan	—	—	—
Michael Goller	—	—	—
Donald W. Glazer(6)	7,632,000	2.4	1.9
Ranjeev Krishana	—	—	—
Ji Li	—	—	—
Ke Tang	—	—	—
Qingqing Yi	—	—	—
Thomas Malley	—	—	—
Xiaodong Wang(7)	17,025,275	5.4	4.2
<b>All Directors, Director Nominee and Executive Officers as a Group (13 persons) (8)</b>	<b>103,231,478</b>	<b>32.5%</b>	<b>25.1%</b>

- (1) Consists of (i) 44,572,171 ordinary shares issuable upon conversion of Series A preferred shares, 26,292,961 ordinary shares issuable upon conversion of Series A-2 preferred shares and 2,296,890 ordinary shares issuable upon exercise of a warrant currently exercisable and directly held by Baker Brothers Life Sciences, L.P.; (ii) 4,382,118 ordinary shares issuable upon conversion of Series A preferred shares, 1,912,167 ordinary shares issuable upon conversion of Series A-2 preferred shares and 238,850 ordinary shares issuable upon exercise of a warrant currently exercisable and directly held by 667, L.P.; and (iii) 582,747 ordinary shares issuable upon conversion of Series A preferred shares and 56,853 ordinary shares issuable upon exercise of a warrant currently exercisable and directly held by 14159, L.P. Baker Bros. Advisors LP is the investment advisor of each of these funds and has sole voting and investment power with respect to the shares held by these 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) Consists of (i) 14,814,814 ordinary shares issuable upon conversion of Series A preferred shares; and (ii) 15,811,965 ordinary shares issuable upon conversion of Series A-2 preferred shares. Hillhouse BGN Holdings Limited is owned by Hillhouse Fund II, L.P., which is a Cayman Islands limited partnership. Hillhouse Capital Management, Ltd. acts as the sole management company of Hillhouse Fund II, L.P. 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 BGN Holdings Limited is c/o Citco B.V. I. Limited, Flemming House, Wickhams Cay, P.O. Box 662, Road Town, Tortola, British Virgin Islands.

- (3) Consists of (i) 18,518,519 ordinary shares issuable upon conversion of Series A preferred shares; and (ii) 5,128,205 ordinary shares issuable upon conversion of Series A-2 preferred shares directly held by Merck Sharp & Dohme Research GmbH. The directors of Merck Sharp & Dohme Research GmbH are Christoph Brombacher, Franz Escherich, Cedric Kineider, Michael Rowley and Mehmet Yavuz, who may be deemed to have voting and dispositive power over the shares held by Merck Sharp & Dohme Research GmbH. Christoph Brombacher, Franz Escherich, Cedric Kineider, Michael Rowley and Mehmet Yavuz disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for this entity is Weystrasse 20, CH-6000, Lucerne 6, Switzerland. The number of shares beneficially owned after this offering includes an additional 7,758,292 ordinary shares held upon the exchange of the outstanding balance of the senior promissory note as of September 30, 2015 at the closing of this offering, computed at the initial public offering price of \$24.00 per ADS.
- (4) Consists of (i) 14,814,814 ordinary shares issuable upon conversion of Series A preferred shares; and (ii) 4,786,324 ordinary shares issuable upon conversion of Series A-2 preferred 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. Jianbiao Zhu and Ms. Ching Nar Cindy Chan may be deemed to have controlling power over CITIC PE Funds Limited. Each of Mr. Jianbiao Zhu 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.
- (5) Consists of (i) 50,381,969 ordinary shares held directly by Mr. Oyler; (ii) 9,340,603 ordinary shares issuable upon conversion of Series A preferred shares held directly by Mr. Oyler; (iii) 10,000,000 ordinary shares held for the benefit of Mr. Oyler in a Roth IRA PENSCO trust account; (iv) 57,777 Series A preferred shares issuable upon exercise of warrant exercisable within 60 days after December 31, 2015; (v) 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; and (vi) 8,000,000 ordinary shares held for the benefit of Mr. Oyler in a grantor retained annuity trust.
- (6) Consists of (i) 5,132,000 ordinary shares held directly by Mr. Glazer; and (ii) 2,500,000 ordinary shares held for the benefit of Mr. Glazer in a Roth IRA PENSCO trust account.
- (7) Consists of (i) 16,381,475 ordinary shares held directly by Dr. Wang; (ii) 447,935 shares issuable to Dr. Wang upon exercise of share options exercisable within 60 days after December 31, 2015; and (iii) 195,865 ordinary shares held in a UTMA account for Dr. Wang's minor child, for which Dr. Wang disclaims beneficial ownership.
- (8) Includes 997,378 ordinary shares issuable upon exercise of options and warrants within 60 days of December 31, 2015.

## 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 December 31, 2015, our authorized share capital was \$72,000 divided into (1) 500,000,000 ordinary shares, par value \$0.0001 per share, (2) 120,000,000 Series A preferred shares, par value \$0.0001 per share and (3) 100,000,000 Series A-2 preferred shares, par value \$0.0001 per share. As of December 31, 2015, there were 116,174,094 ordinary shares issued and outstanding, which included 44,444 issued but unvested restricted shares. All of our issued and outstanding preferred shares will convert into 199,990,641 ordinary shares concurrently with the completion of this initial public offering. Following completion of this offering, our authorized capital will be \$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 amended and restated memorandum and articles of association, or our articles, will become effective upon completion of this offering and will replace our existing memorandum and articles of association in its entirety. The following are summaries of material provisions of our articles, as they are expected to become effective upon completion of this offering, and the Cayman Companies Law insofar as they relate to the material terms of our ordinary shares. Under our articles, our name will continue to be BeiGene, Ltd.

The following discussion primarily concerns ordinary shares and the rights of holders of ordinary shares. The holders of ADSs will not be treated as our shareholders and will be required to surrender their ADSs for cancellation and withdrawal from the depository facility in which the ordinary shares are held in accordance with the provisions of the deposit agreement in order to exercise directly shareholders' rights in respect of the ordinary shares. The depository will agree, 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 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 will be 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.

#### ***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. Our company 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 Shareholders**

Shareholders' meetings may be convened by a majority of our board of directors or our Chairman. As a Cayman Islands exempted company, we are not obligated by the Cayman Companies Law to call shareholders' annual general meetings; however, our corporate governance guidelines will provide that in each year we will hold an annual general meeting of shareholders. The annual general meeting shall be held at such time and place as may be determined by our board of directors.

The Cayman Companies Law provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our articles provide that upon the requisition of shareholders representing not less than a simple majority of the voting rights entitled to vote at general meetings, our board will convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. However, shareholders may propose only ordinary resolutions to be put to a vote at such meeting and shall have no right to propose resolutions with respect to the election, appointment or removal of directors or with respect to the size of the board. Our articles will provide no other right to put any proposals before annual general meetings or extraordinary general meetings.

Advance notice of at least seven calendar days is required for the convening of a general meeting of our shareholders. All general meetings of shareholders shall occur at such time and place as determined by our directors and set forth in the notice for such meeting.

The quorum required for a general meeting of shareholders at which an ordinary resolution has been proposed consists of such shareholders present in person or by proxy who together hold shares which carry the right to at least a simple majority of all votes capable of being exercised on a poll. The quorum required for a general meeting at which a special resolution has been proposed consists of such shareholders present in person or by proxy who together hold shares which carry the right to at least two-thirds of all votes capable of being exercised on a poll.

### **Nomination, Election and Removal of Directors**

Our articles provide that persons standing for election as directors at a duly constituted general meeting with requisite quorum shall be elected by an ordinary resolution of our shareholders, which requires the affirmative vote of a simple majority of the votes cast on the resolution by the shareholders entitled to vote who are present in person or by proxy at the meeting. Our articles further provide that our board of directors will be divided into three groups designated as Class I, Class II and Class III with as nearly equal a number of directors in each group as possible. Directors assigned to Class I shall initially serve until the first annual general meeting of shareholders following the effectiveness of our articles upon completion of this offering, or the Articles Effectiveness Date; directors assigned to Class II shall initially serve until the second annual general meeting of shareholders following the Articles Effectiveness Date; and directors assigned to Class III shall initially serve until the third annual general meeting of shareholders following the Articles Effectiveness Date. Commencing with the first annual general meeting of shareholders following the Articles Effectiveness Date, each director of each class the term of which shall then expire shall, upon the expiration of his or her term, be eligible for re-election at such annual general meeting to hold office for a three-year term and until such director's successor has been duly elected. Our articles provide that, unless otherwise determined by shareholders in a general meeting, our board will consist of not less than three directors. We have no provisions relating to retirement of directors upon reaching any age limit.

In the event of a casual vacancy arising from the resignation of a former director or as an addition to the existing board, our board may, by the affirmative vote of a simple majority of the

remaining directors present and voting at a board meeting, appoint any person to be a director, unless the board resolves to follow any available exceptions or exemptions.

For so long as our shares or ADSs are listed on NASDAQ, our directors shall comply with any director nomination procedures required under the NASDAQ Stock Market Rules and shall include at least such number of independent directors as applicable law and the NASDAQ Stock Market Rules shall require.

Our board shall have a chairman who has been elected and appointed by a majority of the directors then in office. The period for which our chairman holds office shall also be determined by a majority of all of our directors then in office. Our chairman shall preside as chairman at every meeting of our board. To the extent that our chairman is not present at a meeting of our board within 15 minutes after the time appointed for holding the same, the remaining attending directors may choose one of their number to be the chairman of that meeting.

Our directors shall be elected by an ordinary resolution of the holders of ordinary shares at each annual general meeting of the company to fill the seats of those directors whose terms expire at such annual general meeting.

Each of our directors shall hold office until his successor is duly elected or appointed or his earlier resignation or removal, notwithstanding any agreement between the company and the director. Our directors may be removed by a special resolution, with or without cause.

Our board may, from time to time, and except as required by applicable law or the NASDAQ Stock Market Rules, adopt, institute, amend, modify or revoke any of our corporate governance policies or initiatives of the company, which shall be intended to set forth the guiding principles and policies of the company and our board on various corporate governance related matters as the board shall determine by resolution from time to time.

#### ***Proceedings of Board of Directors***

Our articles provide that our business is to be managed and conducted by our board of directors. The quorum necessary for a board meeting may be fixed by the board and, unless so fixed at another number, will be a majority of the directors.

Our articles provide that the board may from time to time at its discretion exercise all powers of our company to raise capital or borrow money, to mortgage or charge all or any part of the undertaking, property and assets (present and future) and uncalled capital of our company and, subject to the Cayman Companies Law, issue debentures, bonds and other securities of our company, whether outright or as collateral security for any debt, liability or obligation of our company or of any third party.

#### ***Inspection of Books and Records***

Holders of our ordinary shares will have no general right under Cayman Companies Law to inspect or obtain copies of our list of shareholders or our corporate records provided that they are entitled to a copy of the current amended and restated memorandum and articles of association.

#### ***Changes in Capital***

Our shareholders may from time to time by ordinary resolution:

- increase the share capital by such sum, to be divided into shares of such classes and amount, as the resolution shall prescribe;

- consolidate and divide all or any of our share capital into shares of a larger amount than our existing shares;
- sub-divide our existing shares, or any of them into shares of a smaller amount, provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in case of the share from which the reduced share is derived; or
- cancel any shares which, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of our share capital by the amount of the shares so cancelled.

Our shareholders may by special resolution, subject to any confirmation or consent required by the Cayman Companies Law, reduce our share capital or any capital redemption reserve in any manner permitted by law.

### **Restrictive Provisions**

Under our amended articles of association, in connection with any change of control, merger or sale of our company, the holders of our ordinary shares shall receive the same consideration with respect to their ordinary shares in connection with any such transaction.

### **Claims Against the Company**

Our amended articles of association will provide that, unless otherwise determined by a simple majority of our board of directors in its sole discretion, consistent with the directors' fiduciary duties to act in the best interests of the company, in the event that (1) any shareholder (the claiming party) initiates or asserts any claim or counterclaim or joins, offers substantial assistance to or has a direct financial interest in any claim against our company and (2) the claiming party (or the third party that received substantial assistance from the claiming party or in whose claim the claiming party had a direct financial interest) does not obtain a judgment on the merits in which the claiming party prevails, then each claiming party shall, 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.

### **Exclusive Forum**

Our amended articles of association will provide that, subject to limited exceptions, the courts of Cayman Islands will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, (3) any action asserting a claim against us arising pursuant to any provision of the Companies Law of the Cayman Islands or the articles of association, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine (as such concept is recognized under the laws of the United States). Any person or entity purchasing or otherwise acquiring any interest in our share capital shall be deemed to have notice of and to have consented to the provisions of our articles of association described above. Although we believe these provisions benefit us by providing increased consistency in the application of Cayman Islands law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. It is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our articles of association to be inapplicable or unenforceable.

## **Exempted Company**

We are an exempted company with limited liability incorporated under the Cayman Companies Law. The Cayman Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except for the exemptions and privileges listed below:

- an exempted company does not have to file an annual return of its shareholders with the Registrar of Companies;
- an exempted company's register of members is not open to inspection;
- an exempted company does not have to hold an annual general meeting;
- an exempted company may issue no par value, negotiable or bearer shares;
- an exempted company may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- an exempted company may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- an exempted company may register as a limited duration company; and
- an exempted company may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.

Upon completion of this offering, we will be subject to reporting and other informational requirements of the Exchange Act, as applicable to U.S. domestic issuers. The NASDAQ Stock Market rules require that every company listed on the NASDAQ hold an annual general meeting of shareholders. In addition, our articles allow directors to call an extraordinary general meeting of shareholders pursuant to the procedures set forth in our articles.

## **Register of Members**

Under the Cayman Companies Law, we must keep a register of members and there should be entered therein:

- the names and addresses of our members, a statement of the shares held by each member, and of the amount paid or agreed to be considered as paid, on the shares of each member;
- the date on which the name of any person was entered on the register as a member; and
- the date on which any person ceased to be a member.

Under Cayman Companies Law, the register of members of our company is prima facie evidence of the matters set out in the register (that is, the register of members will raise a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members is deemed as a matter of Cayman Companies Law to have legal title to the shares as set against its name in the register of members. Upon completion of this offering, the register of members will be immediately updated to record and give effect to the issuance of shares by us to the Depositary (or its nominee) as the depositary. Once our register of members has been updated, the shareholders recorded in the register of members will be deemed to have legal title to the shares set against their names.



If the name of any person is incorrectly entered in or omitted from our register of members, or if there is any default or unnecessary delay in entering on the register the fact of any person having ceased to be a member of our company, the person or member aggrieved (or any member of our company or our company itself) may apply to the Grand Court of the Cayman Islands for an order that the register be rectified, and the Court may either refuse such application or it may, if satisfied of the justice of the case, make an order for the rectification of the register.

### **Differences in Corporate Law**

The Cayman Companies Law is derived, to a large extent, from the older Companies Acts of England and Wales but does not follow recent United Kingdom statutory enactments, and accordingly there are significant differences between the Cayman Companies Law and the current Companies Act of England. In addition, the Cayman Companies Law differs from laws applicable to United States corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Cayman Companies Law applicable to us and the comparable laws applicable to companies incorporated in the State of Delaware in the United States.

### ***Mergers and Similar Arrangements***

The Cayman Companies Law permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (1) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (2) a "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (1) a special resolution of the shareholders of each constituent company, and (2) such other authorization, if any, as may be specified in such constituent company's articles of association. The plan must be filed with the Registrar of Companies together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Court approval is not required for a merger or consolidation effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders. For this purpose a subsidiary is a company of which at least 90% of the issued shares entitled to vote are owned by the parent company.

The consent of each holder of a fixed or floating security interest of a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Except in certain limited circumstances, a dissenting shareholder of a Cayman Islands constituent company is entitled to payment of the fair value of his or her shares upon dissenting from a merger or consolidation. The exercise of such dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, except for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

In addition, there are statutory provisions that facilitate the reconstruction and amalgamation of companies, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made, and who must, in addition, represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;
- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Cayman Companies Law.

When a takeover offer is made and accepted by holders of 90% of the shares affected within four months the offeror may, within a two-month period commencing on the expiration of such four month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction is thus approved, or if a takeover offer is made and accepted, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

### **Shareholders' Suits**

In principle, we will normally be the proper plaintiff to sue for a wrong done to us as a company, and as a general rule, a derivative action may not be brought by a minority shareholder. However, based on English law authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands courts can be expected to follow and apply the common law principles (namely the rule in *Foss v. Harbottle* and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge:

- an act that is illegal or *ultra vires* with respect to the company and is therefore incapable of ratification by the shareholders;
- an act that, although not *ultra vires*, requires authorization by a qualified (or special) majority (that is, more than a simple majority) that has not been obtained; and
- an act that constitutes a "fraud on the minority" where the wrongdoers are themselves in control of the company.

### ***Indemnification of Directors and Executive Officers and Limitation of Liability***

The Cayman Companies Law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our articles provide that we shall indemnify our officers and directors against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such director or officer in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. In addition, we intend to enter into indemnification agreements with our directors and executive officers that will provide such persons with additional indemnification beyond that provided in our articles.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### ***Anti-Takeover Provisions in Our Articles***

Some provisions of our articles may discourage, delay or prevent a change in control of our company or management that shareholders may consider favorable, including limitations on shareholder rights to nominate or remove directors, as well as provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

Under the Cayman Companies Law, our directors may only exercise the rights and powers granted to them under our articles, as amended and restated from time to time, for what they believe in good faith to be in the best interests of our company and for a proper purpose.

### ***Directors' Fiduciary Duties***

Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he or she reasonably believes to be in the best interests of the corporation. He or she must not use his or her corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interests of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, a director must prove the transaction was procedurally fair and provided fair value to the corporation.

As a matter of Cayman law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his or her position as director (unless the company permits him or her to do so), a duty not to put himself or herself in a position where the interests of the company conflict with his or her personal interest or his or her duty to a third party, and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his or her duties a greater degree of skill than may reasonably be expected from a person of his or her knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care, and these authorities are likely to be followed in the Cayman Islands.

### ***Shareholder Proposals***

Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. The Delaware General Corporation Law does not provide shareholders an express right to put any proposal before the annual meeting of shareholders, but in keeping with common law, Delaware corporations generally afford shareholders an opportunity to make proposals and nominations provided that they comply with the notice provisions in the certificate of incorporation or bylaws. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

The Cayman Companies Law provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our articles allow our shareholders holding not less than a simple majority of the voting rights entitled to vote at general meetings to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. However, our shareholders may propose only ordinary resolutions to be put to a vote at such meetings and shall have no right to propose resolutions with respect to the election, appointment or removal of directors. Our articles provide no other right to put any proposals before annual general meetings or extraordinary general meetings. As a Cayman Islands exempted company, we are not obligated by law to call shareholders' annual general meetings. However, our corporate governance guidelines require us to call such meetings every year.

### ***Cumulative Voting***

Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled on a single director, which increases the shareholder's voting power with respect to electing such director. As permitted under the Cayman Companies Law, our articles do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

### ***Removal of Directors***

Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares

entitled to vote, unless the certificate of incorporation provides otherwise. Under our articles, any director may be removed by a special resolution, with or without cause.

### ***Transactions with Interested Shareholders***

The Delaware General Corporation Law contains a business combination statute applicable to Delaware public corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation or bylaws that is approved by its shareholders, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting stock or who or which is an affiliate or associate of the corporation and owned 15% or more of the corporation's outstanding voting stock within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

The Cayman Companies Law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although the Cayman Companies Law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and for a proper corporate purpose and not with the effect of constituting a fraud on the minority shareholders.

### ***Dissolution; Winding Up***

Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board of directors.

Under the Cayman Companies Law and our articles, our company may be wound up only upon resolution of shareholders holding 100% of the total voting rights entitled to vote or if the winding up is initiated by our board of directors, by either a special resolution of our members or, if our company is unable to pay its debts as they fall due, by an ordinary resolution of our members. In addition, a company may be wound up by an order of the courts of the Cayman Islands. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so.

### ***Variation of Rights of Shares***

Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under the Cayman Companies Law and our articles, if our share capital is divided into more than one class of shares, we may materially and adversely vary the rights attached to any class only with the consent in writing of the holders of two-thirds of the shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class.

### ***Amendment of Governing Documents***

Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors. Under the Cayman Companies Law and our articles, our articles may only be amended by special resolution of our shareholders.

### ***Rights of Non-Resident or Foreign Shareholders***

There are no limitations imposed by our articles on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our articles governing the ownership threshold above which shareholder ownership must be disclosed.

### ***Directors' Power to Issue Shares***

Under our articles, our board of directors is empowered to issue or allot shares or grant options, restricted shares, restricted share units, share appreciation rights, dividend equivalent rights, warrants and analogous equity-based rights with or without preferred, deferred, qualified or other special rights or restrictions. In particular, pursuant to our articles, our board of directors has the authority, without further action by the shareholders, to issue all or any part of our capital and to fix the designations, powers, preferences, privileges, and relative participating, optional or special rights and the qualifications, limitations or restrictions therefrom, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of our ordinary shares. Our board of directors, without shareholder approval, may issue preferred shares with voting, conversion or other rights that could adversely affect the voting power and other rights of holders of our ordinary shares. Subject to the directors' duty of acting in the best interest of our company, preferred shares can be issued quickly with terms calculated to delay or prevent a change in control of us or make removal of management more difficult. Additionally, the issuance of preferred shares may have the effect of decreasing the market price of the ordinary shares, and may adversely affect the voting and other rights of the holders of ordinary shares.

### ***Inspection of Books and Records***

Holders of our ordinary shares will have no general right under the Cayman Companies Law to inspect or obtain copies of our list of shareholders or our corporate records. However, we will provide our shareholders with annual audited financial statements. See "Where You Can Find More Information."

### ***Registration Rights***

Upon the completion of this offering, the holders of our registrable shares, as described in the Investors' Rights Agreement, including shares issuable upon the conversion of preferred shares or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act. These rights are provided under the terms of the Investors' Rights Agreement, and include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

### ***Demand Registration Rights***

Upon the completion of this offering, the holders of 271,592,043 shares of our ordinary shares, including shares issued upon the conversion of preferred shares and issuable upon exercise of the warrants, or their permitted transferees, are entitled to demand registration rights. These shares do not include any that will be owned by MSD upon the exchange of the senior promissory note at the completion of this offering and any that will be purchased in connection with this offering by two existing shareholders, Hillhouse BGN Holdings Limited or its affiliates and entities affiliated with Baker Bros. Advisors LP. Under the terms of the Investors' Rights Agreement, we will be required, upon the written request of holders (other than key holders) of at least 11.37%, or key holders of at least 13.71%, of the registrable securities, including ordinary shares, ordinary shares issued pursuant to conversion of our preferred shares or derivative securities held by the holders or key holders, to file a registration statement covering, and use our commercially reasonable efforts to effect the registration of the shares requested to be registered for public resale. We are required to effect only two registrations pursuant to this provision of the Investors' Rights Agreement. A demand for registration may not be made until six months after the completion of this offering.

### ***Short Form Registration Rights***

Upon the completion of this offering, the holders of 271,592,043 shares of our ordinary shares, including shares issued upon the conversion of preferred shares and issuable upon exercise of the warrants, or their permitted transferees are also entitled to short form registration rights. These shares do not include any that will be owned by MSD upon the exchange of the senior promissory note at the completion of this offering and any that will be purchased in connection with this offering by two existing shareholders, Hillhouse BGN Holdings Limited or its affiliates and entities affiliated with Baker Bros. Advisors LP. If at any time we are eligible to file a registration statement on Form S-3, upon the written request of holders of at least 11.37% (other than key holders), or key holders of at least 13.71%, of the registrable securities, including ordinary shares, ordinary shares issued pursuant to conversion of our preferred shares or derivative securities held by the holders or key holders, to sell registrable securities at an aggregate price of at least \$5,000,000, we will be required to file a registration statement covering, and use our commercially reasonable efforts to effect a registration of, such shares. We are required to effect only two registrations in any 12-month period pursuant to this provision of the Investors' Rights Agreement.

### ***Piggyback Registration Rights***

Upon the completion of this offering, the holders of 271,592,043 shares of our ordinary shares, including shares issued upon the conversion of preferred shares and issuable upon exercise of the warrants, or their permitted transferees, are entitled to piggyback registration rights. These shares do not include any that will be owned by MSD upon the exchange of the senior promissory note at the completion of this offering and any that will be purchased in connection with this offering by two existing shareholders, Hillhouse BGN Holdings Limited or its affiliates and entities affiliated with Baker Bros. Advisors LP. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters believe that including these shares would adversely affect the offering.

### ***Indemnification***

Our Investors' Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

### ***Expiration of Registration Rights***

The registration rights granted under the investors' rights agreement will terminate on the fifth anniversary of the completion of this offering.

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Citibank, N.A. has agreed to act as the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is either (i) Citibank Hong Kong, located at 10/F, Two Harbourfront, 22 Tak Fung Street, Hung Hom, Kowloon, Hong Kong, or (ii) Citibank, N.A., London Branch, located Citigroup Centre, Canary Wharf, London E14 5LB.

We have appointed Citibank as depositary bank pursuant to a deposit agreement. A copy of the deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and from the SEC's website ([www.sec.gov](http://www.sec.gov)). Please refer to Registration Number 333-209044 when retrieving such copy.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, 13 ordinary shares that are on deposit with the depositary bank and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary bank. As an ADS holder you appoint the depositary bank to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of the ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws in the United States.



In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depository bank, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

*As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depository bank will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depository bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.*

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depository bank in your name reflecting the registration of uncertificated ADSs directly on the books of the depository bank (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depository bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depository bank to the holders of the ADSs. The direct registration system includes automated transfers between the depository bank and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depository bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depository bank or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depository bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

#### **Dividends and Distributions**

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction the applicable fees, taxes and expenses.

### ***Distributions of Cash***

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the Cayman Islands laws and regulations.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

### ***Distributions of Shares***

Whenever we make a free distribution of the ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of the ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary share ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary share ratio upon a distribution of the ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (i.e., the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

### ***Distributions of Rights***

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The depositary bank will *not* distribute the rights to you if:

- We do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- We fail to deliver satisfactory documents to the depositary bank; or
- It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

### ***Elective Distributions***

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

### ***Other Distributions***

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will *not* distribute the property to you and will sell the property if:

- We do not request that the property be distributed to you or if we ask that the property not be distributed to you; or
- We do not deliver satisfactory documents to the depositary bank; or
- The depositary bank determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

### **Redemption**

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary bank may determine.

### **Changes Affecting Ordinary Shares**

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, your ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary bank may not lawfully distribute such property to you, the depositary bank may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

### **Issuance of ADSs upon Deposit of Ordinary Shares**

Upon completion of this offering, the ordinary shares being offered pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will issue ADSs to the underwriters named in this prospectus. After the completion of this offering, the ordinary shares that are being offered for sale pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will issue ADSs to the underwriters named in this prospectus.

After the closing of this offer, the depositary bank may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary bank will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Cayman Islands legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When you make a deposit of the ordinary shares, you will be responsible for transferring good and valid title to the depositary bank. As such, you will be deemed to represent and warrant that:

- The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- You are duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

#### **Transfer, Combination and Split Up of ADRs**

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary bank and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary bank with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

#### **Withdrawal of Ordinary Shares Upon Cancellation of ADSs**

As a holder, you will be entitled to present your ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Cayman Islands considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary bank may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares

represented by your ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) the ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.
- Obligations to pay fees, taxes and similar charges.
- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

### **Voting Rights**

As a holder, you generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in "Description of Share Capital."

At our request, the depositary bank will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs.

If the depositary bank timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs as follows:

- *In the event of voting by show of hands*, the depositary bank will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- *In the event of voting by poll*, the depositary bank will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

In the event of voting by poll, holders of ADSs in respect of which no timely voting instructions have been received shall be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us to vote the ordinary shares represented by such holders' ADSs; provided, that no such instruction shall be deemed given and no such discretionary proxy shall be given with respect to any matter as to which we inform the depositary that we do not wish such proxy to be given; provided, further, that no such discretionary proxy shall be given (x) with respect to any matter as to which we inform the depositary that (i) there exists substantial opposition, or (ii) the rights of holders of ADSs or the shareholders of our company will be materially adversely affected, and (y) in the event that the vote is on a show of hands.

Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary bank in a timely manner.

## Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

<u>Service</u>	<u>Fees</u>
• Issuance of ADSs upon deposit of shares (excluding issuances as a result of distributions of shares)	Up to U.S. 5¢ per ADS issued
• Cancellation of ADSs	Up to U.S. 5¢ per ADS canceled
• Distribution of cash dividends or other cash distributions (i.e., sale of rights and other entitlements)	Up to U.S. 5¢ per ADS held
• Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
• Distribution of securities other than ADSs or rights to purchase additional ADSs (i.e., spin-off shares)	Up to U.S. 5¢ per ADS held
• ADS Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary bank

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of the ordinary shares on the share register and applicable to transfers of the ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary bank in the conversion of foreign currency;
- the fees and expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to the ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) deposit of the ordinary shares against issuance of ADSs and (ii) surrender of ADSs for cancellation and withdrawal of the ordinary shares are charged to the person to whom the ADSs are delivered (in the case of ADS issuances) and to the person who delivers the ADSs for cancellation (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC or presented to the depositary bank via DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs or the DTC participant(s) surrendering the ADSs for cancellation, as the case may be, on behalf of the beneficial owner(s)

and will be charged by the DTC participant(s) to the account(s) of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participant(s) as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to the ADS holder. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

#### **Amendments and Termination**

We may agree with the depositary bank to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and sell the securities held on deposit. After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).



## **Books of Depository**

The depository bank will maintain ADS holder records at its depository office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depository bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

## **Limitations on Obligations and Liabilities**

The deposit agreement limits our obligations and the depository bank's obligations to you. Please note the following:

- We and the depository bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depository bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depository bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in the ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depository bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depository bank disclaim any liability if we or the depository bank are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our memorandum and articles of association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depository bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our memorandum and articles of association or in any provisions of or governing the securities on deposit.
- We and the depository bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depository bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of the ordinary shares but is not, under the terms of the deposit agreement, made available to you.

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- We and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary bank also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

### **Pre-Release Transactions**

Subject to the terms and conditions of the deposit agreement, the depositary bank may issue to broker/dealers ADSs before receiving a deposit of the ordinary shares. These transactions are commonly referred to as "pre-release transactions," and are entered into between the depositary bank and the applicable broker/dealer. The deposit agreement limits the aggregate size of pre-release transactions (generally not to exceed 30% of the ordinary shares on deposit in the aggregate) and imposes a number of conditions on such transactions (i.e., the need to receive collateral, the type of collateral required, the representations required from brokers, etc.). The depositary bank may retain the compensation received from the pre-release transactions.

### **Taxes**

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

### **Foreign Currency Conversion**

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

**Governing Law/Waiver of Jury Trial**

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of the ordinary shares (including the ordinary shares represented by ADSs) is governed by the laws of the Cayman Islands.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU WAIVE YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY BANK.

## SHARES AND AMERICAN DEPOSITARY SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have 6,600,000 ADSs outstanding representing approximately 21% of our ordinary shares (or 7,590,000 ADSs outstanding representing approximately 23% of our ordinary shares, if the underwriters exercise in full their option to purchase additional ADSs), based on the number of ordinary shares outstanding as of September 30, 2016. This does not include 10,640,734 ordinary shares, representing 2.6% of our outstanding ordinary shares immediately after this offering, that will not be subject to lock-up agreements and may be freely converted into ADSs after this offering from time to time. All of the ADSs sold in this offering and the ordinary shares they represent will be freely transferable by persons other than our "affiliates" without restriction or further registration under the Securities Act. Rule 144 under the Securities Act defines an "affiliate" of a company as a person that, directly or indirectly, through one or more intermediaries, controls or is controlled by, or is under common control with, our company. All outstanding ordinary shares prior to this offering are "restricted securities" as that term is defined in Rule 144 because they were issued in a transaction or series of transactions not involving a public offering. Restricted securities, in the form of ADSs or otherwise, may be sold only if they are the subject of an effective registration statement under the Securities Act or if they are sold pursuant to an exemption from the registration requirement of the Securities Act such as those provided for in Rule 144 or 701 promulgated under the Securities Act, which rules are summarized below. Restricted ordinary shares may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S under the Securities Act. This prospectus may not be used in connection with any resale of the ADSs acquired in this offering by our affiliates.

Sales of substantial amounts of the ADSs in the public market could materially and adversely affect prevailing market prices of the ADSs. Prior to this offering, there has been no public market for our ordinary shares or ADSs, and though the ADSs are approved for listing on the NASDAQ we cannot assure you that a regular trading market will develop in the ADSs. We do not expect that a trading market will develop for our ordinary shares not represented by ADSs.

### Lock-up Agreements

In connection with this offering, all of our directors and executive officers and certain holders of our shares, who collectively held substantially all ordinary shares (assuming conversion of all of our outstanding preferred shares) as of January 19, 2016, and substantially all of our optionholders who are not shareholders, 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 180 days from the date of this prospectus without the prior written consent of each of the representatives. 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 180-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. In addition, our optionholders who have not executed lock-up agreements are nevertheless subject to similar restrictions set forth in the option agreements executed in connection with our 2011 Plan.

### Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned our restricted securities for at least six months is entitled to sell the restricted securities without registration under the Securities Act, subject to certain restrictions. Persons who are our affiliates

(which may include persons beneficially owning 10% or more of our outstanding shares) may sell within any three-month period a number of restricted securities that does not exceed the greater of the following:

- 1% of the number of our ordinary shares then outstanding, in the form of ADSs or otherwise, which will equal approximately 4,097,230 ordinary shares immediately after this offering; and
- the average weekly trading volume of the ordinary shares, in the form of ADSs or otherwise, on NASDAQ during the four calendar weeks preceding the date on which notice of the sale is filed with the U.S. Securities and Exchange Commission, or SEC.

Such sales are also subject to manner-of-sale provisions, notice requirements and the availability of current public information about us.

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, persons who are not our affiliates and have beneficially owned our restricted securities for more than six months but not more than one year may sell the restricted securities without registration under the Securities Act subject to the availability of current public information about us. Persons who are not our affiliates and have beneficially owned our restricted securities for more than one year may freely sell the restricted securities without registration under the Securities Act.

#### **Rule 701**

Beginning 90 days after the date of this prospectus, persons other than affiliates who purchased ordinary shares under a written compensatory plan or contract may be entitled to sell such shares in the United States in reliance on Rule 701 under the Securities Act, or Rule 701. Rule 701 permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. Rule 701 further provides that non-affiliates may sell these shares in reliance on Rule 144 subject only to its manner-of-sale requirements. However, the Rule 701 shares would remain subject to any applicable lock-up arrangements and would only become eligible for sale when the lock-up period expires.

#### **Registration Rights**

Upon completion of this offering, certain holders of our ordinary shares or their transferees will be entitled to request that we register their ordinary shares under the Securities Act, following the expiration of the lock-up agreements described above. See "Description of Share Capital—Registration Rights."

#### **Share Option Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our share option plans or independent options. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. As of January 19, 2016, we estimate that such registration statement on Form S-8 will cover approximately 112.7 million shares.

## TAXATION

*The following is a summary of the material Cayman Islands, PRC and United States federal income tax consequences relevant to an investment in the ADSs and ordinary shares. The discussion is not intended to be, nor should it be construed as, legal or tax advice to any particular prospective purchaser. The discussion is based on laws and relevant interpretations thereof as of the date of this prospectus, all of which are subject to change or different interpretations, possibly with retroactive effect. The discussion does not address U.S. state or local tax laws, or tax laws of jurisdictions other than the Cayman Islands, the People's Republic of China and the United States. You should consult your own tax advisors with respect to the consequences of acquisition, ownership and disposition of the ADSs and ordinary shares. To the extent that this discussion relates to matters of Cayman Islands tax law, it is the opinion of Mourant Ozannes, our special Cayman Islands counsel. To the extent that the discussion relates to PRC tax laws and regulations, it is the opinion of Fangda Partners, our special PRC counsel.*

### **Cayman Islands Taxation**

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty or withholding tax applicable to us or to any holder of the ADSs and ordinary shares. There are no other taxes likely to be material to us levied by the Government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within, the jurisdiction of the Cayman Islands. No stamp duty is payable in the Cayman Islands on the issue of shares by, or any transfers of shares of, Cayman Islands companies (except those which hold interests in land in the Cayman Islands). The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of the ADSs and ordinary shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the ADSs or ordinary shares, as the case may be, nor will gains derived from the disposal of the ADSs or ordinary shares be subject to Cayman Islands income or corporation tax.

### **People's Republic of China Taxation**

Under the EIT Law, an enterprise established outside of China with a "de facto management body" within China is considered a "resident enterprise," which means that it is treated in a manner similar to a Chinese enterprise for enterprise income tax purposes. Although the implementation rules of the EIT Law define "de facto management body" as a managing body that exercises substantive and overall management and control over the production and business, personnel, accounting books and assets of an enterprise, the only official guidance for this definition currently available is set forth in the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprise as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, issued by the State Administration of Taxation, which provides guidance on the determination of the tax residence status of a Chinese-controlled offshore incorporated enterprise, defined as an enterprise that is incorporated under the laws of a foreign country or territory and that has a PRC enterprise or enterprise group as its primary controlling shareholder. 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.

According to Circular 82, a Chinese-controlled offshore incorporated enterprise will be regarded as a PRC tax resident by virtue of having a "de facto management body" in China and will be subject to PRC enterprise income tax on its worldwide income only if all of the following criteria are met:

- the primary location of the enterprise's senior executives of the day-to-day operational management and senior management departments performing their duties is in the PRC;
- decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC;
- the enterprise's primary assets, accounting books and records, company seals, and board and shareholder meeting minutes are located or maintained in the PRC; and
- 50% or more of voting board members or senior executives habitually reside in the PRC.

Currently, some of the members of our management team are located in China. However, we do not believe that we meet all of the conditions outlined in the immediately preceding paragraph. BeiGene, Ltd. and its offshore subsidiaries are incorporated outside the PRC. As a holding company, our key assets and records, including the resolutions and meeting minutes of our board of directors and the resolutions and meeting minutes of our shareholders, are located and maintained outside the PRC. However, we are not aware of any offshore holding companies with a corporate structure similar to ours that has been deemed a PRC "resident enterprise" by the PRC tax authorities. Accordingly, we believe that BeiGene, Ltd. and its offshore subsidiaries should not be treated as a "resident enterprise" for PRC tax purposes if the criteria for "de facto management body" as set forth in Circular 82 were deemed applicable to us. However, as the tax residency status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body" as applicable to our offshore entities, we will continue to monitor our tax status.

The implementation rules of the EIT Law provide that, (1) if the enterprise that distributes dividends is domiciled in the PRC or (2) if gains are realized from transferring equity interests of enterprises domiciled in the PRC, then such dividends or capital gains are treated as China-sourced income. It is not clear how "domicile" may be interpreted under the EIT Law, and it may be interpreted as the jurisdiction where the enterprise is a tax resident. Therefore, if we are considered as a PRC tax resident enterprise for PRC tax purposes, any dividends we pay to our overseas shareholders or ADS holders as well as gains realized by such shareholders or ADS holders from the transfer of our shares or ADSs may be regarded as China-sourced income. 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 up to 10% (or 20% in the case of non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprise 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 also unclear whether, if we are considered a PRC resident enterprise, holders of our shares or ADSs would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas.

#### **Material United States Federal Income Tax Considerations**

The following summary describes the material United States federal income tax consequences of the ownership and disposition of our ordinary shares and ADSs as of the date of this prospectus. The discussion set forth below is applicable only to United States Holders (described below). Except where noted, this summary deals only with United States Holders that are initial purchasers of the ordinary shares and ADSs and that will hold such ordinary shares and ADSs as capital

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assets for U.S. federal income tax purposes. This summary does not address all U.S. federal income tax matters that may be relevant to a particular United States Holder. As used herein, the term "United States Holder" means a beneficial owner of an ordinary share or ADS that is for United States federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for United States federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more United States persons has or have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person.

This summary does not represent a detailed description of all of the United States federal income tax consequences that may be applicable to you if you are subject to special treatment under the United States federal income tax laws, including if you are:

- a dealer in securities or currencies;
- a financial institution;
- a regulated investment company;
- a real estate investment trust;
- an insurance company;
- a tax-exempt organization;
- a person holding our ordinary shares or ADSs as part of a hedging, integrated or conversion transaction, a constructive sale or a straddle;
- a trader in securities that has elected the mark-to-market method of tax accounting;
- a person who owns or is deemed to own 10% or more of our voting stock;
- a partnership or other pass-through entity for United States federal income tax purposes; or
- a person whose "functional currency" is not the United States dollar.

The discussion below is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, current (and, to the extent noted below, proposed) Treasury regulations, rulings and judicial decisions thereunder, and the income tax treaty between the United States and the PRC, or the Treaty, as of the date of this prospectus, and such authorities may be replaced, revoked or modified, perhaps retroactively, and may be subject to differing interpretations which could result in United States federal income tax consequences different from those discussed below. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

If a partnership (or any other entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares or ADSs, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. If you are a partnership holding our ordinary shares or ADSs or a partner in such a partnership, you should



consult your tax advisors as to the particular U.S. federal income tax consequences of owning and disposing of our ordinary shares or ADSs.

This summary does not address all aspects of U.S. federal income tax, does not deal with all tax considerations that may be relevant to stockholders in light of their personal circumstances and does not address the Medicare tax imposed on certain net investment income or any state, local, foreign, gift, estate or alternative minimum tax considerations. If you are considering the purchase of our ordinary shares or ADSs, you should consult your own tax advisors concerning the United States federal income tax consequences to you in light of your particular situation as well as any consequences arising under the laws of any other taxing jurisdiction.

### **ADSs**

If you own ADSs, for United States federal income tax purposes, you generally will be treated as the owner of the underlying ordinary shares that are represented by such ADSs. Accordingly, deposits or withdrawals of ordinary shares for ADSs will not be subject to United States federal income tax.

### **Taxation of Dividends**

Subject to the discussion under "—Passive Foreign Investment Company" below, the gross amount of distributions on the ADSs or ordinary shares (including any amounts withheld in respect of PRC withholding taxes) generally will be taxable as dividends to the extent paid out of our current or accumulated earnings and profits, as determined under United States federal income tax principles. Such income (including withheld taxes) will be includable in your gross income as ordinary income on the day actually or constructively received by you, in the case of the ordinary shares, or by the depository, in the case of ADSs. Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations under the Code. The following discussion assumes that any dividends will be paid in U.S. dollars.

With respect to certain non-corporate United States investors, certain dividends received from a qualified foreign corporation may be subject to reduced rates of taxation. A foreign corporation is treated as a qualified foreign corporation with respect to dividends received from that corporation on ordinary shares (or American depository shares backed by such shares) that are "readily tradable" on an "established securities market" in the United States. The ADSs are approved for listing on the NASDAQ. Internal Revenue Service guidance indicates that ADSs listed on the NASDAQ will be readily tradable on an established securities market in the United States. There can be no assurance that the ADSs will be considered readily tradable on an established securities market in subsequent years. Non-corporate United States Holders that do not meet a minimum holding period requirement during which they are not protected from the risk of loss or that elect to treat the dividend income as "investment income" pursuant to Section 163(d)(4) of the Code will not be eligible for the reduced rates of taxation. In addition, the rate reduction will not apply to dividends if the recipient of a dividend is obligated to make related payments with respect to positions in substantially similar or related property, even if the minimum holding period has been met. The rate reduction will also not apply if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year. In light of the discussion in "—Passive Foreign Investment Company" below, if you are a non-corporate United States Holder, you should assume that dividends generally will not constitute "qualified dividend income" eligible for reduced rates of taxation.

In the event that we were deemed to be a PRC resident enterprise under the EIT Law, you may be subject to PRC withholding taxes on distributions paid to you with respect to the ADSs or ordinary shares. See "—People's Republic of China Taxation." In that case, subject to certain

conditions and limitations, PRC withholding taxes on dividends generally will be treated as foreign taxes eligible for credit against your United States federal income tax liability. For purposes of calculating the foreign tax credit, dividends paid on the ADSs or ordinary shares will be treated as foreign-source income and will generally constitute passive category income. However, in certain circumstances, if you have held the ADSs or ordinary shares for less than a specified minimum period during which you are not protected from risk of loss, or are obligated to make payments related to the dividends, you will not be allowed a foreign tax credit for any PRC withholding taxes imposed on dividends paid on the ADSs or ordinary shares. If you are eligible for Treaty benefits, any PRC taxes on dividends will not be creditable against your United States federal income tax liability to the extent withheld at a rate exceeding the applicable Treaty rate. The rules governing the foreign tax credit are complex. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances. In lieu of claiming a credit, you may elect to deduct such PRC taxes in computing your taxable income, subject to applicable limitations. An election to deduct foreign taxes instead of claiming foreign tax credits must apply to all foreign taxes paid or accrued in the taxable year.

To the extent that the amount of any distribution on the ADSs or ordinary shares exceeds our current and accumulated earnings and profits for a taxable year, as determined under United States federal income tax principles, the distribution will first be treated as a tax-free return of capital, causing a reduction in your adjusted tax basis in the ADSs or ordinary shares (thereby increasing the amount of gain, or decreasing the amount of loss, to be recognized by you on a subsequent disposition of the ADSs or ordinary shares), and the balance in excess of adjusted tax basis will be taxed as capital gain recognized on a sale or exchange, as described below under "—Taxation of Capital Gains." However, we may not calculate earnings and profits in accordance with United States federal income tax principles. Therefore, a distribution to you may be treated as a dividend (as discussed above).

### ***Passive Foreign Investment Company***

The determination of whether any corporation is a "passive foreign investment company" within the meaning of Section 1297 of the Code, or PFIC, for a taxable year depends, in part, on the application of complex U.S. federal income tax rules, which are subject to differing interpretations. In addition, whether any corporation will be a PFIC for any taxable year depends on the composition and character of assets and income and value of the assets of such corporation (which may be determined, in part, based on the market value of the corporation's ADSs or ordinary shares, which may be volatile) over the course of each such taxable year and, as a result, cannot be predicted with certainty as of the date hereof. Each U.S. Holder should consult its own tax advisors regarding our PFIC status and the PFIC status of our subsidiaries.

In general, we will be a PFIC for any taxable year in which:

- at least 75% of our gross income is passive income; or
- at least 50% of the average value of our assets, determined on a quarterly basis, is attributable to assets that produce or are held for the production of passive income.

For this purpose, passive income generally includes dividends, interest, royalties and rents (other than royalties and rents derived in the active conduct of a trade or business and not derived from a related person). Cash and cash equivalents, even if held as working capital, are considered to be assets that produce passive income. If we directly or indirectly own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC tests, as owning our proportionate share of the other corporation's assets and receiving our proportionate share of the other corporation's income.

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Based on current business plans and financial expectations (including that this offering will result in a substantial percentage of our assets being held in cash and cash equivalents), we expect that we may be a PFIC for the current taxable year and in future taxable years.

If we are a PFIC, for any taxable year during a U.S. Holder's holding period, then certain adverse rules may affect the U.S. federal income tax consequences to a U.S. Holder as a result of the acquisition, ownership and disposition of our ADSs or ordinary shares.

If we are a PFIC for any taxable year during which you own our ADSs or ordinary shares, we will generally continue to be treated as a PFIC with respect to your ADSs or ordinary shares for all succeeding years during which you own such ADSs or ordinary shares, even if we cease to meet the threshold requirements for PFIC status unless you elect to recognize gain as if you had sold your ADSs or ordinary shares as of the last day of the last taxable year for which we were a PFIC. You will generally be required to file Internal Revenue Service Form 8621 if you own the ADSs or ordinary shares in any taxable year in which we are a PFIC.

If we are a PFIC for any taxable year during which you own the ADSs or ordinary shares and you do not make a mark-to-market election or a "QEF election," each as discussed below, you will generally be subject to special tax rules with respect to any "excess distribution" received and any gain realized from a sale or other disposition, including a pledge, of ADSs or ordinary shares. Any distributions received in a taxable year that are greater than 125% of the average annual distributions received during the shorter of the three preceding taxable years or your holding period for the ADSs or ordinary shares will be treated as excess distributions. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we were a PFIC, will be taxed as ordinary income; and
- the amount allocated to each other taxable year will be subject to tax at the highest tax rate in effect for that taxable year for individuals or corporations, as appropriate, and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such taxable year.

In addition, certain non-corporate United States Holders will not be eligible for reduced rates of taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year. See "—Taxation of Dividends."

If we are a PFIC for any taxable year during which you own the ADSs or ordinary shares and any of our non-United States subsidiaries or other entities in which we directly or indirectly own equity interests is also a PFIC or a lower-tier PFIC, you would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules and will be subject to U.S. federal income tax according to the PFIC rules described above on (i) certain distributions by a lower-tier PFIC and (ii) a disposition of shares of a lower-tier PFIC, in each case as if you owned such shares directly, even though you have not received the proceeds of those distributions or dispositions. You are urged to consult your tax advisors about the application of the PFIC rules to any of our subsidiaries.

In certain circumstances, in lieu of being subject to the general tax treatment for PFICs discussed above, you may make an election to include gain on the stock of a PFIC as ordinary income under a mark-to-market method, provided that such stock is "regularly traded" on a "qualified exchange." Under current law, the mark-to-market election may be available to United States Holders of ADSs if the ADSs are listed on the NASDAQ, which constitutes a qualified

exchange, and are "regularly traded" for purposes of the mark-to-market election (for which no assurance can be given). The ADSs will be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter.

If you make an effective mark-to-market election, you will include in ordinary income any gain you recognize in a taxable year that we are a PFIC, in an amount equal to the excess of the fair market value of your ADSs at the end of the taxable year over your adjusted tax basis in the ADSs. You will be entitled to deduct as an ordinary loss in each such taxable year the excess of your adjusted tax basis in the ADSs over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. If you make an effective mark-to-market election, in each year that we are a PFIC any gain you recognize upon the sale or other disposition of your ADSs will be treated as ordinary income and any loss will be treated as ordinary loss, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. Your adjusted tax basis in the ADSs will be increased by the amount of any income inclusion and decreased by the amount of any deductions under the mark-to-market rules. If you make an effective mark-to-market election, distributions paid on ADSs will be treated as discussed under "—Taxation of Dividends." If you make a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer regularly traded on a qualified exchange or the Internal Revenue Service consents to the revocation of the election. You are urged to consult your tax advisor about the availability of the mark-to-market election, and whether making the election would be advisable in your particular circumstances. In particular, you should consider carefully the impact of a mark-to-market election with respect to your ADSs given that we may own interests in lower-tier PFICs for which a mark-to-market election may not be available.

Alternatively, you may avoid the general tax treatment for PFICs described above by electing to treat us (and each lower-tier PFIC) as a "qualified electing fund" under Section 1295 of the Code, or QEF, for each of the taxable years during your holding period that we are a PFIC. 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, a PFIC Annual Information Statement containing the information 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.

We will endeavor to cause any lower-tier PFIC to provide to a U.S. Holder the information that may be required to make or maintain a QEF election with respect to the lower-tier PFIC. However, there is no assurance that we will have timely knowledge of the status of any such lower-tier PFIC. In addition, we may not hold a controlling interest in any such lower-tier PFIC and thus there can be no assurance we will be able to cause the lower-tier PFIC to provide the required information. U.S. Holders are urged to consult their own tax advisors regarding the tax issues raised by lower-tier PFICs.

You are urged to consult your own tax advisors regarding the procedure for making a QEF election.

If you make a QEF election, you will be currently taxable on your *pro rata* share of the QEF's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is a PFIC, even if no dividend distributions were received. Any distributions we make out of our earnings and profits that were previously included in your income under the QEF election would not be taxable to you. Your tax basis in your ADSs or ordinary shares would be increased by an amount equal to any income included under the QEF election and decreased by any amount distributed on the ADSs or ordinary shares that is not included in your income. In addition, you will recognize capital gain or loss on the disposition of ADSs or ordinary shares in an amount equal to the difference between the amount realized and your adjusted tax basis in the ADSs or ordinary shares, each as determined in U.S. dollars. You will not be currently taxed on the ordinary income and net capital gain of a QEF for any year that the QEF is not a PFIC.

Based on the nature of our and our subsidiaries' expected income, the expected composition of our and our subsidiaries' assets and our and our subsidiaries' business plans and financial expectations, we do not currently expect to have significant ordinary earnings or net capital gain in any taxable year in which we or our subsidiaries may be a PFIC. Accordingly, it may be advisable to make a QEF election if we or our subsidiaries are a PFIC for any taxable year. Accurate predictions of the nature of our and our subsidiaries' income and the composition of our and our subsidiaries' assets, however, are particularly difficult in view of the volatile nature of the earnings patterns in technological industries such as emerging pharmaceutical and biotechnology industries. Accordingly, there can be no assurance that our expectations described above will be fulfilled. You should consult your tax adviser concerning the merits of making a QEF election if we are a PFIC for any taxable year. In order to make a QEF Election, you must attach a completed IRS Form 8621, including a PFIC Annual Information Statement, to your timely filed United States federal income tax return.

### **Controlled Foreign Corporation Considerations**

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 Code), 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 be a CFC after the completion of the offering. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

### **Taxation of Capital Gains**

For United States federal income tax purposes, you will recognize taxable gain or loss on any sale or exchange of ADSs or ordinary shares in an amount equal to the difference between the amount realized for the ADSs or ordinary shares and your tax basis in the disposed-of ADSs or ordinary shares. Subject to the discussion under "—Passive Foreign Investment Company" above, such gain or loss will generally be capital gain or loss. Capital gains of individuals derived with respect to capital assets held for more than one year are eligible for reduced rates of taxation. The

deductibility of capital losses is subject to limitations. Any gain or loss recognized by you will generally be treated as United States source gain or loss. However, if we were treated as a PRC resident enterprise for EIT Law purposes and PRC tax were imposed on any gain, and if you are eligible for the benefits of the Treaty, you may elect to treat such gain as PRC source gain under the Treaty. If you are not eligible for the benefits of the Treaty or you fail to make the election to treat any gain as PRC source, then you may not be able to use the foreign tax credit arising from any PRC tax imposed on the disposition of the ADSs or ordinary shares unless such credit can be applied (subject to applicable limitations) against tax due on other income derived from foreign sources. You are also urged to consult your tax advisor regarding the tax consequences in case any PRC tax is imposed on gain on a disposition of the ADSs or ordinary shares, including the availability of the foreign tax credit and the election to treat any gain as PRC source, under your particular circumstances.

***Information Reporting and Backup Withholding***

In general, information reporting will apply to dividends in respect of the ADSs or ordinary shares and the proceeds from the sale, exchange or redemption of the ADSs or ordinary shares that are paid to you within the United States (and in certain cases, outside the United States), unless you are an exempt recipient. A backup withholding tax may apply to such payments if you fail to provide a taxpayer identification number or certification of other exempt status or, in the case of dividend payments, if you fail to report in full your dividend and interest income.

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your United States federal income tax liability provided the required information is furnished to the Internal Revenue Service in a timely manner.

Under the Hiring Incentives to Restore Employment Act of 2010, if you are an individual (or, under proposed regulations, a certain type of entity controlled by individuals), you are required to report information relating to your ownership of ADSs or ordinary shares, subject to certain exceptions (including an exception for ADSs or ordinary shares held in accounts maintained by certain financial institutions (in which case the accounts may be reportable if maintained by non-U.S. financial institutions)), by attaching a complete Internal Revenue Service Form 8938, Statement of Specified Foreign Financial Assets, with your tax return for each year in which you own ADSs or ordinary shares. You are urged to consult your own tax advisors regarding information reporting requirements relating to your ownership of the ADSs or ordinary shares.

## UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the ADSs being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of ADSs indicated in the following table. Goldman, Sachs & Co., Morgan Stanley & Co. LLC and Cowen and Company, LLC are the representatives of the underwriters.

<b>Underwriters</b>	<b>Number of ADSs</b>
Goldman, Sachs & Co	2,475,000
Morgan Stanley & Co. LLC	2,475,000
Cowen and Company, LLC	1,320,000
Robert W. Baird & Co. Incorporated	330,000
Total	6,600,000

The underwriters are committed to take and pay for all of the ADSs being offered, if any are taken, other than the ADSs covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 990,000 ADSs from us to cover sales by the underwriters of a greater number of ADSs than the total number set forth in the table above. They may exercise that option for 30 days. If any ADSs are purchased pursuant to this option, the underwriters will severally purchase ADSs in approximately the same proportion as set forth in the table above.

The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 990,000 additional ADSs.

<b>Paid by Us</b>	<b>No Exercise</b>		<b>Full Exercise</b>	
Per ADS	\$	1.68	\$	1.68
Total	\$	11,088,000	\$	12,751,200

ADSs sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any ADSs sold by the underwriters to securities dealers may be sold at a discount of up to \$1.008 per ADS from the initial public offering price. After the initial offering of the ADSs, the representatives may change the offering price and the other selling terms. The offering of the ADSs by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors and holders of substantially all of our ordinary shares have agreed that we will not offer, sell, contract to sell, pledge, grant any option to purchase, purchase any option or contract to sell, make any short sale or otherwise dispose of any of the ADSs or ordinary shares or any of our securities that are substantially similar to the ADSs or ordinary shares, or any options or warrants to purchase any ADSs or ordinary shares, or any securities convertible into, exchangeable for or that represent the right to receive the ADSs or ordinary shares (including, without limitation, ordinary shares or other securities with respect to which we, our officers, directors and holders have beneficial ownership within the rules and regulations of the SEC and securities

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which may be issued upon exercise of an option or warrant), without the prior consent of the representatives, other than transfers of such securities:

- (a) acquired in the offering, or transactions relating to the ordinary shares, ADSs or other securities acquired in open market transactions after the date of the offering;
- (b) as a bona fide gift or gifts;
- (c) to any member of the immediate family of the locked-up person or any trust or other legal entity for the direct or indirect benefit of the locked-up person or the immediate family of the locked-up person, or if the locked-up person is a trust, to any beneficiary (including such beneficiary's estate) of the locked-up person, provided that any such transfer will not involve a disposition for value;
- (d) by will or intestate succession upon the death of the locked-up person;
- (e) by operation of law or by order of a court of competent jurisdiction pursuant to a qualified domestic order or in connection with a divorce settlement;
- (f) by surrender or forfeiture of ordinary shares, ADSs or other securities to us to satisfy (x) tax withholding obligations upon exercise or vesting or (y) the exercise price upon a cashless net exercise, in each case, of share options, equity awards, warrants or other right to acquire ordinary shares or ADSs pursuant to our equity incentive plans described in this prospectus;
- (g) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction occurring after the completion of the offering, in each case made to all holders of our ordinary shares, including in the form of ADSs, involving a change of control, provided that (x) in the event that the tender offer, merger, consolidation or other such transaction is not completed, the locked-up person's securities will remain subject to the terms of the lock-up agreement and (y) no such transfer of ordinary shares, ADS or any such warrant or other security will be permitted pursuant to this provision if such bona fide third-party tender offer, merger, consolidated or other similar transaction is not approved by our board of directors, unless either (A) such transfer is required pursuant to mandatory take-over or squeeze-out provisions under applicable law or (B) the failure to transfer such locked-up person's securities would result in those securities being extinguished without value being received by the locked-up person;
- (h) to us arising as a result of the termination of employment of the locked-up person and pursuant to employment agreements under which we have the option to repurchase such locked-up person's securities or a right of first refusal with respect to transfers of such securities, provided that any filing made pursuant to Section 16(a) of the Exchange Act will include a footnote noting the purpose of the transaction;
- (i) as contemplated by the underwriting agreement and the sale of the securities to the underwriters in connection with the offering; or
- (j) if the locked-up person is a corporation, partnership, limited liability company, trust or other business entity, (x) to another corporation, partnership, limited liability company, trust or other affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the locked-up person (including, for the avoidance of doubt, a fund managed by the same manager or managing member or general partner or management company or by an entity controlling, controlled by, or under common control with such manager or managing member or general partner or management company as the locked-up person or who shares a common investment advisor with the locked-up person) or (y) as part of a distribution without consideration by the locked-up person to its stockholders, partners, members or other equity holders; provided, however, that in any such case, it will be a condition to the transfer that the



transferee execute an agreement stating that the transferee is receiving and holding such locked-up person's securities subject to the provisions of the lock-up agreement and there will be no further transfer of such locked-up person's securities except in accordance with the lock-up agreement, and provided further that any such transfer will not involve a disposition for value.

Provided that, with respect to clauses (a) through (f) above, it will be a condition to such transfer that no filing under the Exchange Act nor any other public filing or disclosure of such transfer by or on behalf of the locked-up person will be required or voluntarily made during the 180-day period described above and, with respect to clauses (a) through (e) and (g), prior to such transfer or distribution, the transferee, donee, trustee or distributee agrees to be bound in writing by the restrictions set forth in the lock-up agreement. For purposes of the lock-up agreements, "immediate family" means any relationship by blood, domestic partnership, marriage or adoption, not more remote than first cousin.

The 180-day restricted period described in the preceding paragraph will be automatically extended if: we cease to be an "emerging growth company" and (1) during the last 17 days of the 180-day restricted period we issue an earnings release or announces material news or a material event; or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 15-day period following the last day of the 180-day period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or material event.

Prior to the offering, there has been no public market for our ordinary shares or ADSs. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the ADSs, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

The ADSs are approved for listing on the NASDAQ under the symbol "BGNE."

In connection with the offering, the underwriters may purchase and sell ADSs in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of ADSs than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional ADSs for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional ADSs or purchasing ADSs in the open market. In determining the source of ADSs to cover the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase additional ADSs pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional ADSs for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of ADSs made by the underwriters in the open market prior to the completion of the offering.

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The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased ADSs sold by, or for the account of, such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the ADSs, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the ADSs. As a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the NASDAQ, in the over-the-counter market or otherwise.

At our request, the underwriters have reserved up to 5% of the ADSs offered by this prospectus for sale, at the initial public offering price, through a directed share program to our directors, officers, employees and business associates. There can be no assurance that any of the reserved ADSs will be so purchased. If purchased by these persons, these shares will be subject to a 180-day lock-up restriction. The number of ADSs available for sale to the general public in this offering will be reduced to the extent that the reserved ADSs are purchased in the directed share program. Any reserved ADSs not purchased through the directed share program will be offered to the general public on the same basis as the other ADSs offered hereby.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of ADSs offered.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$3.8 million. We have agreed to reimburse the underwriters for expenses of up to \$40,000 related to clearance of this offering with the Financial Industry Regulatory Authority, Inc. (FINRA) and for all fees and disbursements of counsel incurred by the underwriters in connection with the directed share program.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the ADSs offered by this prospectus in any jurisdiction where action for that purpose is required. The ADSs offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such ADSs be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any ADSs offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of ADSs to the public in that Relevant Member State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of ADSs to the public in that Relevant Member State at any time:

- (a) to any legal entity that is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of ADSs shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of ADSs to the public" in relation to any ADSs in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase or subscribe the ADSs, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

### **United Kingdom**

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000

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(Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons").

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

### **Canada**

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### **Hong Kong**

The ADSs may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), and no advertisement, invitation or document relating to the ADSs may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

### **Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an

institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ADSs are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, ADSs, debentures and units of ADSs and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the ADSs under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

## **Japan**

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

## LEGAL MATTERS

We are being represented by Goodwin Procter LLP with respect to certain legal matters of United States federal securities and New York State law. The underwriters are being represented as to United States federal securities and New York State law matters by Davis Polk & Wardwell LLP. The validity of the ordinary shares represented by the ADSs offered in this offering and legal matters as to Cayman Islands law will be passed upon for us by Mourant Ozannes. Certain legal matters as to PRC law will be passed upon for us by Fangda Partners and for the underwriters by Jun He Law Offices. Goodwin Procter LLP may rely upon Mourant Ozannes with respect to matters governed by Cayman Islands law and Fangda Partners with respect to matters governed by PRC law. As of the date of this prospectus, certain investment funds associated with, and partners of, Goodwin Procter LLP beneficially owned less than 0.15% of our outstanding equity securities.

## EXPERTS

The consolidated financial statements of BeiGene, Ltd. at December 31, 2013 and 2014, and for the years then ended, appearing in this prospectus and registration statement have been audited by Ernst & Young Hua Ming LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the U.S. Securities and Exchange Commission, or SEC, a registration statement on Form S-1 (File Number 333-207459) under the Securities Act with respect to the ADSs we are offering by this prospectus. A related registration statement on Form F-6 will be filed with the SEC to register the ADSs. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and the ADSs, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the closing of the offering, we will be subject to the informational requirements of the Securities Exchange Act of 1934 and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

We intend to furnish the depositary with our annual reports, which will include a review of operations and annual audited consolidated combined financial statements prepared in conformity with U.S. GAAP, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs and will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

## GLOSSARY OF SCIENTIFIC TERMS

As used herein, the terms set forth below shall have the following meanings:

ADCC	Means antibody-dependent cellular cytotoxicity, a mechanism of cell-mediated immune defense.
ALK	Means anaplastic lymphoma kinase, an enzyme encoded in humans by the ALK gene. ALK mutations are associated with certain lung cancers.
ATM	Means ataxia telangiectasia mutated, a serine/threonine protein kinase that plays a critical role in response to DNA damage.
BRAF	Means a human gene that makes the B-raf protein involved in sending internal cell signals that direct cell growth. In cells expressing mutant BRAF V600E and in conditions of low RAS-GTP, all RAF isoforms exist predominantly as monomers. However, unlike wild-type RAFs, monomeric BRAF V600E is hyperactive. Under conditions where RAS is activated or other BRAF induced resistance, RAF isoforms form dimers (two copies of RAF proteins bind together).
B-cell	Means a type of white blood cell that differs from other lymphocytes like T-cells by the presence of the BCR on the B-cell's outer surface.
BCR	Means B-cell receptor, a specialized receptor protein that allows a B-cell to bind to specific antigens.
BID	Means <i>bis in die</i> or "twice daily," the frequency that a medical prescription or drug is taken by a patient.
BRCA	Means breast cancer susceptibility gene, of which there are two (BRCA1 and BRCA2). BRCA proteins are key components of homologous recombination DNA repair pathway. BRCA deleterious mutations are associated with breast and ovarian cancers.
BTK	Means Bruton's tyrosine kinase. BTK is a key component of the BCR signaling pathway and is an important regulator of cell proliferation and cell survival in various lymphomas.
CD20	Means B-lymphocyte antigen CD20, a B-cell specific cell-surface molecule that is encoded by the MS4A1 gene.
CTLA-4	Means cytotoxic T-lymphocyte-associated protein 4, a protein receptor that functions as an immune checkpoint and downregulates the immune system. CTLA-4 is found on the surface of T-cells.
DNA	Means deoxyribonucleic acid, a self-replicating molecule that carries genetic information and is present in almost all living organisms.
EGFR	Means epidermal growth factor receptor. EGFR is a cell surface protein that binds to epidermal growth factor, and mutations in this gene are associated with lung cancer.
ERK	Means extracellular signal-regulated kinase, which is a downstream signaling molecule of the MAPK pathway.
Fc $\gamma$ RI	Means Fc gamma receptor I, a receptor that binds the most common class of antibody, Immunoglobulin G, or IgG, including IgG1, IgG3 and IgG4. Fc $\gamma$ RI is expressed in certain human immune cells including monocytes, macrophages and dendritic cells and may function to activate these immune cells. Fc $\gamma$ RI has the highest affinity to IgGs among the members of the Fc gamma receptor family.

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GTPase	Means a large family of hydrolase enzymes that can bind and hydrolyze guanosine triphosphate.
Hemoglobin	Means the protein molecule in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues back to the lungs.
HER2	Means human epidermal growth factor receptor 2, also known as receptor tyrosine-protein kinase erbB-2. HER2 is a member of the human epidermal growth factor receptor (HER/EGFR/ERBB) family. Amplification or overexpression of this oncogene is associated with certain aggressive types of breast cancer.
HRAS	Means GTPase Hras, also known as transforming protein p21, an enzyme that is encoded in humans by the HRAS gene.
Immunoglobulin	Means glycoprotein molecules produced by plasma cells (white blood cells), which are also known as antibodies. They act as a critical part of the immune response by specifically recognizing and binding to particular antigens, such as bacteria or viruses, and aiding in their destruction.
ITK	Means interleukin-2-inducible T-cell kinase, a tyrosine-protein kinase that is encoded in humans by the ITK gene and is highly expressed in T-cells.
JAK3	Means tyrosine-protein Janus kinase 3, a non-receptor tyrosine kinase involved in various processes including cell growth, development, or differentiation.
Kinase	Means a type of enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates. The protein kinases make up the majority of all kinases. Protein kinases act on proteins, phosphorylating them on their serine, threonine, tyrosine, or histidine residues. These kinases play a major role in protein and enzyme regulation as well as signaling in the cell.
KRAS	KRAS is known as V-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog. It is an oncogene that is often mutated in a number of cancers. The protein product of the normal KRAS gene performs an essential function in normal tissue signaling, and the mutation of a KRAS gene is an essential step in the development of many cancers.
Lesion	Means almost any abnormal change involving any biological structure, tissue or organ due to disease or injury, similar in meaning to the word "damage."
MAPK	Means mitogen-activated protein kinase. The MAPK pathway is a chain of proteins in the cell that communicates a signal from a receptor on the cell surface to the DNA in the nucleus of the cell. This pathway includes a small G protein (RAS) and three protein kinases (RAF, MEK, and ERK) and plays an essential role in regulating cell proliferation and survival.
MEK	Means mitogen/extracellular signal-regulated kinase, a member of the MAPK signaling cascade that is activated in melanoma.
NRAS	Means neuroblastoma RAS viral (V-Ras) oncogene homolog. It is also a member of RAS gene family. Similar to KRAS, it plays a role in many cancers and the mutation of an NRAS gene involves in the formation and growth of many cancers.



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PAR	Means poly ADP ribose. PAR chains are synthesized by Poly(ADP-ribose) polymerases on various nuclear protein acceptors usually involved in DNA replication, transcription and repair pathways.
PARP	Means poly ADP ribose polymerase, a family of proteins involved in numerous cellular processes, mostly involving DNA replication and transcriptional regulation, which plays an essential role in cell survival in response to DNA damage.
PBMC	Means a peripheral blood mononuclear cell, any blood cell that has a round, as opposed to a lobed, nucleus ( e.g. , a lymphocyte, monocyte, or macrophage, all types of white blood cells).
PD-1	Means programmed cell death protein 1, an immune checkpoint receptor expressed on T-cells and pro-B-cells that binds two ligands, PD-L1 and PD-L2. PD-1 is a cell surface receptor that plays an important role in down-regulating the immune system by preventing the activation of T-cells.
PD-L1	Means programmed death-ligand 1, a protein in humans encoded by the CD274 gene. PD-L1 binds the PD-1 receptor and sends an inhibitory signal inside the T-cell, stopping it from making more poisonous proteins and killing the cells that send the signal via PD-L1 and in the neighborhood.
PDX	Means patient-derived xenograft, created when the cancerous tissue from a human patient's primary tumor is implanted directly into an immunodeficient mouse.
pERK	Means phosphorylated extracellular signal-regulated kinase, which is a modified form of the ERK protein (a downstream signaling molecule of the MAPK pathway).
QD	Means <i>quaque die</i> or "every day," the frequency that a medical prescription or drug is taken by a patient.
RAF	Means Rapidly Accelerated Fibrosarcoma. RAF kinases are a family of three serine/threonine-specific protein kinases that are related to retroviral oncogenes. RAF kinases participate in the RAS-RAF-MEK-ERK MAPK pathway.
RAF dimer	Means a protein complex formed by two copies of RAF proteins. This could be a BRAF-BRAF complex, a BRAF-CRAF complex, or a CRAF-CRAF complex.
Signaling cascade	Means a signal transduction pathway between cells where each signal transduction occurs with a primary extracellular messenger that binds to a receptor and initiates intracellular signals (i.e. molecule A activates several molecule Bs, which then in turn activate several molecule Cs).
T-cell	Means a type of white blood cell that play a large role in immune response and that differs from other white blood cells like B-cells by the presence of the T-cell receptor on the T-cell's outer surface, which is responsible for recognizing antigens bound to major histocompatibility complex molecules.
TEC	Means tyrosine-protein kinase Tec, an enzyme in humans encoded by the TEC gene. The Tec kinase is an integral component of T-cell signaling and has a distinct role in T-cell activation.

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TIM-3	Means T-cell immunoglobulin and mucin-domain containing-3, a Th1-specific cell surface protein that functions as an immune checkpoint, regulating macrophage activation and enhancing the severity of experimental autoimmune encephalomyelitis in mice.
Xenograft	Means the cells, tissues or organs of one species transplanted into another species.

**BEIGENE, LTD.**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of BeiGene, Ltd.

We have audited the accompanying consolidated balance sheets of BeiGene, Ltd. (the "Company") as of December 31, 2013 and 2014, and the related consolidated statements of comprehensive loss, cash flows, and shareholders' deficit for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of BeiGene, Ltd. at December 31, 2013 and 2014, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young Hua Ming LLP

Beijing, People's Republic of China  
August 28, 2015

BEIGENE, LTD.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

	Note	December 31,		Pro forma
		2013	2014	shareholders' equity at December 31, 2014
		\$	\$	\$ (unaudited)
<b>Assets</b>				
Current assets:				
Cash and cash equivalents		3,926	13,898	—
Short-term investments	3	—	30,497	—
Prepaid expenses and other current assets		508	2,793	—
Total current assets		4,434	47,188	—
Property and equipment, net	4	7,052	5,931	—
Other non-current assets		312	502	—
Total non-current assets		7,364	6,433	—
Total assets		11,798	53,621	—
<b>Liabilities and shareholders' deficit</b>				
Current liabilities:				
Short-term bank loan	7	—	322	—
Accounts payable		2,063	2,794	—
Advances from customers		7,860	8,906	—
Accrued expenses and other payables	6	1,763	1,002	—
Subordinated Convertible Promissory Note	10	12,126	—	—
Warrant and Option liabilities	8	50	347	—
Due to related parties	14	7,872	—	—
Total current liabilities		31,734	13,371	—
Non-current liabilities:				
Senior Promissory Note	9	12,515	13,516	—
Convertible Promissory Notes	11	2,723	—	—
Deferred rental		818	798	—
Due to related parties	14	741	—	—
Other long-term liabilities		226	168	—
Total non-current liabilities		17,023	14,482	—
Total liabilities		48,757	27,853	—
Commitments and contingencies	23	—	—	—
Convertible Preferred Shares	13	—	78,809	—
Series A (par value US\$0.0001 per share; 120,000,000 shares authorized; 116,785,517 shares issued and outstanding as of December 31, 2014 (December 31, 2013: nil))				
Non-controlling interests	15	1,767	—	—
Total mezzanine equity		1,767	78,809	—
Shareholders' deficit:				
Ordinary shares (par value of US\$0.0001 per share; 400,000,000 shares authorized; 108,497,428 shares issued and outstanding as of December 31, 2014 (December 31, 2013: 94,516,667 shares))		9	11	23
Additional paid-in capital		3,771	7,941	86,738
Accumulated other comprehensive income	20	309	100	100
Accumulated deficit		(42,815)	(61,093)	(61,093)
Total shareholders' (deficit) equity		(38,726)	(53,041)	25,768
Total liabilities, mezzanine equity and shareholders' (deficit) equity		11,798	53,621	53,621

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

	Note	Year ended December 31,	
		2013 \$	2014 \$
Revenue			
Collaboration revenue	16	11,148	13,035
Total revenue		11,148	13,035
Operating expenses:			
Research and development		(13,463)	(21,862)
General and administrative		(3,143)	(6,930)
Total operating expenses		(16,606)	(28,792)
Loss from operations		(5,458)	(15,757)
Interest income		2	40
Interest expense (including interest expense incurred due to a related party amounting to \$693 and \$831 for the years ended December 31, 2013 and 2014, respectively)		(3,155)	(3,552)
Changes in fair value of financial instruments	8,10,11,14	133	(2,760)
Gain on debt extinguishment	10	—	2,883
Other income		694	806
Other expense		(110)	(206)
Loss before income tax expense		(7,894)	(18,546)
Income tax expense	5	—	—
Net loss		(7,894)	(18,546)
Less: net loss attributable to non-controlling interests		(400)	(268)
Net loss attributable to ordinary shareholders		(7,494)	(18,278)
Loss per share	17		
Basic and diluted		(0.08)	(0.18)
Weighted-average number of ordinary shares used in net loss per share calculation	17		
Basic and diluted		91,484,521	99,857,623
Pro forma basic and diluted loss per share on an as-converted basis	18	—	(0.08)
Shares used in pro forma basic and diluted loss per share computation	18	—	216,643,140
Other comprehensive income (loss), net of tax of nil:			
Foreign currency translation adjustments		176	(168)
Unrealized holding losses		—	(47)
Comprehensive loss		(7,718)	(18,761)
Less: comprehensive loss attributable to non-controlling interests		(392)	(274)
Comprehensive loss attributable to ordinary shareholders		(7,326)	(18,487)

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

	Note	Year ended December 31,	
		2013 \$	2014 \$
<b>Operating activities</b>			
Net loss		(7,894)	(18,546)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation expenses	4	1,592	1,557
Share-based compensation expenses	19	(24)	6,637
Changes in fair value of financial instruments		(133)	2,760
Gain on debt extinguishment		—	(2,883)
Loss on disposal of property and equipment		21	53
Interest expense	11,12,14	2,766	3,265
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		(277)	(2,285)
Other non-current assets		(100)	(190)
Accounts payable		(768)	731
Advances from customers		7,860	1,046
Accrued expenses and other payables		422	(761)
Deferred rental		496	(20)
Other long-term liabilities		112	(58)
Net cash provided by (used in) operating activities		4,073	(8,694)
<b>Investing activities</b>			
Purchases of property and equipment		(264)	(654)
Purchase of available-for-sale securities		—	(30,646)
Proceeds from disposal of available-for-sale securities		—	102
Proceeds from disposal of property and equipment		14	—
Acquisition of non-controlling interest	15	—	(2,443)
Net cash used in investing activities		(250)	(33,641)
<b>Financing activities</b>			
Proceeds from short-term loan	7	—	322
Proceeds from issuance of convertible promissory notes	11	—	25
Proceeds from issuance of secured guaranteed convertible promissory note	12	—	17,500
Payment of convertible preferred shares issuance cost	13	—	(80)
Proceeds from issuance of convertible preferred shares	13	—	35,500
Proceeds from exercise of share options		—	80
Proceeds due to related parties	14	249	103
Repayment to related party	14	(731)	(1,285)
Net cash (used in) provided by financing activities		(482)	52,165
Effect of foreign exchange rate changes, net		(41)	142
Net increase in cash and cash equivalents		3,300	9,972
Cash and cash equivalents at beginning of period		626	3,926
Cash and cash equivalents at end of period		3,926	13,898
Supplemental cash flow disclosures:			
Income taxes paid		—	—
Interest expense paid		334	30
Non-cash activities:			
Repayment of subordinated convertible promissory note, convertible promissory notes and secured guaranteed convertible promissory note	10,11,12	—	33,730
Repayment of due to related parties	14	134	8,204

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

	Attributable to BeiGene, Ltd.							
	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Income/(Loss) (note 20)	Accumulated Deficit	Total	Non- Controlling Interests	Total
	Shares	Amount						
Balance at December 31, 2012	85,416,667	\$ 9	\$ 3,662	\$ 141	\$ (35,321)	\$ (31,509)	\$ 2,159	\$ (29,350)
Issuance of ordinary shares	13,433,334	—	133	—	—	133	—	133
Repurchase of forfeited unvested ordinary shares (note 19)	(4,333,334)	—	—	—	—	—	—	—
Share-based compensation	—	—	(24)	—	—	(24)	—	(24)
Net loss	—	—	—	—	(7,494)	(7,494)	(400)	(7,894)
Other comprehensive income	—	—	—	168	—	168	8	176
Balance at December 31, 2013	94,516,667	9	3,771	309	(42,815)	(38,726)	1,767	(36,959)
Issuance of ordinary shares	14,097,432	2	139	—	—	141	—	141
Repurchase of forfeited unvested ordinary shares (note 19)	(116,671)	—	—	—	—	—	—	—
Share-based compensation	—	—	4,797	—	—	4,797	—	4,797
Issuance of warrants in connection with the secured guaranteed convertible promissory note (note 12)	—	—	184	—	—	184	—	184
Repurchase of non-controlling interest (note 15)	—	—	(950)	—	—	(950)	(1,493)	(2,443)
Net loss	—	—	—	—	(18,278)	(18,278)	(268)	(18,546)
Other comprehensive loss	—	—	—	(209)	—	(209)	(6)	(215)
Balance at December 31, 2014	<u>108,497,428</u>	<u>\$ 11</u>	<u>\$ 7,941</u>	<u>\$ 100</u>	<u>\$ (61,093)</u>	<u>\$ (53,041)</u>	<u>\$ —</u>	<u>\$ (53,041)</u>

The accompanying notes are an integral part of these consolidated financial statements.



**BEIGENE, LTD.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014**

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**1. Organization**

BeiGene, Ltd. (the "Company") is a globally focused, clinical-stage biopharmaceutical company with the goal of becoming a leader in the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. The Company's development strategy is based on a novel translational platform that combines their unique access to internal patient-derived biopsies with strong oncology biology. The Company was incorporated under the laws of the Cayman Islands as an exempted company with limited liability on October 28, 2010.

As at December 31, 2014, the Company's subsidiaries are as follows:

<b>Name of company</b>	<b>Place of incorporation</b>	<b>Date of incorporation</b>	<b>Percentage of ownership by the Company</b>	<b>Principal activities</b>
BeiGene (Hong Kong) Co., Limited.	Hong Kong	November 22, 2010	100%	Investment holding
BeiGene (Beijing) Co., Ltd. ("BeiGene Beijing")	The People's Republic of China ("PRC" or "China")	January 24, 2011	100%*	Medical and pharmaceutical research
BeiGene AUS Pty Ltd.	Australia	July 15, 2013	100%	Clinical trial activities
BeiGene 101 Ltd.	Cayman	August 30, 2012	100%	Medical and pharmaceutical research
BeiGene (USA) Inc., the Company's dormant wholly owned subsidiary was dissolved on December 29, 2014.				

\* BeiGene Beijing became a wholly-owned subsidiary of the Company as of December 19, 2014 (note 15).

**2. Summary of significant accounting policies**

**Basis of presentation and principles of consolidation**

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The consolidated financial statements include the financial statements of the Company and its subsidiaries. All significant intercompany transactions and balances between the Company and its subsidiaries are eliminated upon consolidation.

**Use of estimates**

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, identifying separate accounting units and estimating the best estimate selling price of each

BEIGENE, LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

deliverable in the Company's revenue arrangements, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets and the fair value of the financial instruments. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

**Foreign currency translation and transactions**

The functional currency of the Company, BeiGene AUS Pty Ltd., BeiGene (Hong Kong) Co., Limited and BeiGene 101 Ltd. is the United States dollar ("\$\$"). The Company's PRC subsidiary determined its functional currency to be the Chinese Renminbi ("RMB"). The determination of the respective functional currency is based on the criteria of Accounting Standard Codification ("ASC") 830, *Foreign Currency Matters*. The Company uses the United States dollar as its reporting currency. The Company uses the average exchange rate for the year and the exchange rate at the balance sheet date to translate the operating results and financial position, respectively. Translation differences are recorded in accumulated other comprehensive loss, a component of shareholders' deficit. Transactions denominated in foreign currencies are remeasured into the functional currency at the exchange rates prevailing on the transaction dates. Foreign currency denominated financial assets and liabilities are remeasured at the exchange rates prevailing at the balance sheet date. Exchange gains and losses are included in the consolidated statements of comprehensive loss.

**Cash and cash equivalents**

Cash and cash equivalents consist of cash on hand and bank deposits, which are unrestricted as to withdrawal and use. The Company considers all highly liquid investments with an original maturity date of three months or less at the date of purchase to be cash equivalents.

**Short-term investments**

Short-term debt investments held to maturity are carried at amortized cost when we have the ability and positive intent to hold these securities until maturity. When the Company does not have the ability or positive intent to hold short-term debt investments until maturity, these securities are classified as available-for-sale. None of the Company's fixed maturity securities met the criteria for held-to-maturity classification at December 31, 2013 and 2014.

Available-for-sale securities are stated at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The net carrying value of debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is computed using the effective interest method and included in interest income. Interest and dividends are included in interest income.

When the fair value of a debt security classified as available-for-sale is less than its amortized cost, the Company assesses whether or not: (i) it has the intent to sell the security or (ii) it is more likely than not that the Company will be required to sell the security before its anticipated recovery.

## BEIGENE, LTD.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

If either of these conditions is met, the Company must recognize an other-than-temporary impairment through earnings for the difference between the debt security's amortized cost basis and its fair value. No impairment losses were recorded for any periods presented.

The cost of securities sold is based on the specific identification method.

**Property and equipment**

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	<u>Useful Life</u>
Office Equipment	5 years
Electronic Equipment	3 years
Laboratory Equipment	3 to 5 years
Computer Software	3 to 5 years
Leasehold Improvements	Lesser of useful life or lease term

**Impairment of long-lived assets**

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2013 and 2014, there was no impairment of the value of the Company's long-lived assets.

**Fair value measurements***Fair value of financial instruments*

Financial instruments of the Company primarily include cash and cash equivalents, short-term investments, short-term bank loan, accounts payable, amounts due to related parties, senior promissory note, subordinated convertible promissory note, convertible promissory notes, convertible preferred shares, and warrant and option liabilities. As of December 31, 2013 and 2014, the carrying values of cash and cash equivalents, short-term bank loan, accounts payable, and amounts due to related parties approximated their fair values due to the short-term maturity of these instruments. The short-term investments represented the available-for-sale debt securities which are recorded at fair value based on quoted prices in active markets with unrealized gain or loss recorded in other comprehensive income. The warrant and option liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. The senior promissory note, subordinated convertible promissory note, convertible promissory notes and convertible preferred shares were initially recorded at issue price

## BEIGENE, LTD.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

net of issuance costs. The Company determined the fair values of the warrant and option liabilities with the assistance of an independent third party valuation firm.

The Company applies ASC topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 — Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 — Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Liabilities measured at fair value on a recurring basis as of December 31, 2013 are summarized below:

	<b>Quoted price in active markets for identical assets (Level 1)</b>	<b>Significant other observable inputs (Level 2)</b>	<b>Significant unobservable inputs (Level 3)</b>
	\$	\$	\$
Option to purchase shares by rental deferral (note 8)	—	—	26
Warrants in connection with the Convertible Promissory Notes (note 11, 14)	—	—	24

BEIGENE, LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

2. Summary of significant accounting policies (Continued)

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2014 are summarized below:

	Quoted price in active markets for identical assets (Level 1) \$	Significant other observable inputs (Level 2) \$	Significant unobservable inputs (Level 3) \$
Available-for-sale securities (note 3):			
Corporate fixed income bonds	27,498	—	—
U.S. treasury securities	2,999	—	—
Option to purchase shares by rental deferral (note 8)	—	—	125
Warrants in connection with the Convertible Promissory Notes (note 11, 14)	—	—	222

The Company has measured the option to purchase shares by rental deferral and the warrants in connection with the Convertible Promissory Notes at fair values on a recurring basis using significant unobservable inputs (Level 3) as of the years ended December 31, 2013 and 2014. The significant unobservable inputs used in the fair value measurement and the corresponding impacts to the fair values are presented below:

Financial instrument	Valuation techniques	Unobservable inputs	Estimation	
			2013	2014
Option to purchase shares by rental deferral	Invested capital value allocation by option-pricing model and Black-Scholes option pricing model	Invested capital value	\$19,500	\$145,300
		Volatility for invested capital value allocation	225%–303%	72%
		Volatility for Black-Scholes option pricing model	105%–288%	72%–101%
		Discount for lack of marketability ("DLOM")	44%	17%
Warrants in connection with the Convertible Promissory Notes	Invested capital value allocation by option-pricing model and Black-Scholes option pricing model	Invested capital value	\$19,500	\$145,300
		Volatility for invested capital value allocation	225%–303%	72%
		Volatility for Black-Scholes option pricing model	95%–288%	72%–104%
		DLOM	44%	17%

## BEIGENE, LTD.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

The following table presents a reconciliation of the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2013 and 2014.

	<b>Warrant and option liabilities</b>
	<b>\$</b>
Balance as of December 31, 2012	183
Recognized during the year	—
Unrealized gain	(133)
Settlement	—
Balance as of December 31, 2013	<u>50</u>
Recognized during the year	37
Unrealized loss	260
Settlement	—
Balance as of December 31, 2014	<u>347</u>
The amount of total gain for the year ended December 31, 2013 included in losses	<u>133</u>
The amount of total loss for the year ended December 31, 2014 included in losses	<u>(260)</u>

Realized and unrealized (gain)/losses for the years ended December 31, 2013 and 2014 was recorded as "Changes in fair value of financial instruments" in the consolidated statements of comprehensive loss.

**Revenue recognition**

The Company recognizes revenues from research and development collaborative arrangements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed or determinable, and there is reasonable assurance that the related amounts are collectible in accordance with ASC 605, *Revenue Recognition* ("ASC 605"). The Company's collaborative arrangements may contain multiple elements, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The deliverables under such arrangements are evaluated under ASC 605-25, *Multiple-Element Arrangements*. Pursuant to ASC 605-25, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The collaborative arrangements do not include a right of return for any deliverable. The arrangement's consideration that is fixed or determinable, excluding contingent payments, is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The relative selling price for each deliverable is determined using vendor specific objective evidence ("VSOE") of selling price or third party evidence ("TPE")

BEIGENE, LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

of selling price if VSOE does not exist. If neither VSOE nor TPE exists, the Company uses the best estimate of the selling price ("BESP") for the deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as advances from customers.

Upfront non-refundable payments for licensing the Company's intellectual property are evaluated to determine if the licensee can obtain stand-alone value from the license separate from the value of the research and development services and other deliverables in the arrangement to be provided by the Company. The Company acts as the principal under its arrangements and licensing intellectual property is part of its ongoing major or central operations. The license right is not contingent upon the delivery of additional items or meeting other specified performance conditions. Therefore, when stand-alone value of the license is determinable, the allocated consideration is recognized as collaboration revenue upon delivery of the license rights.

As the Company acts as the principal under its arrangements, and research and development services are also part of its ongoing major or central operations, it recognizes the allocated consideration related to reimbursements of research and development costs as collaboration revenue when delivery or performance of such services occurs.

Product development, royalties and commercial event payments (collectively, "target payments") under collaborative arrangements are triggered either by the results of the Company's research and development efforts, achievement of regulatory goals or by specified sales results by a third party collaborator. Under ASC 605-28, *Milestone Method of Revenue Recognition* an accounting policy election can be made to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The Company elected not to adopt the milestone method of revenue recognition under ASC 605-28.

Targets related to the Company's development-based activities may include initiation of various phases of clinical trials and applications and acceptance for product approvals by regulatory agencies. Due to the uncertainty involved in meeting these development-based targets, the Company would account for development-based targets as collaboration revenue upon achievement of the respective development target. Royalties based on reported sales of licensed products will be recognized as collaboration revenue based on contract terms when reported sales are reliably measurable and collectability is reasonably assured. Targets related to commercial activities may be triggered upon events such as first commercial sale of a product or when sales first achieve a defined level. Since these targets would be achieved after the completion of the Company's development activities, the Company would account for the commercial event targets in the same manner as royalties, with collaboration revenue recognized upon achievement of the target. To date, the products have not progressed to the development stages contemplated by the development based targets and none of the products have been approved. Hence, no revenue has

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**2. Summary of significant accounting policies (Continued)**

been recognized related to the product development targets, royalties or commercial event based targets in any of the periods presented.

Any subsequent payments to be made to the collaborator such as profit sharing payments based on net sales that are not related to research and development services would be recorded as expenses from the collaborative arrangement. To date, no payments have been made to the collaborator.

**Research and development expenses**

Research and development expenses represent costs associated with the collaborative arrangements, which primarily include (i) payroll and related costs (including share-based compensation) associated with research and development personnel, (ii) costs related to clinical trials and preclinical testing of the Company's technologies under development, (iii) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (iv) expenses for research services provided by universities and contract laboratories, including sponsored research funding, and (v) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Company's research and development services and have no alternative future uses.

Clinical trial costs are a significant component of the Company's research and development expenses. The Company has a history of contracting with third parties that perform various clinical trial activities on behalf of the Company in the ongoing development of the Company's product candidates. Expenses related to clinical trials are accrued based on the Company's estimates of the actual services performed by the third parties for the respective period. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company will modify the related accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. There were no material adjustments for a change in estimate to research and development expenses in the accompanying consolidated financial statements for the years ended December 31, 2013 and 2014.

**Government grants**

Government financial incentives that involve no conditions or continuing performance obligations of the Company are recognized as other non-operating income upon receipt.



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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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**2. Summary of significant accounting policies (Continued)**

**Leases**

Leases are classified at the inception date as either a capital lease or an operating lease. The Company assesses a lease to be a capital lease if any of the following conditions exist: a) ownership is transferred to the lessee by the end of the lease term, b) there is a bargain purchase option, c) the lease term is at least 75% of the property's estimated remaining economic life or d) the present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date. A capital lease is accounted for as if there was an acquisition of an asset and an incurrence of an obligation at the inception of the lease. The Company has no capital leases for the years presented.

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over the periods of their respective lease terms. The Company leases office space and employee accommodation under operating lease agreements. Certain of the lease agreements contain rent holidays. Rent holidays are considered in determining the straight-line rent expense to be recorded over the lease term. The lease term begins on the date of initial possession of the lease property for purposes of recognizing lease expense on straight-line basis over the term of the lease.

**Comprehensive loss**

Comprehensive loss is defined as the changes in equity of the Company during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income*, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Company's comprehensive loss includes net loss, foreign currency translation adjustments and unrealized holding losses associated with the available-for-sale securities, and is presented in the consolidated statements of comprehensive loss. The Company adopted ASU No. 2013-02, *Comprehensive Income (Topic 220)* ("ASU 2013-02") in January 2013. There was no material impact to the Company's consolidated financial statements upon adoption.

**Stock-based compensation**

Awards granted to employees

The Company applies ASC 718, *Compensation — Stock Compensation* ("ASC 718"), to account for its employee share-based payments. In accordance with ASC 718, the Company determines whether an award should be classified and accounted for as a liability award or equity award. All the Company's grants of share-based awards to employees were classified as equity awards and are recognized in the financial statements based on their grant date fair values. Specifically, the grant date fair value of share options are calculated using an option pricing model. The Company has elected to recognize compensation expense using the straight-line method for all employee equity awards granted with graded vesting based on service conditions provided that the

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**2. Summary of significant accounting policies (Continued)**

amount of compensation cost recognized at any date is at least equal to the portion of the grant-date value of the options that are vested at that date. The Company uses the accelerated method for all awards granted with graded vesting based on performance conditions. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in the subsequent period if actual forfeitures differ from initial estimates.

Forfeiture rates are estimated based on historical and future expectations of employee turnover rates and are adjusted to reflect future changes in circumstances and facts, if any. Share-based compensation expense is recorded net of estimated forfeitures such that expense is recorded only for those share-based awards that are expected to vest. To the extent the Company revises these estimates in the future, the share-based payments could be materially impacted in the period of revision, as well as in following periods. The Company, with the assistance of an independent third party valuation firm, determined the fair value of the stock options granted to employees. The binomial option pricing model was applied in determining the estimated fair value of the options granted to employees.

Awards granted to non-employees

The Company has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 718 and ASC 505, *Equity*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if the Company had paid cash for the services provided by the non-employees in accordance with ASC 505-50, *Equity-based payments to non-employees*.

Modification of awards

A change in any of the terms or conditions of the awards is accounted for as a modification of the award. Incremental compensation cost is measured as the excess, if any, of the fair value of the modified award over the fair value of the original award immediately before its terms are modified, measured based on the fair value of the awards and other pertinent factors at the modification date. For vested awards, the Company recognizes incremental compensation cost in the period the modification occurs. For unvested awards, the Company recognizes over the remaining requisite service period, the sum of the incremental compensation cost and the remaining unrecognized compensation cost for the original award on the modification date. If the fair value of the modified award is lower than the fair value of the original award immediately before modification, the minimum compensation cost the Company recognizes is the cost of the original award.

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**2. Summary of significant accounting policies (Continued)**

Modification of employment status

When a nonemployee becomes an employee and continues to vest in the award, the fair value of the award should be remeasured on the date the individual becomes an employee. Compensation charges based on the remeasured fair value will be accounted for prospectively from the date of the change in employment status over the remaining vesting period. The fair value of the award subsequently will not be remeasured unless the award is modified or settled.

**Derivative instruments**

ASC 815, *Derivatives and Hedging*, requires all contracts which meet the definition of a derivative to be recognized in the consolidated financial statements as either assets or liabilities and recorded at fair value. Changes in the fair value of derivative financial instruments are either recognized periodically in income/loss or in shareholders' deficit as a component of other comprehensive income depending on the use of the derivative and whether it qualifies for hedge accounting. Changes in fair values of derivatives not qualified as hedges are reported in the consolidated statements of comprehensive loss. The estimated fair values of derivative instruments are determined at discrete points in time based on the relevant market information. These estimates are calculated with reference to the market rates using industry standard valuation techniques with the assistance of an independent third party valuation firm.

**Income taxes**

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. It is the Company's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

**Loss per share**

Loss per share is calculated in accordance with ASC 260, *Earnings Per Share*. Basic loss per ordinary share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period using the two-class method. Under the two-class method, net income is allocated between ordinary shares and participating securities based on dividends declared (or accumulated) and participating rights in

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**2. Summary of significant accounting policies (Continued)**

undistributed earnings as if all the earnings for the reporting period had been distributed. The Company's convertible preferred shares and restricted stock are participating securities because they have contractual rights to share in the profits of the Company.

However, both the convertible preferred shares and restricted stock do not have contractual rights and obligations to share in the losses of the Company. For the periods presented herein, the computation of basic loss per share using the two-class method is not applicable as the Company is in a net loss position.

Diluted loss per share is calculated by dividing net loss attributable to ordinary shareholders as adjusted for the effect of dilutive ordinary equivalent shares, if any, by the weighted average number of ordinary and dilutive ordinary equivalent shares outstanding during the period. Ordinary equivalent shares consist of the ordinary shares issuable upon the conversion of the Company's convertible preferred shares using the if-converted method, and ordinary shares issuable upon the conversion of the share options and unvested restricted stock, using the treasury stock method. Ordinary share equivalents are excluded from the computation of diluted loss per share if their effects would be anti-dilutive. Basic and diluted loss per ordinary share is presented in the Company's consolidated statements of comprehensive loss.

**Unaudited pro forma shareholders' equity and loss per share**

Pursuant to the Company's memorandum and articles of association, upon the completion of the Company's initial public offering on the New York Stock Exchange, or the Nasdaq Stock Market or any other stock exchange acceptable to Baker Bros. Advisors LP (the "Qualified IPO"), the outstanding convertible preferred shares will automatically be converted into ordinary shares. Unaudited pro forma shareholders' equity as of December 31, 2014, as adjusted for the reclassification of the convertible preferred shares from mezzanine equity to shareholders' equity, is set forth on the consolidated balance sheets.

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding as of December 31, 2014, and assumes the automatic conversion of all of the Company's convertible preferred shares into weighted-average shares of ordinary stock upon the closing of the Company's Qualified IPO, as if it had occurred on January 1, 2014.

**Segment information**

In accordance with ASC 280, *Segment Reporting*, the Company's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Company as a whole and hence, the Company has only one reportable segment. The Company does not distinguish between markets or segments for the purpose of internal reporting. As the Company's long-lived assets and revenue are substantially located in and derived from the PRC, no geographical segments are presented.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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**2. Summary of significant accounting policies (Continued)**

**Concentration of risks**

*Concentration of credit risk*

Financial instruments that are potentially subject to credit risk consist of cash and cash equivalents and short-term investments. The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2013 and 2014, \$3,926 and \$13,898 were deposited with various major reputable financial institutions located in the PRC and international financial institutions outside of the PRC. The deposits placed with financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, the Company may be unlikely to claim its deposits back in full. Management believes that these financial institutions are of high credit quality and continually monitors the credit worthiness of these financial institutions. As of December 31, 2013 and 2014, the Company had debt security investments amounting to nil and \$30,497, respectively. The Company's debt security investments comprise of corporate fixed income bonds and U.S. treasury securities. The Company believes that the corporate bonds and the US treasury securities are of high credit quality and continually monitors the credit worthiness of these institutions.

*Customer concentration risk*

For the years ended December 31, 2013 and 2014, substantially all of the Company's revenue has been generated solely from one customer, Merck KGaA ("Merck KGaA").

*Business, customer, political, social and economic risks*

The Company participates in a dynamic high technology industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations or cash flows: changes in the overall demand for services and products; competitive pressures due to new entrants; advances and new trends in new technologies and industry standards; changes in clinical research organizations; changes in certain strategic relationships or customer relationships; regulatory considerations; copyright regulations; and risks associated with the Company's ability to attract and retain employees necessary to support its growth. The Company's operations could be also adversely affected by significant political, economic and social uncertainties in the PRC.

*Currency convertibility risk*

A majority of the Company's expenses and a significant portion of the Company's assets and liabilities are denominated in RMB. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China (the "PBOC"). However, the unification of the exchange rates does not imply that the RMB may be readily convertible into United States dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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**2. Summary of significant accounting policies (Continued)**

currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

*Foreign currency exchange rate risk*

From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. There was appreciation of RMB against US\$ of approximately 2.9% in the year ended December 31, 2013 and depreciation of 2.4% in the year ended December 31, 2014, respectively. While the international reaction to the RMB appreciation has generally been positive, there remains significant international pressure on the PRC government to adopt an even more flexible currency policy, which could result in a further and more significant appreciation of the RMB against the United States dollar.

**Recent accounting pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which will supersede the revenue recognition requirements in Topic 605, *Revenue Recognition*, and most industry-specific guidance when it becomes effective. ASU 2014-09 affects any entity that enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principle of ASU 2014-09 is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. On August 13, 2015, the FASB approved ASU 2015-14— *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which is a one year deferral of ASU 2014-09. ASU 2014-09 is now effective for annual and interim reporting periods beginning after December 15, 2017, and entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company is currently evaluating the method of adoption to be utilized as well as the impact ASU 2014-09 will have on its consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities ("Topic 915"): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* ("ASU 2014-10"). ASU 2014-10 removes all incremental financial reporting requirements from GAAP for development stage entities. The Company early adopted this standard in its consolidated financial statements on January 1, 2012.

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**2. Summary of significant accounting policies (Continued)**

As a result of the early adoption of ASU 2014-10, the accompanying consolidated financial statements do not include the incremental reporting requirements previously required by Topic 915.

In June 2014, the FASB issued ASU No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* ("ASU 2014-12"). The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. For all entities, the amendments in ASU 2014-12 are effective for annual and interim reporting periods beginning after December 15, 2015. Earlier adoption is permitted. The adoption of ASU 2014-12 is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 requires management to evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued or are available to be issued. ASU 2014-15 also requires management to disclose certain information depending on the results of the going concern evaluation. The provisions of ASU 2014-15 are effective for annual periods ending after December 15, 2016, and for interim and annual periods thereafter. Early adoption is permitted. The Company will be required to perform an annual assessment of its ability to continue as a going concern when this standard becomes effective on January 1, 2017; however, the adoption of this guidance is not expected to impact the Company's financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-03, *Interest — Imputation of Interest* ("ASU 2015-03"). To simplify presentation of debt issuance costs, ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this Update. ASU 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company is currently in the process of evaluating the impact of adoption of ASU 2015-03 on the consolidated financial statements and related disclosures.

## BEIGENE, LTD.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

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**3. Short-term investments**

Short-term investments as of December 31, 2014 consist of the following available-for-sale exchange-traded debt securities:

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value (net carrying amount)
	\$	\$	\$	\$
Corporate fixed income bonds	27,545	—	47	27,498
U.S. treasury securities	2,999	—	—	2,999
<b>Total</b>	<b>30,544</b>	<b>—</b>	<b>47</b>	<b>30,497</b>

During the years ended December 31, 2013 and 2014, the net adjustment to unrealized holding losses on available-for-sale securities in other comprehensive income totaled nil and \$47, respectively. Contractual maturities of all debt securities as of December 31, 2014 were within one year. The Company does not intend to sell the investment in corporate fixed income bonds and it is not more likely than not that the Company will be required to sell the investment before recovery of its amortized cost basis, which may be maturity. Therefore, the Company does not consider the investment in corporate fixed income bonds to be other-than-temporarily impaired at December 31, 2014.

**4. Property and equipment**

Property and equipment consist of the following:

	December 31,	
	2013	2014
	\$	\$
Office equipment	228	223
Electronic equipment	373	378
Laboratory equipment	4,349	4,635
Computer software	151	147
Leasehold improvements	5,381	5,385
	10,482	10,768
Less accumulated depreciation and amortization	(3,430)	(4,837)
Property and equipment, net	<u>7,052</u>	<u>5,931</u>

Depreciation expenses for the years ended December 31, 2013 and 2014 were \$1,592 and \$1,557, respectively.



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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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**5. Income taxes**

***Cayman Islands***

The Company is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, the Company is not subject to income tax.

***Australia***

BeiGene AUS Pty Ltd., incorporated in Australia is subject to corporate income tax at a rate of 30%. BeiGene AUS Pty Ltd. has no taxable income for all periods presented and therefore, no provision for income taxes is required.

***Hong Kong***

BeiGene (Hong Kong) Co., Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong Profits Tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with relevant Hong Kong tax laws. The applicable tax rate is 16.5% in Hong Kong. For the years ended December 31, 2013 and 2014, the Company did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented. Under the Hong Kong tax law, BeiGene (Hong Kong) Co., Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

***PRC***

BeiGene Beijing is subject to the statutory rate of 25% for the years ended December 31, 2013 and 2014 in accordance with the Enterprise Income Tax law (the "EIT Law"), which was effective since January 1, 2008. Under the EIT Law, domestic enterprises and foreign investment enterprises are subject to a unified 25% enterprise income tax rate, except for certain entities that enjoyed the tax holidays. Under the EIT Law, dividends paid by PRC enterprises out of profits earned post-2007 to non-PRC tax resident investors are subject to PRC withholding tax of 10%. A lower withholding tax rate may be applied based on applicable tax treaty with certain jurisdictions.

The EIT Law also provides that enterprises established under the laws of foreign countries or regions and whose "place of effective management" is located within the PRC are considered PRC tax resident enterprises and subject to PRC income tax at the rate of 25% on worldwide income. The definition of "place of effective management" refers to an establishment that exercises, in substance, overall management and control over the production and business, personnel, accounting, properties and other aspects of an enterprise. As of December 31, 2014, no detailed interpretation or guidance has been issued to define "place of effective management." Furthermore, as of December 31, 2014, the administrative practice associated with interpreting and applying the concept of "place of effective management" is unclear. If the Company is deemed as a PRC tax resident, it would be subject to PRC tax under the EIT Law. The Company has analyzed the applicability of this law and will continue to monitor the related development and application.

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## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

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## 5. Income taxes (Continued)

Loss before income taxes consists of:

	Year ended December 31,	
	2013	2014
	\$	\$
Cayman	2,669	(5,487)
PRC	(6,276)	(5,808)
Others	(4,287)	(7,251)
	<u>(7,894)</u>	<u>(18,546)</u>

There is no provision for income taxes because the Company and all of its wholly owned subsidiaries are in a current loss position for all the periods presented.

Significant components of deferred tax assets are as follows:

	Year ended December 31,	
	2013	2014
	\$	\$
Deferred tax assets, non-current portion:		
Net operating losses carryforward	6,228	9,656
Less valuation allowance	(6,228)	(9,656)
Total deferred tax assets	<u>—</u>	<u>—</u>

Valuation allowances have been provided on the deferred tax assets where, based on all available evidence, it was considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of December 31, 2013 and 2014.

As of December 31, 2014, the Company had net operating losses of approximately \$36,957, which can be carried forward to offset taxable income. The net operating loss will start to expire in 2017 if not utilized.

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## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**6. Accrued expenses and other payables**

	December 31,	
	2013	2014
	\$	\$
Payroll payables	924	101
Accrued operating expenses	741	605
Other payables	98	296
	<u>1,763</u>	<u>1,002</u>

**7. Short-term bank loan**

On April 8, 2014, the Company obtained a RMB denominated loan with a principal amount of \$322 from China Merchants Bank at an annual interest rate of 7.8% based on a 30% premium of the market rate published by the PBOC. The short-term bank loan matures in one year and is guaranteed by the non-controlling shareholder of a subsidiary. Interest expense and guarantee fee of \$18 and \$7 was recognized for the year ended December 31, 2014, respectively. The short-term bank loan was fully repaid on April 3, 2015.

**8. Warrant and option liabilities**

	December 31,	
	2013	2014
	\$	\$
Option to purchase shares by rental deferral (note i)	26	125
Warrants in connection with the Convertible Promissory Notes (Note 11, 14)	24	222
	<u>50</u>	<u>347</u>

**(i) Option to purchase shares by rental deferral**

On September 1, 2012, in conjunction with a lease agreement of one of its premises, the Company granted the landlord an option to purchase the Company's ordinary shares (the "Option") in exchange for the deferral of the payment of one year's rental expense. The Option shall be exercisable, in whole or in part, after the closing date of a transaction consummated by the Company to issue ordinary shares or preferred shares convertible into ordinary shares of gross proceeds of at least \$25,000 (the "Option Qualified Financing") and prior to the expiration of the Option. If not previously exercised, the Option shall expire on the earlier of the closing of any reorganization, merger or consolidation of the Company or a sale, lease or other disposition of all or substantially all of the assets of the Company (the "Sale Event"); immediately prior to the closing of an initial public offering of the ordinary shares of the Company on a nationally or internationally recognized exchange (the "Initial Public Offering"); or the termination of the lease. If an Initial Public Offering or Sale Event occurs prior to the Option Qualified Financing, this Option shall be

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**8. Warrant and option liabilities (Continued)**

exercisable, in whole or in part, immediately prior to the closing of the Initial Public Offering or Sale Event.

*Number of shares*

The holder of the Option shall have the right by exercising the Option to purchase up to the number of ordinary shares that equals the quotient obtained by dividing (x) 110% of the total amount of rent deferred at the time of exercise by (y) the Exercise Price.

*Exercise price*

*The exercise price per share (the "Exercise Price") shall be equal to:*

i. in the case of an Option Qualified Financing, the price per share paid by purchasers of ordinary shares issued in an Option Qualified Financing, or if the shares sold in an Option Qualified Financing are preferred shares convertible into ordinary shares, a price per share equal to the price per share paid for such preferred shares divided by the number of ordinary shares into which such preferred shares are initially convertible.

ii. in the case of Initial Public Offering, a percentage of the price to the public in the Initial Public Offering (A) equal to 50% if such offering occurs on or prior to the first anniversary of the issuance of the Option or (B) if such offering occurs after that date, 50% reduced by 1% a month through the month on which such offering occurs, provided that such percentage shall in no event be reduced below 25%.

iii. in the case of a Sale Event, a percentage of the value per share of the consideration paid in the Sale Event (A) equal to 50% if the Sale Event occurs prior to or on the first anniversary of the issuance of the Option or (B) if such Sale Event occurs after that date, 50% reduced by 1% a month through the month on which such Sale Event occurs, provided that such percentage shall in no event be reduced to below 25%.

Accounting for the Option

The Option is a freestanding instrument and is recorded as liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*. The Option was initially recognized at fair value with subsequent changes in fair value recorded in losses. The Option has not been exercised as of December 31, 2014. During the years ended December 31, 2013 and 2014, the Company recognized a gain from the decrease in fair value of \$83 and a loss from the increase in fair value of \$99, respectively. The Company determined the fair value of the Option with the assistance of an independent third party valuation firm.

**9. Senior promissory note**

On February 2, 2011, the Company issued a senior promissory note to Merck Sharp & Dohme Research GmbH ("Merck Sharp"), an entity that is unaffiliated with Merck KGaA, with a principal amount of \$10,000 (the "Senior Promissory Note"). The Senior Promissory Note bears an interest

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**9. Senior promissory note (Continued)**

of 8% compounding per annum and has a term of five years. The Company may elect to repay in whole or in part on the outstanding principal and accrued interest any time prior to the maturity of the Senior Promissory Note.

In the event of (A) any voluntary dissolution, winding up the Company, (B) any material representation or warranty made by the Company was untrue; (C) a material breach or violation of any other covenant, agreement or condition by the Company which is not cured within ten business days; (D) any acceleration of indebtedness of the Company as a result of a default of any agreement; (E) the Company admits in writing its inability to repay its debts as they become due; (F) the Company commences any proceeding seeking reorganization or liquidation; or (G) any proceeding is commenced against the Company to have an order for relief entered against it as debtor or seeking reorganization or liquidation (the "Events of Default"), the outstanding principal and accrued interest of the Senior Promissory Note will become due and payable in full. To date, none of the Events of Default have occurred. The Senior Promissory Note was initially recorded as a long-term liability carried at amortized cost of \$10,000 and subsequently accreted to the amount payable upon maturity using the effective interest method. Interest accrued as of December 31, 2013 and 2014 amounted to \$2,515 and \$3,516, respectively.

**10. Subordinated convertible promissory note**

In 2011, the Company issued a subordinated convertible promissory note to Merck Sharp (the "Subordinated Convertible Promissory Note") for an aggregate principal amount of \$10,000.

The key features of the Subordinated Convertible Promissory Note are as follows:

Interest

The Subordinated Convertible Promissory Note bears an interest of 8% compounding per annum.

Conversion Date

Unless earlier converted, or repaid, the Subordinated Convertible Promissory Note will automatically be converted in full on the second anniversary of the issuance date (the "Conversion Date"). On February 1, 2013, Conversion Date was extended to February 2, 2014. On January 30, 2014, Conversion Date was extended to June 2, 2014. On May 27, 2014, Conversion Date was extended to August 2, 2014. On July 29, 2014, Conversion Date was extended to September 30, 2014. On September 30, 2014, Conversion Date was extended to October 7, 2014.

Conversion Features and Rates

*Conversion following the Second Pharma Financing*

If on or prior to the Conversion Date, the Company has consummated a sale of the Company's securities to a pharma company of at least \$20,000 (the "Second Pharma Financing"), but has not consummated a further sale of the Company's securities to a pharma company after

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**10. Subordinated convertible promissory note (Continued)**

the Second Pharma Financing ("the "Third Pharma Financing") or a sale of the Company's preference shares in a single or series of transactions with aggregate gross proceeds of at least US\$10,000 (the "CB Qualified Financing"), then, on the Conversion Date, the principal amount shall be automatically converted into such number of the Company's ordinary shares that equals 19.9% of the Company's ordinary shares equivalents.

*Conversion following the Third Pharma Financing*

If on or prior to the Conversion Date, the Company has consummated a Third Pharma Financing, but has not consummated a CB Qualified Financing, then, on the Conversion Date, the principal amount shall be automatically converted into such number of the Company's ordinary shares that equals 16.6% of the Company's ordinary shares equivalents.

*Conversion upon a CB Qualified Financing*

If on or prior to the Conversion Date, the Company has consummated a CB Qualified Financing then at the closing of the CB Qualified Financing, the principal amount shall automatically be converted into that number of preference shares sold by the Company in the CB Qualified Financing as is equal to the principal amount divided by eighty percent (80%) of the CB Qualified Financing purchase price.

*Other Conversion*

If on or prior to the Conversion Date, the Company has not consummated a Second Pharma Financing, Third Pharma Financing or a CB Qualified Financing, then, on the Conversion Date, the principal amount shall be automatically converted into such number of the Company's ordinary shares that equals 33.0% of the Company's ordinary shares equivalents.

*Conversion in connection with Company Sale*

If the Company consummates a company sale with a third party other than Merck Sharp (the "Company Sale"), the principal amount shall be converted, automatically upon consummation of such Company Sale, into the number of ordinary shares into which the Subordinated Convertible Promissory Note would have converted if the date of consummation of such Company Sale had been the Conversion Date.

Pursuant to the first amendment of the Subordinated Convertible Promissory Note on February 1, 2013, the *Conversion in connection with Company Sale* clause was replaced by the following clause:

Repayment of the principal amount in full unless Merck Sharp elects to convert the principal amount into the number of ordinary shares equal to (A) 200% of the outstanding principal amount if the Company Sale occurs on or prior to the first anniversary of the issuance of the Subordinated Convertible Promissory Note, or (B) if a Company Sale occurs after that date, a percentage equal

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**10. Subordinated convertible promissory note (Continued)**

to 200% increasing monthly by 8% through the month in which the Company Sale occurs, provided that such percentage shall not be above 400%.

The first amendment also added a conversion option in connection with the Initial Public Offering. If an Initial Public Offering occurs within two years and prior to a CB Qualified Financing, then the outstanding principal amount and all accrued and unpaid interest shall be automatically converted into the number of ordinary shares offered in the Initial Public Offering immediately prior to the closing of the Initial Public Offering, at a conversion price equal to a percentage of the price to the public in the Initial Public Offering (A) equal to 50% if such offering occurs on or prior to the first anniversary of the issuance of the Subordinated Convertible Promissory Note or (B) if such offering occurs after that date, 50% reduced by 1% a month through the month on which such offering occurs, provided that such percentage shall in no event be reduced to below 25%.

Redemption

Upon the occurrence of any of the Events of Default, the outstanding principal and accrued interest of the Subordinated Convertible Promissory Note will become due and payable in full.

Accounting for the Subordinated Convertible Promissory Note

As the Subordinated Convertible Promissory Note will be share-settled by a number of shares with a fair value equal to a fixed settlement amount, the settlement is not viewed as a conversion feature but as a redemption feature because the settlement amount does not vary with the share price. This in-substance redemption feature requires bifurcation because it is not clearly and closely related to the debt host that involves a substantial discount. Since there is no conversion feature embedded in the Subordinated Convertible Promissory Note, no beneficial conversion feature was recorded during the years ended December 31, 2013 and 2014. There are no other embedded derivatives that are required to be bifurcated.

The Subordinated Convertible Promissory Note was initially recorded as long-term debt equal to the \$10,000 proceeds received net of the fair value of the bifurcated embedded redemption feature of an immaterial value on the issuance date. During the year ended December 31, 2013, the change in the fair value of the redemption feature was immaterial. During the year ended December 31, 2014, the Company recognized a loss of \$2,500 from the increase in fair value of the redemption feature in losses. Interest is accrued on the Subordinated Convertible Promissory Note using the effective interest method. Interest accrued as of December 31, 2013 amounted to \$2,126. The amendments to the Subordinated Convertible Promissory Note did not result in debt extinguishment accounting.

Conversion

In October 2014, the Company issued 52,592,590 Series A Preferred Shares for cash consideration of \$35,500 (note 13), which met the criteria of a *Conversion upon a CB Qualified Financing*. As a result, the Subordinated Convertible Promissory Note was automatically converted into 18,518,519 Series A Preferred Shares in total. Upon the conversion, the Company recognized a

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**10. Subordinated convertible promissory note (Continued)**

gain on debt extinguishment of \$2,883 due to the forfeiture of interest as only the principal amount of the Subordinated Convertible Promissory Note was eligible for conversion.

**11. Convertible promissory notes and warrants**

During the year ended December 31, 2012, the Company entered into agreements with several investors to issue convertible promissory notes (the "Convertible Promissory Notes"), and related warrants to purchase the Company's preference shares up to 10% of the Convertible Promissory Notes' principal amount (the "Warrants") concurrently for an aggregate principal amount of \$2,385. During the year ended December 31, 2014, the Company entered into agreements with several investors to issue Convertible Promissory Notes and related Warrants concurrently for an aggregate principal amount of \$25.

The key features of the Convertible Promissory Notes are as follows:

*Maturity Date*

Unless earlier converted, the Convertible Promissory Notes shall be due and payable on the earlier of (i) the fifth anniversary of the issuance date, or (ii) upon the occurrence of any Events of Default.

*Interest*

The Convertible Promissory Notes bear interest of 8% per annum for the first three years and 15% per annum for the remaining term.

*Conversion features and rates*

(a) Automatic Conversion at Qualified Financing

If the Company sells its preferred shares for aggregate gross proceeds of at least \$25,000 (the "Qualified Financing") on or prior to the maturity date, the outstanding principal amount of the Convertible Promissory Notes and all accrued and unpaid interest shall automatically convert into fully paid and nonassessable preferred shares issued in such Qualified Financing at the issue price of the preferred shares, and on the same terms and conditions as those applicable to the other purchasers.

(b) Automatic Conversion at Initial Public Offering

If the closing of Initial Public Offering occurs on or prior to the maturity date and a Qualified Financing, the outstanding principal amount of the Convertible Promissory Notes and all accrued and unpaid interest shall convert into fully paid and nonassessable ordinary shares offered in the Initial Public Offering immediately prior to the closing of the Initial Public Offering, at a conversion price equal to a percentage of the price to the public in the Initial Public Offering (A) equal to 50% if such offering occurs on or prior to the first anniversary of the issuance of the Convertible Promissory Notes or (B) if such offering occurs after that date, 50% reduced by 1% a month



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**11. Convertible promissory notes and warrants (Continued)**

through the month on which such offering occurs, provided that such percentage shall in no event be reduced below 25%.

(c) Automatic Conversion at Sale Event

If any Sale Event occurs on or prior to the maturity date, a Qualified Financing or an Initial Public Offering, the outstanding principal amount of the Convertible Promissory Notes and all accrued and unpaid interest shall convert into such number of fully paid and nonassessable ordinary shares of the Company as is equal in value to (A) 200% of the outstanding principal amount of the Convertible Promissory Notes and all accrued and unpaid interest if the Sale Event occurs on or prior to the first anniversary of the issuance of this Note, or (B) if a Sale Event occurs after that date, a percentage equal to 200% increasing monthly by 8% through the month in which the Sale Event occurs, provided that such percentage shall in no event be above 400%.

*Redemption*

Upon the occurrence of any of the Events of Default, the investors may, with the written consent of investors holding more than 50% of the aggregate outstanding principal amount of the Convertible Promissory Notes declare all outstanding obligations payable by the Company to be immediately due and payable.

The key features of the Warrants are as follows:

*Exercise Period*

If not previously exercised, the Warrants shall expire on the earlier of (a) the closing of a Sale Event; or (b) immediately prior to the closing of the Company's Initial Public Offering.

The Warrants shall be exercisable, in whole or in part, after the closing date of a Qualified Financing and prior to the expiration of the Warrants.

*Number of shares to be purchased*

The holders of the Warrants shall have the right to purchase up to the number of preferred shares that equals the quotient obtained by dividing (x) equal to 10% of the principal amount of the Convertible Promissory Note by (y) the Exercise Price (as defined below), prior to the expiration of the Warrants.

*Exercise Price*

*The exercise price per Share (the "Exercise Price") shall be equal to:*

- i. in the case of a Qualified Financing, the price per share paid by the other purchasers of the shares issued in a Qualified Financing;
- ii. in the case of the Initial Public Offering, a percentage of the price to the public in the Initial Public Offering (A) equal to 50% if such offering occurs on or prior to the first

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11. Convertible promissory notes and warrants (Continued)

anniversary of the issuance of the Warrants or (B) if such offering occurs after that date, 50% reduced by 1% a month through the month on which such offering occurs, provided that such percentage shall in no event be reduced to below 25%; or

- iii. in the case of a Sale Event, a percentage of the value per share of the consideration paid in the Sale Event (A) equal to 50% if the Sale Event occurs prior to or on the first anniversary of the issuance of the Warrants or (B) if such Sale Event occurs after that date, 50% reduced by 1% a month through the month on which such Sale Event occurs, provided that such percentage shall in no event be reduced to below 25%.

Accounting for the Convertible Promissory Notes and the Warrants

The Warrants are freestanding instruments and are recorded as liabilities in accordance with ASC480. The Convertible Promissory Note was initially recorded as long-term debt equal to the proceeds received of \$2,385 and \$25, net of the fair value allocated to the Warrants of \$92 and nil, respectively, in 2012 and 2014. The Warrants are initially recognized at fair value, with subsequent changes in fair value recorded in losses. For the years ended December 31, 2013 and 2014, the Company recognized a gain from the decrease in fair value of the Warrants of \$39 and a loss from the increase in fair value of \$127, respectively. As the Convertible Promissory Notes will be share-settled by a number of shares with a fair value equal to a fixed settlement amount, the settlement is not viewed as a conversion feature but as a redemption feature because the settlement amount does not vary with the share price. The in-substance redemption feature requires bifurcation because it is not clearly and closely related to the debt host that involves a substantial discount. The bifurcated embedded redemption feature had an immaterial value on the respective issuance dates. For the years ended December 31, 2013 and 2014, changes in fair value of the redemption feature were immaterial.

The Convertible Promissory Note is subsequently accreted to the amount payable upon maturity using the effective interest method. Interest accrued as of December 31, 2013 amounted to \$430. Since there is no conversion feature embedded in the Convertible Promissory Notes, no beneficial conversion feature was recorded. The Company determined the value of the Warrants with the assistance of an independent third party valuation firm.

Conversion

In October 2014, the Company issued 52,592,590 Series A Preferred Shares for cash consideration of \$35,500 (note 13), which met the criteria of an *Automatic Conversion at Qualified Financing*. As a result, the Convertible Promissory Notes were automatically converted into 4,310,279 Series A Preferred Shares in total. No gain or loss resulted from the debt extinguishment. The Warrants in connection with the Convertible Promissory Notes were not exercised and remain outstanding as of December 31, 2014.

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**12. Secured guaranteed convertible promissory note and warrants**

On August 12, 2014, the Company issued secured guaranteed convertible promissory note (the "Secured Guaranteed Convertible Promissory Note") and warrants to purchase up to 2,592,593 ordinary shares of the Company (the "BB Warrants") to entities affiliated with Baker Bros. Advisors LP (collectively, "Baker Brothers") for an aggregate principal amount of \$17,500.

The key features of the Secured Guaranteed Convertible Promissory Note are as follows:

*Maturity Date*

Unless earlier converted, the Secured Guaranteed Convertible Promissory Note shall be due and payable on the earlier of (i) February 12, 2015, or (ii) upon the occurrence of any of the Events of Default.

*Interest*

The Secured Guaranteed Convertible Promissory Note bears interest of 10% per annum, provided that the accrued interest shall not be less than three months of interest in the aggregate.

*Prepayment*

The Company may prepay the Secured Guaranteed Convertible Promissory Note, without premium or penalty, in whole or in part, with accrued interest to the date of such prepayment on the amount prepaid.

*Conversion*

Upon issuance of the preferred shares to investors of at least \$31,500 (the "BB Qualified Financing") on or prior to the Maturity Date, the outstanding principal amount of the Secured Guaranteed Convertible Promissory Note and all accrued and unpaid interest shall automatically convert into fully paid and nonassessable preferred shares issued in such BB Qualified Financing at the conversion price and on the same terms and conditions as those applicable to the other purchasers.

*Participation right*

If the BB Qualified Financing does not occur within the 45-day exclusivity period, the Company shall permit the funds advised by Baker Brothers to invest \$10,000 in the aggregate in the first equity financing of at least \$25,000 the Company engages in with unrelated third parties at the same price per share on the same terms and conditions as those of the lead investor in such equity financing.

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**12. Secured guaranteed convertible promissory note and warrants (Continued)**

The key features of the BB Warrants are as follows:

*Exercise Period*

If not previously exercised, the BB Warrants shall expire on the earlier of (a) the exercise of the participation right by Baker Brothers; (ii) the closing of a Sale Event; (iii) the closing of the Qualified IPO; or (iv) August 12, 2019.

*Exercise Price*

The exercise price shall be \$0.68 per ordinary share.

Accounting for the Secured Guaranteed Convertible Promissory Note and the BB Warrants

The BB Warrants are freestanding instruments that represent a right to purchase the Company's ordinary shares (which are not redeemable), and do not impose an obligation to the Company. Further, the BB Warrants are indexed to the Company's stock and can only be settled by the issuance of Company's ordinary shares. In addition, the BB Warrants meet all the criteria required by ASC 815 for equity classification and thus, the BB Warrants are classified in equity. The BB Warrants are not remeasured as long as they continue to meet the conditions for equity classification.

The principal amount of \$17,500 was initially allocated to the Secured Guaranteed Convertible Promissory Note and the BB Warrants based on relative fair value method. As the Secured Guaranteed Convertible Promissory Note will be share-settled by a number of shares with a fair value equal to the fixed settlement amount, the settlement is not viewed as a conversion feature but as a redemption feature because the settlement amount does not vary with the share price.

The in-substance redemption feature requires bifurcation because it is not clearly and closely related to the debt host that involves a substantial discount. The Secured Guaranteed Convertible Promissory Note was initially recorded as a short-term liability equal to \$17,316. The value allocated to the BB Warrants was \$184, which was recorded in equity. The bifurcated embedded redemption feature was of an immaterial value on the issuance date. For the period from the issuance date to immediately before conversion, the change in the fair value of the redemption feature was immaterial. The Secured Guaranteed Convertible Promissory Note is subsequently accreted to the amount payable upon maturity using the effective interest method. Since there is no conversion feature embedded in the Subordinated Convertible Promissory Note, no beneficial conversion feature was recorded. The Company determined the fair value of the BB Warrants with the assistance of an independent third party valuation firm.

Conversion

In October 2014, the Company issued 52,592,590 Series A Preferred Shares for cash consideration of \$35,500 (note 13), which met the criteria of a *BB Qualified Financing*. As a result, the Secured Guaranteed Convertible Promissory Note was automatically converted into 26,574,074

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**12. Secured guaranteed convertible promissory note and warrants (Continued)**

Series A Preferred Shares in total. No gain or loss was resulted from the debt extinguishment. The BB Warrants were not exercised and remain outstanding as of December 31, 2014. The BB Warrants continue to meet the conditions for equity classification as of December 31, 2014.

**13. Convertible preferred shares**

In October 2014, the Company issued 52,592,590 Series A convertible preferred shares (the "Series A Preferred Shares") with a par value of \$0.0001 per share for cash consideration of \$35,500 or \$0.68 per share. At the same time, the Subordinated Convertible Promissory Note (note 10), Convertible Promissory Notes (note 11), Secured Guaranteed Convertible Promissory Note (note 12), advances and Convertible Promissory Notes due to the related party (note 14) were automatically converted into 64,192,927 Series A Preferred Shares in aggregate.

The significant terms of the Series A Preferred Shares are summarized below.

*Dividends*

The holders of the Series A Preferred Shares shall be entitled to receive dividends accruing at the rate of 8% per annum. In addition, holders of the Series A Preferred Shares shall also be entitled to dividends on the Company's ordinary shares on an as if converted basis.

*Voting rights*

Each holder of Series A Preferred Shares shall have the right to vote the number of votes per ordinary share into which their Series A Preferred Shares could be converted, and shall vote along with the ordinary shares, on all matters in respect to which the holders of ordinary shares are entitled to vote.

*Liquidation preference*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or any deemed liquidation event as defined in the Series A Preferred Shares agreements ("Liquidation Transaction"), the holders of Series A Preferred Shares then outstanding are entitled to be paid out of the assets of the Company available for distribution to its members before any payment shall be made to the holders of any other class of Shares by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series A original issue price, plus accrued but unpaid dividends; or (ii) such amount per share as would have been payable had all Series A Preferred Shares been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or deemed liquidation event.

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**13. Convertible preferred shares (Continued)**

*Conversion rights*

- (i) Optional conversion: Each Series A Preferred Share shall be convertible into the Company's ordinary shares at the option of the holder at any time after the issuance date by dividing the Series A original issue price by the Series A conversion price, which is initially equal to the Series A original issue price. All unpaid, cumulative dividends on the Series A Preferred Shares shall no longer be payable.
- (ii) Automatic conversion: All outstanding Series A Preferred Shares shall automatically be converted into ordinary shares at the then effective Series A conversion price upon (i) the closing of a Qualified IPO; or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 78.9% of the then outstanding Series A Preferred Shares. Upon conversion of the Series A Preferred Shares, all unpaid, cumulative dividends on the Series A Preferred Shares shall no longer be payable.

*Drag-along right*

In the event that each of (i) (A) Baker Brothers or (B) Hillhouse BGN Holdings Limited ("Hillhouse") and CB Biotech Investment Limited ("CITIC PE") jointly; (ii) a majority of the Board of Directors; and (iii) the holders of more than 66.66% of the then-outstanding ordinary shares (other than those issued or issuable upon conversion of the Series A Preferred Shares and any other derivative securities) approve a sale of the Company in writing, then each preferred shareholder agrees to certain joint actions to be taken to ensure such sale of the Company could be completed.

Accounting for Series A Preferred Shares

The Series A Preferred Shares are classified as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event (i.e. a Liquidation Transaction). The holders of the Series A Preferred Shares have a liquidation preference and will not receive the same form of consideration upon the occurrence of the conditional event as the ordinary shareholders would. The initial carrying amount of the Series A Preferred Shares of \$78,809 is the issue price at the date of issuance of \$78,889 net of issuance costs of \$80. The holders of Series A Preferred Shares have the ability to convert the instrument into the Company's ordinary shares. The conversion option of the convertible preferred shares do not qualify for bifurcation accounting because the conversion option is clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily convertible into cash. The contingent redemption options of the convertible preferred shares do not qualify for bifurcation accounting because the underlying ordinary shares are not publicly traded nor readily convertible into cash. There are no other embedded derivatives that are required to be bifurcated.

Beneficial conversion features exist when the conversion price of the convertible preferred shares is lower than the fair value of the ordinary shares at the commitment date, which is the issuance date in the Company's case. When a beneficial conversion feature exists as of the

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13. Convertible preferred shares (Continued)

commitment date, its intrinsic value is bifurcated from the carrying value of the convertible preferred shares as a contribution to additional paid-in capital. On the commitment date, the most favorable conversion price used to measure the beneficial conversion feature of the Series A Preferred Shares was \$0.68. No beneficial conversion feature was recognized for the Series A Preferred Shares as the fair value per ordinary share at the commitment date was \$0.28, which was less than the most favorable conversion price. The Company determined the fair value of ordinary shares with the assistance of an independent third party valuation firm.

The Company concluded that the Series A Preferred Shares are not redeemable currently, and is not probable that the Series A Preferred Shares will become redeemable because the likelihood of a Liquidation Transaction is remote. Therefore, no adjustment will be made to the initial carrying amount of the Series A Preferred Shares until it is probable that they will become redeemable. The liquidation preference amount was \$75,878 as of December 31, 2014.

14. Related party balances and transactions

(a) The Company had the following related party transactions for the periods presented:

	For the year ended December 31,	
	2013	2014
	\$	\$
Consulting service fee paid to shareholders(1)	100	100
Advances due to senior executives(2)	249	103
Repayment of advances by cash(2)	(731)	(1,285)
Repayment of advances by issuance of ordinary shares(2)	(134)	(61)
Interest accrued on advances due to senior executives(2)	626	775
Interest on Convertible Promissory Note(3)	67	56
Repayment of indebtedness due to senior executives by issuance of preferred shares(4)	—	(8,143)
Total	<u>177</u>	<u>(8,455)</u>

- (1) During the years ended December 31, 2013 and 2014, shareholders provided consulting services to the Company at a fee of \$100 and \$100, respectively.
- (2) During the years ended December 31, 2013 and 2014, senior executives advanced \$249 and \$103, respectively, to the Company. The advances bear interest at a rate comparable to the interest rate borne by the Company on its outstanding third party debt. During the year ended December 31, 2013, the Company repaid advances amounting to \$731 and \$134 in cash and issuance of ordinary shares, respectively. The excess of the fair value of the ordinary shares over the amount due to the senior executives amounting to \$4 (note 19) was recognized in losses immediately. On

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14. Related party balances and transactions (Continued)

September 15, 2014, the Company entered into a supplemental agreement with the senior executives to clarify its original intention that the indebtedness including interest expense can be converted into convertible preferred shares based on the same conversion terms in the Subordinated Convertible Promissory Note agreement the Company entered into with Merck Sharp (note 10). For the period from January 1, 2014 through October 7, 2014, the Company repaid advances amounting to \$1,285 and \$61 in cash and by issuance of 6,069,000 ordinary shares with fair value of \$61, respectively.

- (3) During the year ended December 31, 2012, the Company issued Convertible Promissory Notes and related Warrants to the senior executives for an aggregate principal amount of \$650. The Warrants are initially recognized at fair value of \$25, with subsequent changes in fair value recorded in losses. For the years ended December 31, 2013 and 2014, the Company recognized a gain from the decrease in fair value of the Warrants of \$11 and a loss from the increase in fair value of \$34, respectively. The terms and conditions underlying the Convertible Promissory Notes and related Warrants are the same as the Convertible Promissory Notes, and Warrants issued to all the other holders (note 11).
- (4) On October 7, 2014, all outstanding indebtedness due to senior executives was settled by the issuance of the Company's Series A Preferred Shares with fair value of \$9,983. The advances outstanding (including interest expense), and the Convertible Promissory Notes (including interest expense) were converted into 13,629,629 and 1,160,426 of the Company's Series A Preferred Shares, respectively (note 13). The difference of \$1,840 was recognized in losses as a result of the settlement of indebtedness (note 19). The Warrants originally issued to the senior executives in connection with the Convertible Promissory Notes were not converted and remain outstanding as of December 31, 2014.



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## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**14. Related party balances and transactions (Continued)**

## (b) Balances due to related parties

	As of	
	December 31,	December 31,
	2013	2014
	\$	\$
<i>Current liabilities</i>		
Advances due to senior executives	6,825	—
Interest accrued on advances due to senior executives	1,047	—
Total	<u>7,872</u>	<u>—</u>
<i>Non-current liabilities</i>		
Convertible Promissory Notes	625	—
Interest on Convertible Promissory Notes	116	—
Total	<u>741</u>	<u>—</u>

The ending balances (including interest) above are accumulated balances due to senior executives.

Except as disclosed above, balances with related parties are unsecured and repayable upon demand.

**15. Non-controlling interests**

On April 9, 2012, Zhongguancun Development Group ("ZDG") acquired a 7% equity interest in Beigene Beijing for \$2,389. Due to a capital injection by the Company into Beigene Beijing during the year ended December 31, 2013, ZDG's equity interest was diluted to 5% as of December 31, 2013. The non-controlling interests balance for the periods presented represents the interest of ZDG in Beigene Beijing based on its proportionate interests in Beigene Beijing adjusted for its proportionate share of losses from operations. The non-controlling interests are classified as mezzanine equity as they are contingently redeemable at the option of ZDG upon the occurrence of any events of default as stipulated in the agreement between ZDG and the Company. The redemption amount is ZDG's capital contribution plus accrued interest computed on the basis of the actual number of days that have elapsed from ZDG's capital contribution date to the redemption date. On December 19, 2014, ZDG exercised its option and the Company repurchased the outstanding equity interest held by ZDG for \$2,443. The acquisition of the non-controlling interest by the Company is accounted for as an equity transaction. The difference between the consideration transferred and the carrying amount of the non-controlling interest of \$950 is recognized as an adjustment to additional paid-in capital.

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15. Non-controlling interests (Continued)

A reconciliation of the carrying amounts of BeiGene Beijing is as follows:

	December 31,			
	2013		2014	
	Company	Non-controlling interests	Company	Non-controlling interests
	\$	\$	\$	\$
Beginning balance	22	2,159	1,006	1,767
Capital contribution	6,700	—	5,000	—
Repurchase of non-controlling interest	—	—	1,493	(1,493)
Transactions with owners acting in their capacity as owners	—	—	—	—
Net loss	(5,875)	(400)	(5,540)	(268)
Other comprehensive income (loss)	159	8	(132)	(6)
Ending balance	1,006	1,767	1,827	—

16. Research and development collaborative arrangements

The Company has developed and controls certain technology and proprietary materials related to its proprietary BRAF inhibitor ("BRAF," "BGB-283") and poly (ADP-ribose) polymerase inhibitor ("PARP," "BGB-290"). In 2013, Merck KGaA and the Company entered into worldwide research and development collaborative arrangements for BRAF and PARP ("Collaborative Arrangements"), respectively. Upon execution of the Collaborative Arrangements, the Company delivered to Merck KGaA the exclusive right to develop and commercialize the BRAF and PARP inhibitors worldwide except PRC ("Ex-PRC"). The Company has retained the exclusive right to develop and commercialize the BRAF and PARP inhibitors in PRC.

Under the terms of the BRAF Collaborative Arrangements, the Company has received an upfront non-refundable payment and upfront Phase I research and development fees in 2013. Upon the dosing of the 5<sup>th</sup> patient in 2014, the Company received an additional Phase I research and development fee. Subsequent to the completion of the Phase I research and development phase, the Company may be eligible to receive product development payments based on the successful achievement of development and regulatory goals, commercial event payments based on the successful achievement of commercialization goals, and royalty payments based on a predetermined percentage of Merck KGaA's aggregate annual net sales of all products in the Ex-PRC territories for a period not to exceed ten years from the date of the first commercial sale. In addition, the Company will pay Merck KGaA profit sharing payments amounting to a predetermined percentage of aggregate annual net sales of BGB-283 products in PRC for a period not to exceed ten years from the date of the first commercial sale.

Under the terms of the PARP Collaborative Arrangements, the Company has received an upfront non-refundable payment and upfront Phase I research and development fees in 2013. Upon

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**16. Research and development collaborative arrangements (Continued)**

the dosing of the 5<sup>th</sup> patient in 2014, the Company received an additional Phase I research and development fee. Subsequent to the completion of the Phase I research and development phase, the Company may be eligible to receive product development payments based on the successful achievement of development and regulatory goals, commercial event payments based on the successful achievement of commercialization goals, and royalty payments based on a predetermined percentage of Merck KGaA's aggregate annual net sales of all products in the Ex-PRC territories for a period not to exceed ten years from the date of the first commercial sale. In addition, the Company will pay Merck KGaA profit sharing payments amounting to a predetermined percentage of aggregate annual net sales of BGB-290 products in PRC for a period not to exceed ten years from the date of the first commercial sale.

The Company has determined that the deliverables related to the collaboration with Merck KGaA, including the licenses of exclusive rights granted to Merck KGaA, as well as the Company's performance obligations to provide Phase I research and development services, will be accounted for as separate units of accounting. This determination was made because each deliverable has a stand-alone value to Merck KGaA and the arrangement does not include a right of return for any deliverable. The Company is recognizing the upfront non-refundable license fee upon the delivery of the license right and the reimbursement of the Phase I research and development services on a straight-line basis over the performance period of three years from the execution date of the respective collaboration arrangements. The Company has made an allocation of revenue recognized as collaboration revenue between the license and the services. This allocation is based upon the relative selling price determined using the BESP of each deliverable. Management utilized a discounted cash-flow model and considered a variety of factors in determining the best estimate of selling price of each deliverable, including, but not limited to: the rights that Merck KGaA was granted under the license, the early stage of the product candidates, the relative risks of successful development of the product candidates, the size of the potential market for the product candidates, competing products and the life-cycle of the product candidates. There have been no significant changes in either the selling price or the method or assumptions used to determine the selling price for a specific unit of accounting during any of the periods presented.

The Company did not elect the milestone method of revenue recognition under ASC 605-28. Therefore, the additional Phase I research and development fees related to the 5th patient dosing will be combined with the other consideration received in the arrangement, being the license and Phase I research and development reimbursements. Based on the above, the additional fee related to the 5th patient dosing will be allocated based on the relative selling price percentages determined for the separate units of account at the inception of the Collaborative Arrangements. Upon completion of the 5th patient dosing, the fee allocated to the license will be recognized immediately and the fee allocated to research and development reimbursements will be recognized on a straight-line basis over the performance period under the cumulative catch-up approach. The 5th patient dosing was completed, and the Company received \$5,000 for BRAF and \$9,000 for PARP on May 14, 2014 and September 17, 2014, respectively.

License revenue was approximately \$9,758 and \$6,679 while research and development revenue was approximately \$1,382 and \$6,275 million of the collaboration revenue for the years

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## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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**16. Research and development collaborative arrangements (Continued)**

ended December 31, 2013 and 2014, respectively. The Company recorded advances from customers related to the collaboration of approximately \$7,860 and \$8,906 at December 31, 2013 and 2014 respectively.

To date, the products have not progressed to the development stages contemplated by the development based targets and none of the products have been approved. Hence, no revenue has been recognized related to the product development targets, royalties or commercial event based targets in any of the periods presented. In addition, no payments have been made to the collaborator for any of the periods presented.

*Other revenue*

The Company provided research and development services to other customers in the PRC amounting to \$8 and \$81, respectively, for the years ended December 31, 2013 and 2014.

**17. Loss per share**

Loss per share was calculated as follows:

	For the year ended December 31	
	2013	2014
Numerator:		
Net loss attributable to ordinary shareholders for computing basic and diluted loss per ordinary share	\$ (7,494)	\$ (18,278)
Denominator:		
Weighted average number of ordinary shares outstanding for computing basic and diluted loss per ordinary share	91,484,521	99,857,623
Basic and diluted loss per share	\$ (0.08)	\$ (0.18)

For the years ended December 31, 2013 and 2014, the computation of basic loss per share using the two-class method was not applicable as the Company was in a net loss position.

The effects of all convertible preferred shares, stock options, restricted stock, subordinated convertible promissory note, convertible promissory notes, the secured guaranteed convertible promissory note, warrants and option to purchase ordinary or preferred shares were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive during the years ended December 31, 2013 and 2014.

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**18. Unaudited pro forma net loss per share**

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding and assumes the automatic conversion of all of the Company's Series A Preferred Shares (note 13) as of December 31, 2014, into 116,785,517 weighted-average shares of ordinary stock upon the closing of the Company's Qualified IPO, as if it had occurred on January 1, 2014. The Company believes the unaudited pro forma net loss per share provides material information to investors, as the automatic conversion of the Company's Series A Preferred Shares and the disclosure of pro forma net loss per ordinary share provides an indication of net loss per ordinary share that is comparable to what will be reported by the Company as a public company following the closing of the Qualified IPO.

The following table summarizes the unaudited pro forma net loss per share attributable to ordinary shareholders:

	<b>Year ended December 31, 2014</b>
<b>Numerator:</b>	
Net loss attributable to ordinary shareholders	\$ (18,278)
<b>Denominator:</b>	
Weighted average number of ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	99,857,623
Add: adjustment to reflect assumed effect of automatic conversion of Series A Preferred Shares	116,785,517
Pro forma weighted average number of shares outstanding — basic and diluted	216,643,140
Pro forma net loss per share attributable to ordinary shareholders — basic and diluted	<u>\$ (0.08)</u>

The effects of all convertible preferred shares, stock options, restricted stock, subordinated convertible promissory note, convertible promissory notes, the secured guaranteed convertible promissory note, warrant and option to purchase ordinary or preferred shares were excluded from the calculation of diluted pro forma net loss as their effect would have been anti-dilutive.

**19. Share-based compensation****Share options**

On April 15, 2011, the Board of Directors approved the 2011 Share Incentive Plan (the "Plan"), which is administered by the Board of Directors or any of its committees such as the Option Committee. Under the Plan, the Board of Directors may grant options to its employees, directors and consultants to purchase an aggregate of no more than 17,000,000 ordinary shares of the Company (the "Option Pool"). On June 29, 2012, March 28, 2013, August 10, 2014 and October 6,

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**19. Share-based compensation (Continued)**

2014, the Board of Directors approved the increase in the Option Pool to 19,000,000 ordinary shares, 24,600,000 ordinary shares, 27,100,000 ordinary shares and 30,560,432 ordinary shares, respectively. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting one calendar year after the grant date and the remainder of the awards vesting on a monthly basis thereafter.

Under the Plan the Company granted 9,849,429 and 3,766,000 options to employees, as well as 1,401,000 and 125,000 options to non-employees, during the years ended December 31, 2013 and 2014, respectively.

As of December 31, 2014, share-based awards to purchase 21,779,991 ordinary shares were outstanding and share-based awards to purchase 8,780,441 ordinary shares were available for future grant under the Plan.

*Modification of exercise price*

On April 22, 2013, the Option Committee resolved to reduce the exercise price of 9,177,357 options related to certain individuals from \$0.20 per share to \$0.01 per share. The fair value of the share options immediately after the modification was higher than that immediately before the modification. Incremental compensation costs related to vested options amounting to \$14 were recognized immediately. Incremental compensation costs related to unvested options amounting to \$17 will be recognized over the remaining vesting period.

There were no other modifications to the Company's share option arrangements for the periods presented.

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19. Share-based compensation (Continued)

The following table summarizes the Company's employee share option activities under the share option plans:

	<u>Number of options</u>	<u>Weighted average exercise price</u> \$	<u>Weighted average grant date fair value</u> \$	<u>Weighted average remaining contractual term</u> Years	<u>Aggregate intrinsic value</u> \$
Outstanding at December 31, 2013	19,552,606	0.02	0.02	8.39	—
Granted	3,766,000	0.01	0.01	—	—
Exercised*	(2,654,447)	0.02	0.02	—	737
Forfeited	(1,078,670)	0.02	0.01	—	—
Outstanding at December 31, 2014	<u>19,585,489</u>	0.02	0.02	7.74	—
Exercisable as of December 31, 2014	<u>12,282,008</u>	0.02	—	7.28	3,366
Vested or expected to vest at December 31, 2014	<u>20,346,354</u>	0.02	—	7.67	5,642

\* Represents share options exercised for which corresponding ordinary shares have not been issued.

The aggregate intrinsic value in the table above represents the difference between the fair value of Company's ordinary shares as at the balance sheet date and the exercise price. Total intrinsic value of options exercised for the years ended December 31, 2013 and 2014 was nil and \$737, respectively.

The total weighted average grant-date fair value of the equity awards granted during the years ended December 31, 2013 and 2014 were \$0.01 and \$0.01 per option, respectively. The total fair value of the equity awards vested during the years ended December 31, 2013 and 2014 were \$55 and \$87, respectively.

As of December 31, 2014, there was \$123 of total unrecognized share-based compensation expenses, net of estimated forfeitures, related to unvested share-based awards which are expected to be recognized over a weighted-average period of 3.21 years. Total unrecognized compensation cost may be adjusted for future changes in estimated forfeitures.

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19. Share-based compensation (Continued)

The following table summarizes the Company's non-employee share option activities under the share option plans:

	Number of options	Weighted average exercise price \$	Weighted average grant date fair value \$	Weighted average remaining contractual term Years	Aggregate intrinsic value \$
Outstanding at December 31, 2013	3,030,410	0.06	0.02	8.38	—
Granted	125,000	0.01	0.01	—	—
Exercised	(960,908)	0.01	0.02	—	278
Forfeited	—	—	—	—	—
Outstanding at December 31, 2014	<u>2,194,502</u>	0.08	0.02	7.58	—
Exercisable as of December 31, 2014	<u>900,125</u>	0.15	—	6.75	133
Vested or expected to vest at December 31, 2014	<u>2,194,502</u>	0.08	—	7.58	482

The aggregate intrinsic value in the table above represents the difference between the fair value of Company's ordinary share as at the balance sheet date and the exercise price. Total intrinsic value of options exercised for the years ended December 31, 2013 and 2014 was nil and \$278, respectively.

The total weighted average grant-date fair value of the equity awards granted during the years ended December 31, 2013 and 2014 were \$0.01 and \$0.01 per option, respectively. The total fair value of the equity awards vested during the years ended December 31, 2013 and 2014 were \$2 and \$251, respectively.

As of December 31, 2014, there was \$374 of total unrecognized share-based compensation expenses, net of estimated forfeitures, related to unvested share-based awards which are expected to be recognized over a weighted-average period of 3.10 years. Total unrecognized compensation cost may be adjusted for future changes in estimated forfeitures.

The binomial option-pricing model was applied in determining the estimated fair value of the options granted. The model requires the input of highly subjective assumptions including the estimated expected stock price volatility and, the exercise multiple for which employees are likely to exercise share options. For expected volatilities, the Company has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Company. For the exercise multiple, the Company has no historical exercise patterns as reference, thus the exercise multiple is based on management's estimation, which the Company believes is



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**19. Share-based compensation (Continued)**

representative of the future exercise pattern of the options. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury Bills yield curve in effect at the time of grant. The estimated fair value of the ordinary shares, at the option grant dates, was determined with assistance from an independent third party valuation firm. The Company's management is ultimately responsible for the determination of the estimated fair value of its ordinary shares.

The following table presents the assumptions used to estimate the fair values of the share options granted in the years presented:

	Year ended December 31,	
	2013	2014
Fair value of ordinary share	0.01	0.30
Risk-free interest rate	1.4%~3.0%	1.9%~2.6%
Expected exercise multiple	2.2~2.8	2.2~2.8
Expected volatility	102%~107%	99%~104%
Expected dividend yield	0%	0%
Contractual life	10 years	10 years

**Restricted stock***Forfeiture of unvested restricted stock*

As stipulated in the stock subscription agreement executed between the Company and the employees, upon the forfeiture of unvested restricted stock, the Company will repurchase the unvested restricted stock at par value of \$0.0001 per ordinary share (the original consideration paid by the employees on the issuance date). On February 6, 2013, and October 15, 2014, the Company repurchased 4,333,334 and 116,671 unvested restricted stock that were forfeited for \$0.43, and \$0.01, respectively.

*Modification of restricted stock*

On November 3, 2010, a consultant was issued with 4,000,000 ordinary shares (the "Consultant"). On May 18, 2012, the Board of Directors approved a resolution that 1,000,000 out of the 4,000,000 ordinary shares granted to the Consultant would vest immediately effective on May 2, 2012 ("Modification Date"). The total incremental compensation cost for the modification was \$25, which was recognized on Modification Date. Subsequently on February 2, 2013 (the "Date of the Change in Employment Status"), the Company's shareholders nominated the Consultant to be a member of the Board of Directors.

Under the terms of the original stock subscription agreement, the individual retains the restricted stock on a change in status; hence, there is no modification to account for. The fair value of the restricted stock to the Consultant has been re-measured on the Date of the Change in Employment Status and compensation charges have been accounted for prospectively over the remaining vesting period. The fair value of the ordinary share on February 2, 2013 amounted to

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19. Share-based compensation (Continued)

\$0.01 per ordinary share. The Consultant had 2,555,556 unvested ordinary shares as of February 2, 2013. There were no other modifications to the Company's restricted stock arrangements for the periods presented.

The following table summarizes the Company's employee restricted stock activities:

	<u>Numbers of shares</u>	<u>Weighted average grant date fair value</u> \$
Outstanding at December 31, 2013	694,449	0.05
Granted	9,021,000	0.09
Vested	(9,021,000)	0.09
Forfeited	(116,671)	0.05
Outstanding at December 31, 2014	<u>577,778</u>	<u>0.05</u>
Expected to vest at December 31, 2014	<u>577,778</u>	<u>0.05</u>

The following table summarizes the Company's non-employee restricted stock activities:

	<u>Numbers of shares</u>	<u>Weighted average grant date fair value</u> \$
Outstanding at December 31, 2013	4,116,667	0.05
Granted	1,616,000	0.25
Vested	(4,216,000)	0.12
Forfeited	—	—
Outstanding at December 31, 2014	<u>1,516,667</u>	<u>0.05</u>
Expected to vest at December 31, 2014	<u>1,516,667</u>	<u>0.05</u>

The fair value of restricted stock on the grant date was derived from the fair value of the underlying ordinary shares. The Company, with the assistance of an independent third party valuation firm, determined the fair value of the underlying ordinary shares. The aggregate fair value of the restricted stock at the grant dates were determined to be \$5,959 and such amount shall be recognized as compensation expense using the straight-line method for all restricted stock granted with graded vesting. As of December 31, 2014, there was \$652 of total unrecognized share-based compensation expenses, net of estimated forfeitures, related to unvested restricted shares, which are expected to be recognized over a weighted-average period of 0.8 years. Total unrecognized compensation cost may be adjusted for future changes in estimated forfeitures.

**Other awards granted**

On April 5, 2013, the Company issued 13,433,334 fully vested ordinary shares to senior executives to settle advances due amounting to \$134. The total fair value of the ordinary shares

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**19. Share-based compensation (Continued)**

issued to the senior executives amounted to \$138. The excess of the fair value of the ordinary shares over the amount due to senior executives amounting to \$4 was recognized in losses immediately. On July 20, 2014, the Company issued 6,069,000 fully vested ordinary shares with fair value of \$61 to senior executives to settle advances due amounting to \$61.

On October 7, 2014, the Company issued 14,790,055 Series A Preferred Shares with fair value of \$9,983 to senior executives in exchange for their surrender of \$8,143 indebtedness that the Company owed them, pursuant to an agreement, dated September 15, 2014 (note 14). The difference amounting to \$1,840 was recognized in losses immediately with a corresponding credit entry to mezzanine equity (note 14).

The following table summarizes total compensation cost recognized for the years ended December 31, 2013 and 2014:

	<b>Year ended December 31,</b>	
	<b>2013</b>	<b>2014</b>
	<b>\$</b>	<b>\$</b>
Research and development	(79)	4,030
General and administrative	55	2,607
	<u>(24)</u>	<u>6,637</u>

The compensation benefit in 2013 is primarily due to the decrease in the fair value of the awards granted to non-employees during the year-ended December 31, 2013 as compared to the corresponding period in the prior year.

**20. Accumulated other comprehensive income**

The movement of accumulated other comprehensive income is as follows:

	<b>Foreign currency translation adjustments</b>	<b>Unrealized losses</b>	<b>Total</b>
<b>Balance as of December 31, 2012</b>	141	—	141
Other comprehensive income	168	—	168
<b>Balance as of December 31, 2013</b>	309	—	309
Other comprehensive loss	(162)	(47)	(209)
<b>Balance as of December 31, 2014</b>	<u>147</u>	<u>(47)</u>	<u>100</u>

**21. Restricted net assets**

The Company's ability to pay dividends may depend on the Company receiving distributions of funds from its PRC subsidiary. Relevant PRC statutory laws and regulations permit payments of

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**21. Restricted net assets (Continued)**

dividends by the Company's PRC subsidiary only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Company's PRC subsidiary.

In accordance with the company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's PRC subsidiary was established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2013 and 2014, no appropriation to statutory reserves was made because the PRC subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Company's PRC subsidiary is restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulation in the PRC may further restrict the Company's PRC subsidiary from transferring funds to the Company in the form of dividends, loans and advances. As of December 31, 2013 and 2014, amounts restricted are the net assets of the Company's PRC subsidiary, which amounted to \$1,006 and \$1,827, respectively.

**22. Employee defined contribution plan**

Full time employees of the Company in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that the Company's PRC subsidiary make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Company has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were \$938 and \$1,030 for the years ended December 31, 2013 and 2014, respectively. The Company did not have full time employees in its remaining wholly owned subsidiaries mainly because the relevant activities were outsourced to third party service providers.

**23. Commitments and Contingencies**

***Exit costs***

During the year ended December 31, 2012, the Company terminated a license agreement and as a result it closed the associated operations that were based in one office in Beijing, PRC. The closure of the office and related operations were completed by the end of February 2013. The

## BEIGENE, LTD.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**23. Commitments and Contingencies (Continued)**

cumulative exit costs incurred were mainly attributed to one-time employee termination benefits, rental contract termination costs, and write-off of leasehold improvements, which amounted to \$280, \$38, and \$35, respectively. Exit costs of \$280 and \$73 were included in the general and administrative expenses during the years ended December 31, 2012 and 2013, respectively. There were no other exit costs or commitments other than those disclosed above for the periods presented.

**Operating lease commitments**

The Company leases office facilities under non-cancelable operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases, and the terms of the leases do not contain rent escalation, contingent rent, renewal, or purchase options.

There are no restrictions placed upon the Company by entering into these leases. Total expenses under these operating leases were \$939 and \$940 for the years ended December 31, 2013 and 2014, respectively.

Future minimum payments under non-cancelable operating leases consist of the following as of December 31, 2014:

	\$
Year ending December 31:	
2015	1,109
2016	1,087
2017	915
2018	915
2019 and thereafter	1,985
	<u>6,011</u>

**24. Subsequent Events**

On April 9, 2015, the Company incorporated a new subsidiary, BeiGene (Suzhou) Co., Ltd. in Suzhou, PRC.

On April 17, 2015, the Board of Directors approved an increase in the number of shares available for issuance under the 2011 Share Incentive Plan by 13,000,000 shares to 40,100,000 shares.

On April 21, 2015, the Company issued 83,205,124 Series A-2 convertible preferred shares (the "Series A-2 Preferred Shares") with a par value of \$0.0001 per share for an aggregate purchase price of \$97,350 or \$1.17 per share. The Series A-2 Preferred Shares are classified as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event (i.e. a Liquidation Transaction). There are no embedded derivatives that are

BEIGENE, LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2014

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**24. Subsequent Events (Continued)**

required to be bifurcated. No beneficial conversion feature was recognized for the Series A-2 Preferred Shares as the fair value per ordinary share at the commitment date was less than the most favorable conversion price.

On July 8, 2015, the Company incorporated a new subsidiary in Delaware, United States.

**25. Events (unaudited) subsequent to the date of the report of the independent registered public accounting firm**

On September 2, 2015, the Company's subsidiary, BeiGene (Suzhou) Co., Ltd. entered into a loan agreement with Suzhou Industrial Park and China Construction Bank, to borrow \$18,880 at a 7% fixed annual interest rate. Fifty percent of the loan will be repaid on September 30, 2018, and the remaining balance will be repaid on September 30, 2019. This loan is secured by certain of the Company's assets.

On September 11, 2015, the Company incorporated a new subsidiary in Shanghai, PRC.

On October 1, 2015, the Company entered into a purchase of rights agreement with Merck KGaA pursuant to which, the Company will purchase from Merck KGaA all its exclusive rights to develop and commercialize the PARP inhibitors in the Ex-PRC territories for a consideration of \$10,000, and reduce the future milestone payments the Company is eligible to receive under the PRC license agreement. Upon the execution of the purchase of rights agreement, Merck KGaA has no further rights and obligations in the Ex-PRC territories under the PARP Collaborative Agreements. In connection with such purchase of rights, the Company also provided Merck KGaA with global access to the Company's PARP supplies for Merck KGaA's combination clinical trials at any time during the period from October 1, 2015 until the first regulatory approval received for the commercialization of the Company's PARP inhibitor in certain major countries.

On January 26, 2016, the Company entered into a note amendment and exchange agreement with Merck Sharp to extend the maturity date of the Senior Promissory Note to May 2, 2016. In addition, if the IPO occurs on or prior to May 2, 2016, subject to certain limitations, the outstanding unpaid principal and interest of this Senior Promissory Note as of the effectiveness date of the Company's IPO (the "Exchanged Balance"), will be automatically exchanged, effective immediately prior to the closing of the IPO, into up to a number of the Company's ordinary shares equal to the quotient of (1) the Exchanged Balance divided by (2) the per ordinary share public offering price in the IPO.

BEIGENE, LTD.

AUDITED CONSOLIDATED BALANCE SHEET AS OF DECEMBER 31, 2014 AND  
UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEET AS OF SEPTEMBER 30, 2015

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

	Note	December 31, 2014 \$	September 30, 2015 \$ (unaudited)	Pro forma shareholders' equity at September 30, 2015 \$ (unaudited)
<b>Assets</b>				
Current assets:				
Cash and cash equivalents		13,898	27,450	—
Short-term investments	3	30,497	93,894	—
Prepaid expenses and other current assets		2,793	6,867	—
Total current assets		47,188	128,211	—
Property and equipment, net	5	5,931	6,541	—
Other non-current assets		502	856	—
Total non-current assets		6,433	7,397	—
Total assets		53,621	135,608	—
<b>Liabilities and shareholders' deficit</b>				
Current liabilities:				
Short-term bank loan		322	—	—
Accounts payable		2,794	4,301	—
Advances from customers		8,906	4,765	—
Accrued expenses and other payables	6	1,002	4,087	—
Senior Promissory Note		—	14,323	—
Warrant and Option liabilities	7	347	841	—
Total current liabilities		13,371	28,317	—
Non-current liabilities:				
Senior Promissory Note		13,516	—	—
Long-term loan	8	—	6,306	—
Deferred rental		798	779	—
Other long-term liabilities		168	129	—
Total non-current liabilities		14,482	7,214	—
Total liabilities		27,853	35,531	—
Commitments and contingencies	17	—	—	—
Convertible Preferred Shares	9	78,809	176,084	—
Series A (par value US\$0.0001 per share; 120,000,000 shares authorized; 116,785,517 shares issued and outstanding as of September 30, 2015 (December 31, 2014: 116,785,517 shares)) and Series A-2 (par value US\$0.0001 per share; 100,000,000 shares authorized; 83,205,124 shares issued and outstanding as of September 30, 2015 (December 31, 2014: nil))		—	—	—
Total mezzanine equity		78,809	176,084	—
Shareholders' deficit:				
Ordinary shares (par value of US\$0.0001 per share; 500,000,000 shares authorized; 116,174,094 shares issued and outstanding as of September 30, 2015 (December 31, 2014: 400,000,000 shares authorized; 108,497,428 shares outstanding))		11	12	32
Additional paid-in capital		7,941	16,059	192,123
Accumulated other comprehensive income/(loss)	15	100	(1,133)	(1,133)
Accumulated deficit		(61,093)	(90,945)	(90,945)
Total shareholders' (deficit) equity		(53,041)	(76,007)	100,077
Total liabilities, mezzanine equity and shareholders' (deficit) equity		53,621	135,608	135,608

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.

BEIGENE, LTD.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF  
COMPREHENSIVE LOSS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2015

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

	Note	Nine months ended September 30,	
		2014 \$ (unaudited)	2015 \$ (unaudited)
Revenue			
Collaboration revenue	11	11,654	4,139
Total revenue		11,654	4,139
Operating expenses:			
Research and development		(15,654)	(30,147)
General and administrative		(5,304)	(4,361)
Total operating expenses		(20,958)	(34,508)
Loss from operations		(9,304)	(30,369)
Interest income		4	1,286
Interest expense (including interest expense incurred due to a related party amounting to \$815 and nil for the nine months ended September 30, 2014 and 2015, respectively)		(3,239)	(840)
Changes in fair value of financial instruments		(2,778)	(502)
Disposal loss on available-for-sale securities		—	(298)
Other income		616	996
Other expense		(107)	(125)
Loss before income tax expense		(14,808)	(29,852)
Income tax expense		—	—
Net loss		(14,808)	(29,852)
Less: net loss attributable to non-controlling interests		(281)	—
Net loss attributable to ordinary shareholders		(14,527)	(29,852)
Loss per share			
Basic and diluted	12	(0.15)	(0.28)
Weighted-average number of ordinary shares used in net loss per share calculation			
Basic and diluted	12	96,939,630	107,015,707
Pro forma basic and diluted loss per share on an as-converted basis	13	—	(0.10)
Shares used in pro forma basic and diluted loss per share computation	13	—	307,006,348
Other comprehensive loss, net of tax of nil:			
Foreign currency translation adjustments		(65)	(509)
Unrealized holding losses		—	(724)
Comprehensive loss		(14,873)	(31,085)
Less: comprehensive loss attributable to non-controlling interests		(286)	—
Comprehensive loss attributable to ordinary shareholders		(14,587)	(31,085)

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.



BEIGENE, LTD.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2015

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

	Note	Nine months ended September 30,	
		2014 \$ (unaudited)	2015 \$ (unaudited)
<b>Operating activities</b>			
Net loss		(14,808)	(29,852)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation expenses	5	1,184	1,127
Share-based compensation expenses		6,089	8,043
Changes in fair value of financial instruments		2,778	502
Loss on disposal of property and equipment		52	3
Disposal loss on available-for-sale securities		—	298
Interest expense		3,090	833
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		(62)	(4,074)
Other non-current assets		86	(354)
Accounts payable		791	1,507
Advances from customers		2,427	(4,141)
Accrued expenses and other payables		279	3,085
Deferred rental		(11)	(19)
Other long-term liabilities		(44)	(39)
Net cash provided by (used in) operating activities		<u>1,851</u>	<u>(23,081)</u>
<b>Investing activities</b>			
Purchases of property and equipment		(268)	(1,892)
Purchase of available-for-sale securities		—	(103,292)
Proceeds from disposal of available-for-sale securities		—	38,973
Proceeds from disposal of property and equipment		3	3
Net cash used in investing activities		<u>(265)</u>	<u>(66,208)</u>
<b>Financing activities</b>			
Proceeds from long-term loan		—	6,294
Proceeds from short-term loan		326	—
Proceeds from issuance of secured convertible promissory note		17,500	—
Proceeds from issuance of convertible preferred shares	9	—	97,350
Proceeds from issuance of ordinary shares		80	77
Proceeds from issuance of convertible promissory notes		25	—
Payment of convertible preferred shares issuance cost	9	—	(75)
Repayment of short-term loan		—	(322)
Repayment to related party	10	(98)	—
Net cash provided by financing activities		<u>17,833</u>	<u>103,324</u>
Effect of foreign exchange rate changes, net		(13)	(483)
Net increase in cash and cash equivalents		19,406	13,552
Cash and cash equivalents at beginning of period		3,926	13,898
Cash and cash equivalents at end of period		<u>23,332</u>	<u>27,450</u>
Supplemental cash flow disclosures:			
Income taxes paid		—	—
Interest expense paid		24	7
Non-cash activities:			
Acquisitions of equipment included in accounts payable		6	91

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.

**BEIGENE, LTD.**

**NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)**

**1. Organization**

BeiGene, Ltd. (the "Company") is a globally focused, clinical-stage biopharmaceutical company with the goal of becoming a leader in the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. The Company's development strategy is based on a novel translational platform that combines their unique access to internal patient-derived biopsies with strong oncology biology. The Company was incorporated under the laws of the Cayman Islands as an exempted company with limited liability on October 28, 2010.

On April 9, 2015, the Company incorporated a new subsidiary, BeiGene (Suzhou) Co., Ltd. ("BeiGene (Suzhou)") in Suzhou, PRC.

On July 8, 2015, the Company incorporated a new subsidiary, BeiGene USA, Inc. in Delaware, United States.

On September 11, 2015, the Company incorporated a new subsidiary, BeiGene (Shanghai) Co., Ltd. in Shanghai, PRC.

These unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information using accounting policies that are consistent with those used in the preparation of the Company's audited consolidated financial statements for the year ended December 31, 2014. Accordingly, these unaudited interim condensed consolidated financial statements do not include all of the information and footnotes required by U.S. GAAP for annual financial statements.

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all normal recurring adjustments necessary to present fairly the financial position, operating results and cash flows of the Company for each of the periods presented. The results of operations for the nine months ended September 30, 2015 are not necessarily indicative of results to be expected for any other interim period or for the full year of 2015. The consolidated balance sheet as of December 31, 2014 was derived from the audited consolidated financial statements at that date but does not include all of the disclosures required by U.S. GAAP for annual financial statements. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2014.

**2. Summary of significant accounting policies**

**Basis of presentation and principles of consolidation**

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with U.S. GAAP. The unaudited interim condensed consolidated financial statements include the financial statements of the Company and its subsidiaries. All significant intercompany transactions and balances between the Company and its subsidiaries are eliminated upon consolidation.

BEIGENE, LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

**Use of estimates**

The preparation of the unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, identifying separate accounting units and estimating the best estimate selling price of each deliverable in the Company's revenue arrangements, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets and the fair value of the financial instruments. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

**Fair value measurements**

*Fair value of financial instruments*

Financial instruments of the Company primarily include cash and cash equivalents, short-term investments, accounts payable, senior promissory note, convertible preferred shares, and warrant and option liabilities. As of September 30, 2015, the carrying values of cash and cash equivalents, and accounts payable approximated their fair values due to the short-term maturity of these instruments. The short-term investments represented the available-for-sale debt securities which are recorded at fair value based on quoted prices in active markets with unrealized gain or loss recorded in other comprehensive income. The warrant and option liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. The convertible preferred shares were initially recorded at issue price net of issuance costs. The Company determined the fair values of the warrant and option liabilities with the assistance of an independent third party valuation firm.

The Company applies ASC topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 — Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 — Include other inputs that are directly or indirectly observable in the marketplace.
- Level 3 — Unobservable inputs which are supported by little or no market activity.

BEIGENE, LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

2. Summary of significant accounting policies (Continued)

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2014 are summarized below:

	Quoted price in active market for identical assets (Level 1) \$	Significant other observable inputs (Level 2) \$	Significant unobservable inputs (Level 3) \$
Available-for-sale securities:			
Corporate fixed income bonds (note 3)	27,498	—	—
U.S. treasury securities (note 3)	2,999	—	—
Option to purchase shares by rental deferral (note 7)	—	—	125
Warrants in connection with the Convertible Promissory Notes (note 7)	—	—	222

Assets and liabilities measured at fair value on a recurring basis as of September 30, 2015 are summarized below:

	Quoted price in active markets for identical assets (Level 1) \$ (unaudited)	Significant other observable inputs (Level 2) \$ (unaudited)	Significant unobservable inputs (Level 3) \$ (unaudited)
Available-for-sale securities:			
Corporate fixed income bonds (note 3)	84,977	—	—
U.S. treasury securities (note 3)	8,917	—	—
Option to purchase shares by rental deferral (note 7)	—	—	468
Warrants in connection with the Convertible Promissory Notes (note 7)	—	—	373

## BEIGENE, LTD.

## NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**2. Summary of significant accounting policies (Continued)**

The following table presents a reconciliation of the assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2015.

	<b>Warrant and option liabilities</b>
	<b>\$</b>
Balance as of December 31, 2014	347
Recognized during the period	—
Unrealized loss	502
Effect of foreign currency translation	(8)
Balance as of September 30, 2015 (unaudited)	<u>841</u>
The amount of total loss for the nine months ended September 30, 2015 included in losses (unaudited)	<u>502</u>

Realized and unrealized gain for the nine months ended September 30, 2015 was recorded as "Changes in fair value of financial instruments" in the unaudited interim condensed consolidated statements of comprehensive loss.

**Deferred initial public offering ("IPO") costs**

Direct costs incurred by the Company attributable to its proposed IPO of ordinary shares in the U.S. have been deferred and recorded in prepaid expenses and other current assets and will be charged against the gross proceeds received from such offering.

**Unaudited pro forma shareholders' equity and loss per share**

Pursuant to the Company's memorandum and articles of association, upon the completion of the Company's initial public offering on the New York Stock Exchange, or the Nasdaq Stock Market or any other stock exchange acceptable to Baker Bros. Advisors LP (the "Qualified IPO"), the outstanding convertible preferred shares will automatically be converted into ordinary shares. Unaudited pro forma shareholders' equity as of September 30, 2015, as adjusted for the reclassification of the convertible preferred shares from mezzanine equity to shareholders' equity, is set forth on the unaudited consolidated balance sheet.

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding as of September 30, 2015, and assumes the automatic conversion of all of the Company's convertible preferred shares into weighted-average shares of ordinary stock upon the closing of the Company's Qualified IPO, as if it had occurred on January 1, 2015.

BEIGENE, LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**3. Short-term investments**

Short-term investments as of December 31, 2014 consist of the following available-for-sale exchange-traded debt securities:

	<u>Amortized cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Fair value (net carrying amount)</u>
	\$	\$	\$	\$
Corporate fixed income bonds	27,545	—	47	27,498
U.S. treasury securities	2,999	—	—	2,999
<b>Total</b>	<b>30,544</b>	<b>—</b>	<b>47</b>	<b>30,497</b>

Short-term investments as of September 30, 2015 consist of the following available-for-sale exchange traded debt securities:

	<u>Amortized cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Fair value (net carrying amount)</u>
	\$	\$	\$	\$
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Corporate fixed income bonds	85,616	—	639	84,977
U.S. treasury securities	9,002	—	85	8,917
<b>Total</b>	<b>94,618</b>	<b>—</b>	<b>724</b>	<b>93,894</b>

During the nine months ended September 30, 2014 and 2015, the net adjustment to unrealized holding losses on available-for-sale securities in other comprehensive income totaled nil and \$724, respectively. Contractual maturities of all debt securities as of September 30, 2015 were generally within one year. The Company does not intend to sell the investment in corporate fixed income bonds and it is not more likely than not that the Company will be required to sell the investment before recovery of its amortized cost basis, which may be maturity. Therefore, the Company does not consider the investment in corporate fixed income bonds to be other-than-temporarily impaired at September 30, 2015.

**4. Income taxes**

There is no provision for income taxes because the Company and all of its wholly owned subsidiaries are in a current loss position for all the periods presented.

The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of December 31, 2014 and September 30, 2015. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

## BEIGENE, LTD.

## NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**5. Property and equipment**

Property and equipment consist of the following:

	<u>December 31, 2014</u>	<u>September 30, 2015</u>
	\$	\$
		(unaudited)
Office equipment	223	217
Electronic equipment	378	413
Laboratory equipment	4,635	5,669
Computer software	147	189
Leasehold improvements	5,385	5,838
	<u>10,768</u>	<u>12,326</u>
Less accumulated depreciation and amortization	(4,837)	(5,785)
Property and equipment, net	<u>5,931</u>	<u>6,541</u>

Depreciation expenses for the nine months ended September 30, 2014 and 2015 were \$ 1,184 and \$1,127, respectively.

**6. Accrued expenses and other payables**

	<u>December 31, 2014</u>	<u>September 30, 2015</u>
	\$	\$
		(unaudited)
Payroll payables	101	135
Accrued operating expenses	605	1,065
Other payables	296	2,887
	<u>1,002</u>	<u>4,087</u>

**7. Warrant and option liabilities**

	<u>December 31, 2014</u>	<u>September 30, 2015</u>
	\$	\$
		(unaudited)
Option to purchase shares by rental deferral	125	468
Warrants in connection with the Convertible Promissory Notes	222	373
	<u>347</u>	<u>841</u>

BEIGENE, LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**8. Long-term loan**

On September 2, 2015, BeiGene (Suzhou) entered into a loan agreement with Suzhou Industrial Park and China Construction Bank, to borrow \$18,885 at a 7% fixed annual interest rate. Fifty percent of the loan will be repaid on September 30, 2018, and the remaining balance will be repaid on September 30, 2019. As of September 30, 2015, the Company has drawn down \$6,294, which is secured by certain of BeiGene (Suzhou)'s assets. Interest accrued as of September 30, 2015 amounted to \$12.

**9. Convertible preferred shares**

In October 2014, the Company issued 52,592,590 Series A convertible preferred shares (the "Series A Preferred Shares") with a par value of \$0.0001 per share for cash consideration of \$35,500 or \$0.68 per share. At the same time, the Subordinated Convertible Promissory Note, Convertible Promissory Notes, Secured Guaranteed Convertible Promissory Note, advances and Convertible Promissory Notes due to the related party were automatically converted into 64,192,927 Series A Preferred Shares in aggregate.

On April 21, 2015, the Company issued 83,205,124 Series A-2 convertible preferred shares (the "Series A-2 Preferred Shares") with a par value of \$0.0001 per share for cash consideration of \$97,350 or \$1.17 per share.

The Series A Preferred Shares and the Series A-2 Preferred Shares are collectively referred to as the "Preferred Shares."

The significant terms of the Preferred Shares are summarized below.

*Dividends*

The holders of the Preferred Shares shall be entitled to receive dividends accruing at the rate of 8% per annum. In addition, holders of the Preferred Shares shall also be entitled to dividends on the Company's ordinary shares on an as if converted basis.

*Voting rights*

Each holder of Preferred Shares shall have the right to vote the number of votes per ordinary share into which their Preferred Shares could be converted, and shall vote along with the ordinary shares, on all matters in respect to which the holders of ordinary shares are entitled to vote.

*Liquidation preference*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or any deemed liquidation event as defined in the Preferred Shares agreements ("Liquidation Transaction"), the holders of Preferred Shares then outstanding are entitled to be paid out of the assets of the Company available for distribution to its members before any payment shall be made to the holders of any other class of Shares by reason of their ownership thereof, an amount per share equal to the greater of (i) the original issue price, plus accrued but unpaid dividends; or (ii) such amount per share as would have been payable had all Preferred Shares



BEIGENE, LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**9. Convertible preferred shares (Continued)**

been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or deemed liquidation event.

*Conversion rights*

- (i) **Optional conversion:** Each Preferred Share shall be convertible into the Company's ordinary shares at the option of the holder at any time after the issuance date by dividing the original issue price by the conversion price, which is initially equal to the original issue price. All unpaid, cumulative dividends on the Preferred Shares shall no longer be payable.
- (ii) **Automatic conversion:** All outstanding Preferred Shares shall automatically be converted into ordinary shares at the then effective Preferred Shares conversion price upon (i) the closing of a Qualified IPO; or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 80.63% of the then outstanding Preferred Shares. Upon conversion of the Preferred Shares, all unpaid, cumulative dividends on the Preferred Shares shall no longer be payable.

*Drag-along right*

In the event that each of (i) (A) Baker Brothers or (B) Hillhouse BGN Holdings Limited ("Hillhouse") and CB Biotech Investment Limited ("CITIC PE") jointly; (ii) a majority of the Board of Directors; and (iii) the holders of more than 66.66% of the then-outstanding ordinary shares (other than those issued or issuable upon conversion of the Series A Preferred Shares and any other derivative securities) approve a sale of the Company in writing, then each preferred shareholder agrees to certain joint actions to be taken to ensure such sale of the Company could be completed.

Accounting for the Preferred Shares

The Preferred Shares are classified as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event (i.e. a Liquidation Transaction). The holders of the Preferred Shares have a liquidation preference and will not receive the same form of consideration upon the occurrence of the conditional event as the ordinary shares holders would. The initial carrying amount of the Series A-2 Preferred Shares of \$97,275 is the issue price at the date of issuance of \$97,350 net of issuance costs of \$75. The holders of the Preferred Shares have the ability to convert the instrument into the Company's ordinary shares. The conversion option of the convertible preferred shares do not qualify for bifurcation accounting because the conversion option is clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily convertible into cash. The contingent redemption options of the convertible preferred shares do not qualify for bifurcation accounting because the underlying ordinary shares are neither publicly traded nor readily convertible into cash. There are no other embedded derivatives that are required to be bifurcated.

Beneficial conversion features exist when the conversion price of the convertible preferred shares is lower than the fair value of the ordinary shares at the commitment date, which is the

## BEIGENE, LTD.

## NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**9. Convertible preferred shares (Continued)**

issuance date in the Company's case. When a beneficial conversion feature exists as of the commitment date, its intrinsic value is bifurcated from the carrying value of the convertible preferred shares as a contribution to additional paid-in capital. On the commitment date of Series A-2 Preferred Shares, the most favorable conversion price used to measure the beneficial conversion feature was \$1.17. No beneficial conversion feature was recognized for the Series A-2 Preferred Shares as the fair value per ordinary share at the commitment date was \$0.47, which was less than the most favorable conversion price. The Company determined the fair value of ordinary shares with the assistance of an independent third party valuation firm.

The Company concluded that the Preferred Shares are not redeemable currently, and is not probable that the Preferred Shares will become redeemable because the likelihood of a Liquidation Transaction is remote. Therefore, no adjustment will be made to the initial carrying amount of the Preferred Shares until it is probable that they will become redeemable. The liquidation preference amount was \$ 210,292 as of September 30, 2015.

**10. Related party balances and transactions**

(a) The Company had the following related party transactions for the periods presented:

	Nine months ended September 30,	
	2014	2015
	\$	\$
	(unaudited)	(unaudited)
Consulting service fee paid to shareholders(1)	75	75
Repayment of advances by cash(2)	(98)	—
Repayment of advances by issuance of ordinary shares(2)	(61)	—
Interest accrued on advances due to senior executives(2)	760	—
Interest on Convertible Promissory Note(3)	55	—
Total	<u>731</u>	<u>75</u>

- (1) During the nine months ended September 30, 2014 and 2015, shareholders provided consulting services to the Company at a fee of \$75, and \$75, respectively.
- (2) Advances due to senior executives bear interest at a rate comparable to the interest rate borne by the Company on its outstanding third party debt. During the nine months ended September 30, 2014, the Company repaid advances amounting to \$98 and \$61 in cash and by issuance of 6,069,000 ordinary shares with fair value of \$61, respectively, and accrued interest amounting to \$760 on the advances outstanding that were due to the senior executives.

BEIGENE, LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**10. Related party balances and transactions (Continued)**

- (3) During the nine months ended September 30, 2014, the Company accrued interest amounting to \$55 on the Convertible Promissory Notes outstanding that were due to the senior executives.

On October 7, 2014, all outstanding indebtedness (including interest expense) due to the senior executives was settled by the issuance of the Company's Series A Preferred Shares. There were no balances due to related parties as of December 31, 2014 and September 30, 2015.

**11. Research and development collaborative arrangements**

The Company did not enter into any new collaborative arrangements during the nine months ended September 30, 2015.

License revenue was approximately \$6,679 and nil while research and development revenue was approximately \$ 4,895 and \$4,139 of the collaboration revenue under historical collaborative arrangements for the nine months ended September 30, 2014 and 2015, respectively. The Company recorded advances from customers related to the collaboration of approximately \$8,906 and \$4,765 at December 31, 2014 and September 30, 2015, respectively.

To date, the products have not progressed to the development stages contemplated by the development based targets and none of the products have been approved. Hence, no revenue has been recognized related to the product development targets, commercial event based targets or royalties in any of the periods presented. In addition, no payments have been made to the collaborator for any of the periods presented.

*Other revenue*

The Company provided research and development services to other customers in the PRC amounting to \$80 and nil, respectively, for the nine months ended September 30, 2014 and 2015.

## BEIGENE, LTD.

## NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**12. Loss per share**

Loss per share was calculated as follows:

	Nine months ended September 30	
	2014 (unaudited)	2015 (unaudited)
Numerator:		
Net loss attributable to ordinary shareholders for computing basic and diluted loss per ordinary share	\$ (14,527)	\$ (29,852)
Denominator:		
Weighted average number of ordinary shares outstanding for computing basic and diluted loss per ordinary share	96,939,630	107,015,707
Basic and diluted loss per share	\$ (0.15)	\$ (0.28)

For the nine months ended September 30, 2014 and 2015, the computation of basic loss per share using the two-class method was not applicable as the Company was in a net loss position.

The effects of all convertible preferred shares, stock options, restricted stock, subordinated convertible promissory note, convertible promissory notes, the secured guaranteed convertible promissory note, warrant and option to purchase ordinary or preferred shares were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive during the nine months ended September 30, 2014 and 2015.

**13. Unaudited pro forma net loss per share**

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding and assumes the automatic conversion of all of the Company's Series A and Series A-2 Preferred Shares (note 9) as of September 30, 2015, into 199,990,641 weighted-average shares of ordinary stock upon the closing of the Company's Qualified IPO, as if it had occurred on January 1, 2015. The Company believes the unaudited pro forma net loss per share provides material information to investors, as the automatic conversion of the Company's Series A and Series A-2 Preferred Shares and the disclosure of pro forma net loss per ordinary share provides an indication of net loss per ordinary share that is comparable to what will be reported by the Company as a public company following the closing of the Qualified IPO.

## BEIGENE, LTD.

## NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**13. Unaudited pro forma net loss per share (Continued)**

The following table summarizes the unaudited pro forma net loss per share attributable to ordinary shareholders:

	Nine months ended <u>September 30, 2015</u> (unaudited)
Numerator:	
Net loss attributable to ordinary shareholders	\$ (29,852)
Denominator:	
Weighted average number of ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	107,015,707
Add: adjustment to reflect assumed effect of automatic conversion of Series A and Series A-2 Preferred Shares	<u>199,990,641</u>
Pro forma weighted average number of shares outstanding — basic and diluted	<u>307,006,348</u>
Pro forma net loss per share attributable to ordinary shareholders — basic and diluted	<u>\$ (0.10)</u>

The effects of all convertible preferred shares, stock options, restricted stock, warrant and option to purchase ordinary or preferred shares were excluded from the calculation of diluted pro forma net loss as their effect would have been anti-dilutive during the nine months ended September 30, 2015.

**14. Share-based compensation**

On February 3, 2015, the Board of Directors approved to issue 2,621,200 options with an exercise price of \$0.30.

On April 17, 2015, the Board of Directors approved an increase in the number of shares available for issuance under the 2011 Share Incentive Plan by 13,000,000 shares to 40,100,000 shares.

On April 20, 2015, the Board of Directors approved to issue 400,400 options with an exercise price of \$0.50.

On June 29, 2015, the Board of Directors approved to issue 4,230,000 options with an exercise price of \$0.50.

On July 1, 2015, the Board of Directors approved to issue 8,900,000 options with an exercise price of \$0.50.

## BEIGENE, LTD.

## NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)

**14. Share-based compensation (Continued)**

On July 19, 2015, the Board of Directors approved to issue 15,200,667 options, with an exercise price of \$0.50, outside of the Option Plan. The Board of Directors also approved to issue 1,462,000 options, with an exercise price of \$0.50, under the Option Plan.

These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting one calendar year after the grant date and the remainder of the awards vesting on a monthly basis thereafter.

**15. Accumulated other comprehensive income**

The movement of accumulated other comprehensive income is as follows:

	<b>Foreign currency translation adjustments</b>	<b>Unrealized losses</b>	<b>Total</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Balance as of December 31, 2014</b>	<b>147</b>	<b>(47)</b>	<b>100</b>
Other comprehensive income before reclassifications	(509)	(1,022)	(1,531)
Amounts reclassified from accumulated other comprehensive income	—	298	298
Net current-period other comprehensive income	(509)	(724)	(1,233)
<b>Balance as of September 30, 2015 (unaudited)</b>	<b>(362)</b>	<b>(771)</b>	<b>(1,133)</b>

**16. Restricted net assets**

As a result of PRC laws and regulations, the Company's PRC subsidiaries are restricted in its ability to transfer a portion of its net assets to the Company. As of December 31, 2014 and September 30, 2015, amounts restricted are the net assets of the Company's PRC subsidiaries, which amounted to \$1,827 and \$3,867, respectively.

**17. Commitments and Contingencies*****Operating lease commitments***

The Company leases office facilities under non-cancelable operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases, and the terms of the leases do not contain rent escalation, contingent rent, renewal, or purchase options. There are no restrictions placed upon the Company by entering into these leases. Total expenses under these operating leases were \$690 and \$830 for the nine months ended September 30, 2014 and 2015, respectively.

**BEIGENE, LTD.****NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands of U.S. Dollars ("\$"), except for number of shares and per share data)

**17. Commitments and Contingencies (Continued)**

Future minimum payments under non-cancelable operating leases consist of the following as of September 30, 2015 (unaudited):

	\$
Three months ending December 31, 2015:	283
Year ending December 31, 2016	1,105
Year ending December 31, 2017	902
Year ending December 31, 2018	895
Year ending December 31, 2019 and thereafter	1,942
	<u>5,127</u>

**18. Subsequent Events**

On October 1, 2015, the Company entered into a purchase of rights agreement with Merck KGaA pursuant to which, the Company will purchase from Merck KGaA all its exclusive rights to develop and commercialize the PARP inhibitors in the Ex-PRC territories for a consideration of \$10,000, and reduce the future milestone payments the Company is eligible to receive under the PRC license agreement. Upon the execution of the purchase of rights agreement, Merck KGaA has no further rights and obligations in the Ex-PRC territories under the PARP Collaborative Agreements. In connection with such purchase of rights, the Company also provided Merck KGaA with global access to the Company's PARP supplies for Merck KGaA's combination clinical trials at any time during the period from October 1, 2015 until the first regulatory approval received for the commercialization of the Company's PARP inhibitor in certain major countries.

On January 26, 2016, the Company entered into a note amendment and exchange agreement with Merck Sharp to extend the maturity date of the Senior Promissory Note to May 2, 2016. In addition, if the IPO occurs on or prior to May 2, 2016, subject to certain limitations, the outstanding unpaid principal and interest of this Senior Promissory Note as of the effectiveness date of the Company's IPO (the "Exchanged Balance"), will be automatically exchanged, effective immediately prior to the closing of the IPO, into up to a number of the Company's ordinary shares equal to the quotient of (1) the Exchanged Balance divided by (2) the per ordinary share public offering price in the IPO.

6,600,000 American Depositary Shares  
Representing 85,800,000 Ordinary Shares

**BeiGene, Ltd.**

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BeiGene

PROSPECTUS

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**Goldman, Sachs & Co.**

**Morgan Stanley**

**Cowen and Company**

**Baird**

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Through and including February 27, 2016 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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