BeiGene, Ltd.
Form 10-K
March 30, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-37686

BEIGENE, LTD.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**98-1209416**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
c/o Mourant Ozannes Corporate Services (Cayman) Limited **94 Solaris Avenue, Camana Bay** **Grand Cayman** **Cayman Islands**	
(Address of Principal Executive Offices)	**KY1-1108** (Zip Code)

+1 (345) 949 4123

(Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
American Depositary Shares, each representing 13 ordinary shares, par value $0.0001 per share	**The NASDAQ Stock Market LLC**
Ordinary Shares, par value $0.0001 per share*	**The NASDAQ Stock Market LLC**

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes o No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

As of March 25, 2016, 427,442,865 ordinary shares, par value $0.0001 per share, were outstanding, of which 107,786,614 ordinary shares were held in the form of 8,291,278 American Depositary Shares, each representing 13 ordinary shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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BeiGene, Ltd.

Annual Report on Form 10-K

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Forward-Looking Statements and Market Data

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, co similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, timing, progress and results of our preclinical studies and clinical trials and our research and development programs;
- our ability to advance our drug candidates into, and successfully complete, clinical trials;
- the ability of our drug candidates to be granted or to maintain Category 1 designation with the China Food and Drug Administration;
- our reliance on the success of our clinical-stage drug candidates BGB-3111, BGB-A317, BGB-290 and BGB-283 and certain other drug candidates;
- 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 developments in the United States, China and other jurisdictions;

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

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

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

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

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

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

- our ability to effectively manage our anticipated growth;

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

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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;

- the future trading price of the American Depositary Shares, or ADSs, and impact of securities analysts reports on these prices; and

- other risks and uncertainties, including those listed under Part I Item 1A Risk Factors.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this Annual Report, particularly in Part I Item 1A Risk Factors, that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report and the documents that we have filed as exhibits to the Annual Report with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report 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.

Please see the Glossary of Scientific Terms on page 72 for definitions of scientific terms used in this Annual Report.

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PART I

Unless the context requires otherwise, references in this report to BeiGene, the Company, we, us, and our refer to BeiGene, Ltd. and its subsidiaries, on a consolidated basis.

Item 1. 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 March 25, 2016, our four clinical-stage drug candidates have been dosed in over 400 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 collaborations with leading cancer hospitals in China. Beyond the substantial market opportunities we expect to have in the United States, Europe and Japan, we believe our location in China provides us the opportunity to bring best-in-class monotherapies and combination therapeutics to our home market where many global standard-of-care therapies are currently not approved or available. We have assembled a team of more than 240 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

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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-290 and BGB-283 and one immuno-oncology agent, BGB-A317. BGB-3111 is a potent and selective small molecule inhibitor of BTK. BGB-290 is a highly selective small molecule inhibitor of PARP1 and PARP2. BGB-283 is a small molecule designed to inhibit both the monomer and dimer forms of the RAF kinase. 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 all commercial rights for all of 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 collaborations with leading cancer hospitals in China. In addition, China accounts for approximately 20 25% of the world s cancer population and is experiencing rapid growth in the market for cancer therapeutics. 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 (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 approximately 240 employees and consultants, including a global research and development team of over 160 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 private equity financing from our dedicated group of investors, including leading healthcare-focused funds, major mutual funds, China-based funds and our founders. On February 8, 2016, we completed our initial public offering and received net proceeds of approximately $166.6 million, after deducting underwriting discounts and offering expenses.

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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, we believe that the emergence of resistance is a major problem and that better outcomes will be achievable by combining multiple drugs as it is done in treating infectious diseases.

The next generation of cancer therapies will be based, we believe, on 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 i.e., 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

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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 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. In addition, tumors from these cell lines have been transplanted in immune-compromised hosts in commonly-used xenograft tumor models. 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 partnerships 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.

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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, one of only two companies 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.

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The following table summarizes our clinical pipeline:

(1) Limited collaboration with Merck KGaA.

(2) Partnered with Merck KGaA outside China.

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 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 initiated a combination trial with obinutuzumab, an anti-CD20 monoclonal antibody recently approved for chronic lymphocytic leukemia in the United States. We have dosed over 100 patients with BGB-3111 in monotherapy and combination trials as of March 25, 2016. In the completed dose-escalation phase of our clinical trial, no protocol-defined dose-limiting toxicities, or treatment discontinuations due to drug-related adverse events were observed. BGB-3111 achieved up to approximately a 3.5- to 7-fold higher exposure level than the approved doses of ibrutinib. 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.

We plan to advance BGB-3111 to global registration studies in 2016, pending feedback from regulatory authorities. In addition to monotherapy studies and a combination trial with obinutuzumab, we plan to initiate a combination trial of BGB-3111 with BGB-A317, our proprietary PD-1 monoclonal antibody, in blood-borne and solid organ tumors.

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We also filed a Clinical Trial Application in China in December 2014 and received CTA approval in February 2016 for all phases of clinical testing. 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-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, or Fc 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 and a combination trial with our PARP inhibitor, BGB-290, in Australia. We have dosed over 100 patients as of March 25, 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.

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 BRCA gene 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 over 50 patients with BGB-290 in monotherapy and combination trials as of March 25, 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-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

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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 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 the dose-escalation phase of our clinical 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 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.

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.

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- 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.

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.

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

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

- A fast track drug registration approval pathway will be available for the following drugs registration application with distinctive clinical benefits for prevention and treatment of HIV, phthisis, virus hepatitis, orphan diseases, cancer, children s diseases, and geriatrics.

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

The CFDA is soliciting public opinions on detailed policies regarding 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. Until a recent CFDA announcement issued on March 4, 2016, these different types of applications were known as Category 1 and Category 3 applications, respectively.

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.

Domestic Innovative Drug Registration Process

For domestically manufactured innovative drug applications, companies are required to obtain approval of a Clinical Trial Application before conducting Phase 1 clinical trials in China. The domestic innovative drug 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 is a faster and more efficient path to approval in the Chinese market than Category 3.

Imported Innovative Drug Registration Process

For 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 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 domestic innovative registration process, the imported innovative drug registration process is more complex and evolving.

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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 has typically taken 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.

The Chinese State Council and the CFDA have recently issued several statements and circulars aimed at improving and accelerating the new drug approval process in general. These include the August 2015 statement issued by the State Council, *Opinions on reforming the review and approval process for pharmaceutical products and medical devices*; the November 2015 CFDA No. 230 Circular, *Circular Concerning Several Policies on Drug Registration Review and Approval*; February 2016 CFDA Circular, *Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog*; and the March 2016 CFDA No. 51 Circular, *Announcement on Reforms of Pharmaceutical Registration Classification* issued by the CFDA on March 4, 2016. In the March 4, 2016 CFDA announcement, the drugs approved outside China seeking marketing approval in China are now called Category 5. We believe these new regulatory initiatives will likely accelerate the approval process for new drugs, including 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 research and development, clinical trial capabilities, and commercial manufacturing facilities in China. As a result, we expect that 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. In February 2016 the CFDA approved our Clinical Trial Application including all phases of our clinical trials for BGB-3111. We have filed similar Clinical Trial Applications for 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.

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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.

*Note: Data from World Health Organization (2012). * New cancer incidences estimated to increase to $19 and $25 million in 2025 and 2035, respectively.*

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.

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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 by 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, Ireesa, 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.

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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-A317, we plan to initiate a monotherapy dose-expansion trial for various cancers. 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-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. 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, PD-1 inhibitor, PARP inhibitor and RAF dimer inhibitor. We believe that we are one of only two companies today to wholly own both a clinical-stage BTK inhibitor 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.

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- **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 FDA and EMA and appears to exhibit greater target inhibition as well.

We have completed the 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 initiated a combination study with obinutuzumab, an anti-CD20 monoclonal antibody recently approved for chronic lymphocytic leukemia in the United States. We have dosed over 100 patients with BGB-3111 in monotherapy and combination trials as of March 25, 2016. In the completed dose-escalation phase of our clinical trial, no protocol-defined dose-limiting toxicities, or treatment discontinuations due to drug-related adverse events were observed. BGB-3111 achieved up to approximately a 3.5- to 7-fold higher exposure level than the approved doses of ibrutinib. 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

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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 in disease originating tissues, such as bone marrow and spleen, in mice and rats was not sustained over a 24-hour period.

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- *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-medicated 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.

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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_{50}. 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.

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- *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. Pharmacokinetic data from our clinical studies 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.

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- *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. 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.

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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 expansion-cohort part of the monotherapy trial, and we have initiated a combination trial with obinutuzumab. As of March 25, 2016, over 100 patients have been dosed with BGB-3111 in monotherapy and combination trials.

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, patients with relapsed or refractory non-Hodgkin s lymphoma and chronic lymphocytic leukemia were enrolled in five dose cohorts (40, 80, 160, and 320 mg QD; 160 mg BID). No dose-limiting toxicities were 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 show that, consistent with BGB-3111 s pharmacokinetic profile, 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. In addition, sustained full BTK occupancy was achieved in the lymph node for both 320 mg QD and 160 mg BID dosing regimens. No protocol-defined dose-limiting toxicities or treatment discontinuations due to drug-related adverse events were observed during dose escalation. Based on the pharmacokinetics, pharmacodynamics, safety and efficacy of BGB-3111 in the dose-escalation phase, 320 mg QD and 160 mg BID are being further explored in the ongoing dose-expansion phase of our clinical trial. 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 including chronic lymphocytic leukemia, mantle cell lymphoma, and Waldenström s Macroglobulinemia.

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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, pending feedback from regulatory authorities. 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 received approval for Clinical Trial Application in February 2016 for all phases of clinical testing. We plan to start an abbreviated dose-escalation trial followed by potential single-arm registration trials in 2016 in chronic lymphocytic leukemia and mantle cell lymphoma. 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.

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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-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 and a combination trial with our PARP inhibitor, BGB-290, in Australia. As of March 25, 2016, we have dosed over 100 patients with BGB-A317 in monotherapy and combination trials. 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

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approved by the FDA for treating certain patients with metastatic melanoma, non-small cell lung cancer and, in the case of nivolumab, renal cell carcinoma.

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 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. In preclinical studies, BGB-A317 showed better cellular functional activities in blocking PD-1 mediated reverse signal transduction and in activating human T-cells and primary PBMCs.

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In addition to differentiation in complementarity-determining regions 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 RI mediated effector function. Both nivolumab and pembrolizumab bind to Fc RI, while BGB-A317 has no binding to Fc RI. A recent paper, as well as our unpublished data, show that in preclinical models Fc RI binding may compromise the activity of PD-1 antibodies.

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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.

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, the combination of BGB-3111 and BGB-A317 significantly prolonged survival.

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In addition, the combination of BGB-3111 and BGB-A317 was explored 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.

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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, and the results showed the synergistic efficacy of BGB-283 and BGB-A317.

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

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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 continue to enroll patients in the dose-escalation phase of the trial, including schedule-expansion cohorts at 2 and 5 mg/kg dosing levels, and we plan to 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.

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 cancers 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 BRCA gene or deficiencies in homologous recombination or mismatch repair, including ovarian, breast, prostate, colorectal, and pancreatic cancers, as well as platinum-sensitive ovarian cancer. As of March 25, 2016, over 100 patients have been dosed with BGB-A317 in monotherapy and combination trials.

We plan to focus development programs on Asia-prevalent tumors including liver, gastric, esophageal, and lung cancers. 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 and combination trials in 2016 or 2017. We plan to initiate our combination trials 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 BRCA gene 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 have completed the dose-escalation phase of our clinical trial in Australia and are initiating the dose-expansion phase of our clinical trial. We have dosed over 50 patients with BGB-290 in monotherapy and combination trials as of March 25, 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

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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, who 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

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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%. 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. BGB-290 has 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.

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- *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, BGB-290 appears well-tolerated, and the only drug-related adverse events that occurred in over 10% of patients are nausea, fatigue, vomiting and diarrhea.

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- *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.

- *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. BGB-290 induced 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.

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Summary of Clinical Results

BGB-290 has completed the dose-escalation phase of our multi-center, open-label clinical trial in Australia and New Zealand. Patients with relapsed or refractory solid tumors were enrolled in seven cohorts receiving monotherapy BGB-290 in doses ranging from 2.5 mg BID to 120 mg BID. Dose-limiting toxicities were observed at 120 mg BID 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 were enrolled to confirm the safety of an 80 mg BID dose as a potential recommended Phase 2 dose. Preliminary safety and efficacy data suggest that BGB-290 is well-tolerated with objective responses seen in multiple ovarian cancer patients including a patient receiving the lowest dose (2.5 mg) of BGB-290.

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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 BRCA gene 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 have dosed over 50 patients with BGB-290 in monotherapy and combination trials as of March 25, 2016. 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. We plan to present updated dose-escalation data in 2016 and the data from our combination trial with BGB-A317 in 2016 or 2017.

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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 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 over 150 patients in our trials in Australia, New Zealand, and China as of March 25, 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 below 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. 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. 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.

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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 first-generation, FDA-approved BRAF inhibitors have limited activity outside of melanoma, non-small cell lung cancer and thyroid cancers. In addition, these first-generation BRAF inhibitors do not exhibit activity against KRAS and NRAS mutations.

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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

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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 disregulated MAPK pathways resistant to first-generation BRAF inhibitors could result in a clinically significant effect.

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- *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*.

- *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 in Australia and New Zealand was completed in June 2015. This trial was designed to assess the safety, tolerability and pharmacokinetic properties of BGB-283 as a monotherapy. 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.

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. The dose-limiting toxicity of BGB-283 in the dose-escalation phase of our clinical trial conducted in Australia and New Zealand was thrombocytopenia. Based on preliminary safety data, 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. As of January 15, 2016, severe adverse events that were considered to be drug-related included fever, fatigue, dehydration, thrombocytopenia, Drug Reaction with Eosinophila and Systemic Symptoms syndrome, sepsis, hyponatraema, febrile neutropenia, and constipation. Other drug-related adverse events included rash, hand-foot syndrome, 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. Initial anti-tumor activities of BGB-283 were observed in patients with both BRAF-mutated and KRAS-mutated patients.

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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 planned trials that combine BGB-283 and BGB-A317. 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 the dose-escalation phase of our clinical trial in China. 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 as of January 15, 2016 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. In total, over 150 patients have been treated with BGB-283 in Australia, New Zealand, and China as of March 25, 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

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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

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 March 15, 2016, we own four issued U.S. patents and ten pending U.S. patent applications as well as corresponding patents and patent applications internationally. In addition, we own five pending international patent applications under the Patent Cooperation Treaty, or PCT, which we plan to file nationally in the United States and

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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 March 15, 2016 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-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.

- ***BGB-290.*** We own one issued U.S. patent, 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. The expected expiration for the issued U.S. patent is 2031, 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 2031. We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries.

- ***BGB-283.*** We own one issued U.S. patent, 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. The expected expiration for the issued U.S. patent is 2031, 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 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 2036. 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.

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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 Item 1A 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

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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 Item 1A 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 December 31, 2015, we have received $9 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 $14 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.

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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 12th or 13th 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

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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 (IMBRUVICA) 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, 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 AstraZeneca/Acerta s ACP-196 currently in Phase 3 trials.

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 and metastatic non-small cell lung cancer patients. Nivolumab has also been approved for advanced renal cell carcinoma 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 durvalumab and Pfizer/Merck Serono s avelumab, together with anti-PD-1 antibodies, Merck s pembrolizumab and Bristol-Myers Squibb s nivolumab, 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.

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

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three or more prior lines of chemotherapy or a combination of chemotherapies. 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 Medivation. 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 Medivation s talazoparib is currently in Phase 3 trials for BRCAm breast cancer.

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.

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.

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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 licensing of the 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

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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.

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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:

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- 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

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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 an NDA or BLA, upon the request of an applicant, the FDA may grant the NDA for a new molecular entity 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

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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 or revoke a biologics license 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

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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 active moiety if it is a drug composed of small molecules, or the same 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

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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. 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.

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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.

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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 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).

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- 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 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,

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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.

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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-A317, BGB 290 and BGB-283 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-A317 and BGB-290.

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.

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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.

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

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

- A fast track drug registration approval pathway will be available for the following drugs registration application with distinctive clinical benefits for prevention and treatment of HIV, phthisis, virus hepatitis, orphan diseases, cancer, children s diseases, and geriatrics.

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

The CFDA may release 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.

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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 December 31, 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. In April 2008, the State Administration of Taxation, the Ministry of Science and Technology and the Ministry of Finance jointly issued the *Administrative Rules for the Certification of High and New Technology Enterprises* specifying the criteria and procedures for the certification of HNTEs. In January 2016, revised version of the *Administrative Rules for the Certification of High and New Technology Enterprises* has been issued by the State Administration of Taxation, the Ministry of Science and Technology and the Ministry of Finance and replaced the 2008 version, while the material criteria of HNTEs remains unchanged.

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, 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 Phases 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.

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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.

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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.

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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 RMB 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 RMB by restricting how the converted RMB 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, RMB capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC. In addition, SAFE strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such RMB capital may not be changed without SAFE s approval, and such RMB capital may not, in any case, be used to repay RMB loans 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 RMB 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 RMB 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

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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 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 RMB 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.

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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 an 11,000 square meter space to build 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 antibody drug substances. 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, which 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

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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 were engaged in full-time research and development and laboratory operations and 43 were 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.

Financial Information and Segments

The financial information required under this Item 1 is incorporated herein by reference to the section of this Annual Report titled Part II Item 8 Financial Statements and Supplementary Data. We operate in one business segment. See Note 2 to our consolidated audited financial statements included in this Annual Report. For financial information regarding our business, see Part II Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report and our consolidated audited financial statements and related notes included elsewhere in this Annual Report.

Corporate 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*. We do not incorporate the information on or accessible through our website into this Annual Report, and you should not consider any information on, or that can be accessed through, our website as part of this Annual Report.

We own various applications and unregistered trademarks and servicemarks, including BeiGene, and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this Annual Report 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.

Available Information

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the U.S. Securities and Exchange Commission, or SEC, in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% shareholders pursuant to Section 16 under the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. We use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD.

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Glossary of Scientific Terms

As used in this Annual Report, the scientific 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 *bis in die* 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 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 RI is expressed in certain human immune cells including monocytes, macrophages and dendritic cells and may function to activate these immune cells. Fc RI has the highest affinity to IgGs among the members of the Fc gamma receptor family.
GTPase	Means a large family of hydrolase enzymes that can bind and hydrolyze guanosine triphosphate.

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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.
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

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	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 *quaque die* 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.
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.

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Item 1A. Risk Factors

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report, including our financial statements and the related notes and Part II Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, before deciding to invest in the ADSs. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of the ADSs could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a globally focused biopharmaceutical company formed in October 2010. Our operations to date have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our current drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283. We have not yet demonstrated 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, 2014 and 2015, we reported a net loss of $7.9 million, $18.5 million and $57.1 million, respectively, and had a deficit accumulated of $118.2 million as of December 31, 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

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third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our shareholders equity and working capital.

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

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

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

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

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

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

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

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

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

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

- 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

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Agency, or EMA; or other comparable regulatory authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these drugs.

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

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

We have financed our operations with a combination of equity and debt offerings, contracts, and private and public grants. Through December 31, 2015, we raised approximately $170 million in private equity financing and $10 million in non-convertible debt financings. To date, we have received a total of $37 million in upfront payments and milestone payments through our collaboration arrangements with Merck KGaA for BGB-283 and BGB-290. On February 8, 2016, we completed our initial public offering of the ADSs and received net proceeds of approximately $166.6 million, after deducting underwriting discount and offering expenses. Our drug candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any product sales revenue.

Our operations have consumed substantial amounts of cash since inception. Our operating activities provided $4.1 million, used $8.7 million, and used $39.8 million of net cash during the years ended December 31, 2013, 2014 and 2015, respectively. We expect to continue to spend substantial amounts on drug discovery advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

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

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;

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- 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 our initial public offering, together with our existing cash and cash equivalents, will not be sufficient to enable us to complete all necessary global development or commercially launch our current drug candidates. Accordingly, we will require further funding through other public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of the ADSs or our ordinary shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other

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operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of the ADSs to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

We incur portions of our expenses, and may in the future derive revenues, in currencies other than the U.S. dollar, in particular, the RMB and Australian dollars. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. For example, a significant portion of our clinical trial activities are conducted outside of the United States, and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy adopted by the PRC, Australia and other non-U.S. governments. Specifically in the PRC, on July 21, 2005, the PRC government changed its policy of pegging the value of the RMB to the U.S. dollar. Following the removal of the U.S. dollar peg, the RMB appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted and the exchange rate between the RMB and the U.S. dollar remained within a narrow band. Since June 2010, the PRC government has allowed the RMB to appreciate slowly against the U.S. dollar again, and it has appreciated more than 10% since June 2010. In April 2012, the PRC government announced that it would allow more RMB exchange rate fluctuation. On August 11, 2015, China s central bank executed a 2% devaluation in the RMB. Over the following two days, Chinese currency fell 3.5% against the dollar. However, it remains unclear what further fluctuations may occur or what impact this will have on the currency.

It is difficult to predict how market forces or PRC, Australian, U.S. or other government policies may impact the exchange rate between the Australian dollar, RMB, U.S. dollar and other currencies in the future. There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which could result in greater fluctuation of the RMB against the U.S. dollar. Substantially all of our revenues are denominated in U.S. dollar and our costs are denominated in U.S. dollar, Australian dollars and RMB, and a large portion of our financial assets and a significant portion of our debt is denominated in U.S. dollar. Any significant revaluation of the RMB may materially reduce any dividends payable on the ADSs in U.S. dollar. To the extent that we need to convert U.S. dollar we received from our initial public offering into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive. Conversely, if we decide to convert our RMB into U.S. dollar for the

purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount we would receive.

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

We had cash and cash equivalents of $3.9 million, $13.9 million and $17.9 million and short-term investments of $0, $30.5 million and $82.6 million at December 31, 2013, 2014 and 2015, respectively. At December 31, 2015, our short-term investments mainly consisted of high credit quality corporate fixed income bonds and U.S. Treasury securities. On February 8, 2016, we completed our initial public offering of the ADSs and received net proceeds of approximately $166.6 million, after deducting underwriting discount and offering expenses. We may invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper and money market instruments, which may not yield a favorable return to our shareholders. All of these investments are subject to credit, liquidity, market and interest

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rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. Our primary exposure to market risk relates to fluctuations in the interest rates of the PRC and the United States. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

Risks Related to Clinical Development of Our Drug Candidates

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

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

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

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

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

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

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

- protecting our rights in our intellectual property;

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

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

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

- competition with other drug candidates and drugs; 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.

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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;
- 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;

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- competing clinical trials for similar therapies or other new therapeutics;

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

- our ability to obtain and maintain patient consents;

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

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

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

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

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

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

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

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

- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;

- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

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

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

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

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

- be delayed in obtaining regulatory approval for our drug candidates;

- not obtain regulatory approval at all;

- obtain approval for indications that are not as broad as intended;

- have the drug removed from the market after obtaining regulatory approval;

- be subject to additional post-marketing testing requirements;

- be subject to restrictions on how the drug is distributed or used; or

- be unable to obtain reimbursement for use of the drug.

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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 that a biologic product candidate is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate s clinical and other benefits outweigh its safety risks;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- delay or failure in adding new clinical trial sites;

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

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

- 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;

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

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

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

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

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

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

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

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

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

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

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

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

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approval or clearance of the companion diagnostics could delay or prevent approval of our drug candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. A failure of such companion diagnostics to gain market acceptance would have an adverse effect on our ability to derive revenues from sales of our drugs. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the diagnostic we anticipate using in connection with development and commercialization of our drug candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our drug candidates.

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

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CFDA, EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our trials could be suspended or terminated and the FDA, CFDA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Undesirable adverse events caused by BGB-3111 may include, but are not limited to, neutropenia, petechiae, purpura (subcutaneous bleeding), bruising, rash, peripheral neuropathy, and fatigue. Undesirable adverse events caused by BGB-290 may include, but are not limited to, nausea, vomiting, diarrhea, lethargy, neutropenia, anemia, thrombocytopena, hypophosphataemia, and hot flush. Undesirable adverse events caused by BGB-283 may include, but are not limited to, thrombocytopenia, fatigue, rash, hand-foot syndrome, hypertension, and anorexia. Drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly.

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

- we may suspend marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop 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.

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

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

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

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

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

We may seek Orphan Drug Exclusivity for some of our drug candidates, and we may be unsuccessful.

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

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

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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

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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-A317, BGB-290 and BGB-283 are each currently undergoing clinical trials. We cannot predict whether these trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In the United States, we have not submitted an NDA or BLA for any of our drug candidates. An NDA or BLA must include extensive preclinical and clinical data and supporting information to establish, in the case of an NDA, the drug candidate s safety and effectiveness or, in the case of a BLA, safety, purity and potency for each desired indication. The NDA or BLA must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA or BLA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

Regulatory authorities outside of the United States, such as the EMA or regulatory authorities in Australia and New Zealand and in emerging markets, such as in the PRC, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. The non-U.S. regulatory approval

process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all.

Specifically, in China, the CFDA categorizes domestically-manufactured innovative drug applications as Category 1 and imported innovative drug applications as Category 3. To date, most of local companies domestically-manufactured drug applications are filed in Category 1 if the drug has not already been approved by the FDA or EMA. Most multinational pharmaceutical companies drug registration applications are filed in Category 3. These two categories have distinct approval pathways, as described in Item 1 Business Regulatory

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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.

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

- A fast track drug registration or clinical trial approval pathway will be available for the following drug registration applications with distinctive clinical benefits: (1) registration of innovative drugs not sold within or outside China; (2) registration of innovative drug transferred to be manufactured in China; (3) registration of drugs using advanced technology, using innovative treatment methods, or having distinctive treatment advantages; (4) clinical trial applications for drugs patent expiry within three years, and marketing authorization applications for drugs with patent expiry within one year; (5) concurrent applications for new drug clinical trials which are already approved in the United States or European Union, or concurrent drug registration applications for drugs which have applied for

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marketing authorization and passed onsite inspections in the United States or European Union and are manufactured using the same production line in China; (6) traditional Chinese medicines (including ethnic medicines) with clear position in prevention and treatment of serious diseases; and (7) registration of new drugs sponsored by national key technology projects or national key development projects.

- A fast track drug registration approval pathway will be available for the following drugs registration application with distinctive clinical benefits for prevention and treatment of HIV, phthisis, virus hepatitis, orphan diseases, cancer, children s diseases, and geriatrics.

The CFDA may issue 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-A317, BGB-3111, BGB-290 and BGB-283. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;

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- 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.

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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 Item 1 Business Competition.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain approval from the FDA, CFDA, EMA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and or slow our regulatory approval.

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

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

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significantly shorter marketing exclusivity period as provided under the Drug Price Competition and Patent Term Restoration Act of 1984.

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

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

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

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, we expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second line or first line therapy. In addition, 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

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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;

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

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

We intend to seek approval to market our drug candidates in the United States, China, Europe and in other selected jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some non-U.S. countries, particularly those in the European Union, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures.

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

In the United States, PRC, European Union and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain regulatory approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this

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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;

- 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.

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

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

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

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

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

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

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

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

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

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

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

Neither the U.S. government nor the U.S. courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

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

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

Non-U.S. markets are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management s attention from the acquisition or development of drug candidates;

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- 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 March 15, 2016, we own four issued U.S. patents and ten pending U.S. patent applications as well as corresponding patents and patent applications internationally. In addition, we own five 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.

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The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the Leahy-Smith America Invents Act enacted in 2011, the United States moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in interference *inter* partes review, post grant review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights.

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

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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.

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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.

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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.

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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

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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

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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.

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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. We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

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

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, CFDA, EMA or other comparable regulatory authorities must approve any manufacturers as part of their regulatory oversight of our drug candidates. This approval would require new testing and cGMP-compliance inspections by FDA, CFDA, EMA or other comparable regulatory authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs.

- our manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates.

- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.

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

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

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with cGMPs and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. We do not have control over third-party manufacturers compliance with these regulations and requirements.

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- 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

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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 Item 1 Business Collaboration with Merck KGaA in this Annual Report. 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;

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- 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, Chairman of our scientific advisory board and director; John V. Oyler, our Founder, Chief Executive Officer and Chairman of the board; and the other principal members of our management and scientific teams and scientific advisory board. Although we have formal employment agreements with each of our executive officers except for our Chief Executive Officer, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain key person insurance for any of our executives or other 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

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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,

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

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

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

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

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

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

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

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

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

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

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

- increased operating expenses and cash requirements;

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- 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.

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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

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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 $102 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.

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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 an 11,000 square meter

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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.

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.

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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 84 million. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

Risks Related to Our Doing Business in the PRC

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

Our research operations and manufacturing facilities are in China, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See Item 1 Business Regulatory Framework and Structural Advantages of Being a China-Based Research and Development Organization for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the Chinese government s policies, but we cannot ensure that our strategy and approach will continue to be aligned.

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

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

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

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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.

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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% of more of the shares, equity or voting rights of the subject entity; (2) holding less than 50% of the voting rights of the subject entity but having the power to secure at least 50% of the seats on the board or other equivalent decision making bodies, or having the voting power to exert material influence on the board, the shareholders meeting or other equivalent decision making bodies; or (3) having the power to exert decisive influence, via contractual or trust arrangements, over the subject entity s operations, financial matters or other key aspects of business operations. Once an entity is determined to be an FIE, it will be subject to the foreign investment restrictions or prohibitions, if the FIE is engaged in the industry listed in the negative list which will be separately issued by the State Council later. Unless the underlying business of the FIE falls within the negative list, which calls for market entry clearance by the Ministry of Commerce or its local counterparts, prior approval from the government authorities as mandated by the existing foreign investment legal regime would no longer be required for establishment of the FIE.

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

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

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

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implementation rules, or the failure of future PRC-resident beneficial owners of our company to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our PRC subsidiaries to fines and legal sanctions. Furthermore, SAFE Circular 37 is unclear how this regulation, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant PRC government authorities, and we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiaries and limit our PRC subsidiaries ability to distribute dividends to us. These risks could in the future have a material adverse effect on our business, financial condition and results of operations.

Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

We and our directors, executive officers and other employees who are PRC residents have participated in our employee equity incentive plans. Upon completion of our initial public offering, we became an overseas listed company. Pursuant to SAFE Circular 37, PRC residents who participate in share incentive plans in overseas non-publicly-listed companies may submit applications to SAFE or its local branches for the foreign exchange registration with respect to offshore special purpose companies. Our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted shares or options may follow SAFE Circular 37 to apply for the foreign exchange registration before our company 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 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. Upon completion of our initial public offering, we became an overseas listed company, and therefore, we and our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted shares or options 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.

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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 December 31, 2015, these restricted assets totaled RMB 21.9 million ($3.4 million).

The EIT Law and its implementation rules, both of which became effective on January 1, 2008, provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor s jurisdiction of 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

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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

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

our subsidiaries.

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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 Annual Report is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our shareholders are deprived of the benefits of such inspection.

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

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

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

In December 2012, the SEC brought administrative proceedings against five accounting firms in China, including our independent registered public accounting firm, alleging that they had refused to produce audit work papers and other documents related to certain other PRC-based companies under investigation by the SEC. On January 22, 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. The decision is neither final nor legally effective unless and until reviewed and approved by the SEC. On February 12, 2014, four of these PRC-based accounting firms appealed to the SEC against this decision. In February 2015, each of the four PRC-based accounting firms agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC. These firms ability to continue to serve all their respective clients is not affected by the settlement. The settlement requires these firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms audit documents via the China Securities Regulatory Commission. If these firms do not follow these procedures, the SEC could impose penalties such as suspensions, or it could restart the administrative proceedings. The settlement did not require these firms to admit to any violation of law and preserves these firms legal defenses in the event the administrative proceeding is restarted. In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies 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.

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

Risks Related to the American Depositary Shares

An active public trading market for the ADSs may not develop or persist.

Prior to our recently completed initial public offering, there was no public market for the ADSs or our ordinary shares underlying the ADSs. The ADSs are listed on the NASDAQ. However, a liquid public market for the ADSs may not develop or persist. If an active trading market for the ADSs does not develop, the market price and liquidity of the ADSs may be materially and adversely affected. The lack of an active market may reduce the fair market value of the ADSs or impair your ability to sell the ADSs at the time you may wish to sell them or at a price that you consider reasonable. 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 purchased an aggregate of approximately $63 million of the ADSs offered in our initial public 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.

We completed our initial public offering on February 8, 2016, and there has been a public market for the ADSs for only a short period of time. The trading price of the ADSs is likely to be volatile and could fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in China that have listed their securities in the United States may affect the volatility in the price of and trading volumes for the ADSs. Some of these companies have experienced significant volatility, including significant price declines after their initial public offerings. The trading performances of these PRC companies securities at the time of or after their offerings may affect the overall investor sentiment towards other PRC companies listed in the United States and consequently may impact the trading performance of the ADSs.

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

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

- announcements of therapeutic innovations or new products by us or our competitors;

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

- any adverse changes to our relationship with manufacturers or suppliers;

- the results of our testing and clinical trials;

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

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

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

- announcements concerning our competitors or the pharmaceutical industry in general;

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- 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 RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs;
- sales or perceived potential sales of additional ordinary shares or ADSs;

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

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

- changes in accounting principles;

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

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

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

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

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

The ADS price may be volatile, and in the past companies that have experienced volatility in the market price of their ADSs have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management s attention from other business concerns, which could seriously harm our business.

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

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

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As of March 25, 2016, we had 427,442,865 ordinary shares outstanding, of which 107,786,614 ordinary shares were held in the form of 8,291,278 American Depositary Shares. The resale of approximately 318,132,131 ordinary shares, or 74.4% of our outstanding ordinary shares as of March 25, 2016 is currently prohibited or otherwise restricted as a result of lock-up agreements entered into by our shareholders with the underwriters of our initial public offering; however, subject to applicable securities law restrictions, these ordinary shares will be able to be sold in the public market beginning as early as August 1, 2016.

We have also registered the offer and sale of all ordinary shares that we may issue under our equity compensation plans, including upon the exercise of share options. These ordinary shares can be freely sold in the public market upon issuance, subject to the lock-up agreements expiring on August 1, 2016.

As of March 25, 2016, the holders of approximately 313,452,707 ordinary shares, or 73.3%, of our outstanding ordinary shares, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their ordinary shares or to include their ordinary shares in registration statements that we may file for ourselves or other shareholders. Once we register the offer and sale of ordinary shares for the holders of registration rights, they can be freely sold in the public market.

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

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

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

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

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

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

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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 depositary for the ADSs will endeavor to vote your underlying ordinary shares in accordance with these instructions. Under our articles of association, the minimum notice period required for convening a general meeting is seven calendar days. When a general meeting is convened, you may not receive sufficient notice of a shareholders meeting to permit you to withdraw your ordinary shares to allow you to cast your vote with respect to any specific matter at the meeting. In addition, the depositary and its agents may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but you may not receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ordinary shares are not voted as you requested.

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 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

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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 our initial public 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 our initial public 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; or

- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that, if you fail to give voting instructions to the depositary, you cannot prevent 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,

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subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders meeting or we are paying a dividend on our ordinary shares.

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

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

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

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

The depositary of the ADSs has agreed to pay you the cash dividends or other distributions it or the custodian for the ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares that your ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by the depositary. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may materially reduce the value of your ADSs.

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

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

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

Our directors, executive officers and principal shareholders beneficially owned approximately 65.5% of our outstanding ordinary shares as of March 25, 2016. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control

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

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

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

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

U.S. investors should be aware that, based on current business plans and financial expectations (including that a substantial percentage of our assets are held in cash and cash equivalents), we expect that we may be a passive foreign investment company within the meaning of Section 1297 of the Internal Revenue Code of 1986, as amended, or PFIC, for the current taxable year and in future taxable years. If we are a PFIC for any taxable year during a U.S. shareholder s holding period of the ADSs or ordinary shares, then such U.S. shareholder generally will

be required to treat any gain realized upon a disposition of the ADSs or ordinary shares, or any excess distribution received on the ADSs or ordinary shares, as ordinary income earned over the U.S. shareholder s holding period for the ADSs or ordinary shares, and to pay the applicable taxes on such ordinary income along with an interest charge at the rate applicable to underpayments of tax on a portion of the resulting tax liability, unless the shareholder makes a timely and effective qualified electing fund election, or QEF election, or mark-to-market election with respect to the

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ADSs or ordinary shares. A U.S. shareholder who makes an effective QEF election generally must report on a current basis its share of our net capital gain and ordinary earnings for any taxable year in which we are a PFIC, whether or not we distribute any amounts to our shareholders. If a QEF election is not in effect for the first taxable year in your holding period in which we are a PFIC, a QEF election can only be made if you elect to recognize gain as if you had sold the ADSs or ordinary shares for their fair market value on the first day of your taxable year in which the PFIC becomes a QEF pursuant to the QEF election. The gain recognized on this deemed sale would be subject to the general tax treatment of PFICs discussed above. We intend to determine our PFIC status at the end of each taxable year and to satisfy any applicable record keeping and reporting requirements that apply to a QEF, and will endeavor to provide to you, for each taxable year that we determine we are or may be a PFIC, the information that is necessary for you to make a QEF election with respect to us (and any of our subsidiaries which are lower-tier PFICs). We may elect to provide such information on our website. However, there can be no assurances that we will make the necessary information available to you. You are urged to consult your own tax advisors regarding the availability of, and procedure for making, a QEF election. A U.S. shareholder who makes an effective mark-to-market election generally must include as ordinary income any gain recognized in a year that we are a PFIC in an amount equal to the excess of the fair market value of the ADSs over the shareholder s adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the ADSs or ordinary shares.

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 our initial public offering. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

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 11,000 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.

Item 3. 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.

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Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

On February 3, 2016, the ADSs began trading on the NASDAQ Global Select Market under the symbol BGNE. Prior to that time, there was no public market for the ADSs. As a result, we have not set forth quarterly information with respect to the high and low prices for the ADSs for the two most recent fiscal years or provided a performance graph. ADSs sold in our initial public offering were priced at $24.00 per ADS. On March 24, 2016, the last reported sale price of the ADSs was $28.03 per ADS.

Shareholders

As of March 25, 2016, there were approximately 89 holders of record of our ordinary shares. Because many ordinary shares held in the form of ADSs are held by broker nominees, we are unable to estimate the total number of holders represented by these record holders.

Dividend Policy

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

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

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 the section of this Annual Report titled Part I Item 1A 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to the section of this Annual Report titled Part III Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Recent Sales of Unregistered Securities

During the year ended December 31, 2015, we issued the following securities that were not registered under the Securities Act:

1. 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. All Series A-2 preferred shares were automatically converted into ordinary shares at the closing of our initial public offering on February 8, 2016.

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2. From January 1, 2015 to December 31, 2015, we granted options exercisable for an aggregate of 17,613,600 ordinary shares to certain of our employees and consultants under our 2011 Option Plan, or 2011 Plan. The number of options and the related exercise price of each tranche of grants are detailed in the table below:

Grant Date	Number of Options	Exercise Price
February 3, 2015	2,621,200	$ 0.30
April 20, 2015	400,400	$ 0.50
June 29, 2015	4,230,000	$ 0.50
July 1, 2015	8,900,000	$ 0.50
July 19, 2015	1,462,000	$ 0.50

3. On July 19, 2015, we granted options to purchase 15,200,667 ordinary shares to certain employee and consultant outside our 2011 Plan at an exercise price of $0.50 per share.

We deemed the offers, sales and issuances of the securities described in paragraph 1 above to be exempt from registration under the Securities Act, either (1) under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and sophisticated investors and did not involve any public offering within the meaning of Section 4(a)(2) or (2) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States.

We deemed the grants of share options described in paragraphs 2 and 3 above and the issuance of ordinary shares upon the exercise of share options as exempt pursuant to (1) Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2), (2) Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation or (3) Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States.

All certificates representing the securities issued in the transactions described in this section included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this section.

Issuer Purchases of Equity Securities

During the quarter ended December 31, 2015, there were no purchases made by us, on our behalf, or by any affiliated purchasers of shares of our equity securities.

Use of Proceeds from Registered Securities

On February 8, 2016, we closed the sale of 7,590,000 ADSs to the public at an initial public offering price of $24.00 per ADS, including the exercise in full by the underwriters of their option to purchase additional ADSs. The ordinary shares in the form of ADSs in our initial public offering were registered under the Securities Act pursuant to a registration statements on Form S-1 (File No. 333-207459), which was filed with the SEC on October 16, 2015 and amended subsequently and declared effective on February 2, 2016. Following the sale of the ADSs in connection with the closing of our initial public offering, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. The underwriters of the offering were Goldman, Sachs & Co., Morgan Stanley, and Cowen and Company acting as joint book-running managers for the offering and as representatives of the underwriters. Baird acted as co-manager for the offering.

We raised approximately $166.6 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses of approximately $15.6 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

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To date, we have not yet used the net proceeds from our initial public offering. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities in accordance with our investment policy. As described in our final prospectus filed with the SEC on February 3, 2016 pursuant to Rule 424(b) under the Securities Act, we expect to use the net proceeds from our initial public offering to fund the costs of ongoing clinical development for our clinical drug candidates, BGB-3111, BGB-A317, BGB-290 and BGB-283, and preclinical drug candidates, as well as for working capital, capital expenditures and general corporate purposes.

Taxation

Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty 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

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- 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.

Item 6. Selected Consolidated Financial Data

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. The following selected consolidated financial data should be read in conjunction with Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and the notes thereto included elsewhere in this Annual Report. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,		
	2013	2014	2015
	(in thousands, except share and per share data)		
Statements of Operations:			
Revenue	$ 11,148	$ 13,035	$ 8,816
Operating expenses:			
Research and development	(13,463)	(21,862)	(58,250)
General and administrative	(3,143)	(6,930)	(7,311)
Total operating expenses	(16,606)	(28,792)	(65,561)
Loss from operations	(5,458)	(15,757)	(56,745)
Interest income	2	40	1,788
Interest expense	(3,155)	(3,552)	(1,229)

Changes in fair value of financial instruments	133	(2,760)	(1,826)
Disposal loss on available-for-sale securities			(314)
Gain on debt extinguishment		2,883	
Other income	694	806	1,309
Other expense	(110)	(206)	(85)
Net loss	(7,894)	(18,546)	(57,102)
Less: net loss attributable to non-controlling interests	(400)	(268)	
Net loss attributable to ordinary shareholders	$ (7,494)	$ (18,278)	$ (57,102)
Loss per ordinary share attributable to ordinary shareholders, basic and diluted(1)	$ (0.08)	$ (0.18)	$ (0.52)
Weighted-average ordinary shares outstanding, basic and diluted	91,484,521	99,857,623	110,597,263
Pro forma net loss per ordinary share attributable to ordinary shareholders, basic and diluted(1)			$ (0.18)
Pro forma weighted-average ordinary shares outstanding, basic and diluted			318,530,218

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(1) See Notes 14 and 15 to our audited consolidated financial statements appearing elsewhere in this Annual Report 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.

	Year Ended December 31,		
	2013	2014	2015
		(in thousands)	
Statements of Comprehensive Loss:			
Net loss	$ (7,894)	$ (18,546)	$ (57,102)
Other comprehensive income/(loss), net of tax of nil:			
Foreign currency translation adjustments	176	(168)	(749)
Unrealized holding loss		(47)	(1,160)
Comprehensive loss	$ (7,718)	$ (18,761)	$ (59,011)

	As of December 31,		
	2013	2014	2015
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 3,926	$ 13,898	$ 17,869
Short-term investments		30,497	82,617
Working capital	(27,300)	33,817	71,097
Total assets	11,798	53,621	116,764
Total liabilities	48,757	27,853	42,445
Preferred shares		78,809	176,084
Non-controlling interests	1,767		
Total shareholders deficit	(38,726)	(53,041)	(101,765)

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Item 7. 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 Item 6 Selected Consolidated Financial Data and our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Part I Item 1A Risk Factors and under Forward-Looking Statements and Market Data in this Annual Report.

Overview

We are a globally focused, clinical-stage 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-290 and BGB-283 and one immuno-oncology agent, BGB-A317. BGB-3111 is a potent and selective small molecule inhibitor of BTK. BGB-290 is a highly selective small molecule inhibitor of PARP1 and PARP2. BGB-283 is a small molecule inhibitor of both the monomer and dimer forms of RAF. 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 December 31, 2015, we raised an aggregate of $150.3 million of gross proceeds from sales of our preferred shares, and additionally received $18.0 million from the Merck KGaA Collaboration to fund our operations. At December 31, 2015, we had cash, cash equivalents and short-term investments of $100.5 million. Although it is difficult to predict our liquidity requirements, based upon our current operating plan and the successful completion of our initial public 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 $7.9 million, $18.5 million and $57.1 million for the years ended December 31, 2013, 2014 and 2015, respectively. As of December 31, 2015, we had an accumulated deficit of $118.2 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:

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- 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.

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, $5 million in milestone payment in 2014 and $4 million in milestone payment in 2015. 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, respectively, and another $14 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. 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, in payments upon the successful achievement of pre-specified clinical and regulatory milestones in the PRC Territory respectively. 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 that 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. The remaining $3 million of deferred revenue related to PARP as of October 1, 2015 was netted against the $10 million repurchase consideration. In addition, if Merck KGaA exercises its PRC commercialization option, as further described in the section of this Annual Report titled Part I Item 1 Business Collaboration with

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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 Part I Item 1 Business Collaboration with Merck KGaA.

We recognized $11.1 million, $13.0 million and $8.8 million of collaboration revenue from the Merck KGaA Collaboration for the years ended December 31, 2013, 2014 and 2015, respectively. The following table summarizes the revenue recognition schedule of an aggregate of $34.0 million in revenue from our collaboration agreements with Merck KGaA, comprised of an aggregate of $22.0 million related to BGB-283 and $12.0 million related to BGB-290. The revenue consists of an upfront non-refundable license fee, Phase 1 research and development fees, and a development based target payment related to the collaborative arrangements for BRAF, excluding the $3 million in deferred revenue that was netted against the $10 million repurchase consideration relating to the PARP inhibitors under the ex-PRC license agreement. In accordance with our revenue recognition policy, we recognize these amounts as shown in the table below:

	BGB-283	BGB-290	Total
		(in thousands)	
2013	$ 8,317	$ 2,823	$ 11,140
2014	5,906	7,048	12,954
2015	6,707	2,109	8,816
2016	1,070		1,070
Total	**$ 22,000**	**$ 11,980**	**$ 33,980**

For the years ended December 31, 2013, 2014 and 2015, substantially all of our revenue were generated solely from Merck KGaA. 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;

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

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-A317, BGB-290 and BGB-283 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 general and administrative personnel. Other general and administrative expenses include professional fees for legal, 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-A317, BGB-290 and BGB-283 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-based compensation charges,

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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 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. In February 2016, in connection with the closing of our initial public offering, the outstanding unpaid principal and interest of the MSD senior promissory note was automatically exchanged into 7,942,314 of our ordinary shares.

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

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2015

The following table summarizes the results of our operations for the years ended December 31, 2014 and 2015, respectively, together with the changes from year-to-year:

	Year Ended December 31,		
	2014	2015	Change
		(in thousands)	
Collaboration revenue	$ 13,035	$ 8,816	$ (4,219)
Operating expenses:			
Research and development	(21,862)	(58,250)	(36,388)
General and administrative	(6,930)	(7,311)	(381)
Loss from operations	(15,757)	(56,745)	(40,988)
Net interest income (expense)	(3,512)	559	4,071
Changes in fair value of financial instruments	(2,760)	(1,826)	934
Disposal loss on available-for-sale securities		(314)	(314)
Gain on Debt Extinguishment	2,883		(2,883)
Net other income	600	1,224	624

Net loss	$ (18,546)	$ (57,102)	$ (38,556)

Revenue

Revenue from the Merck KGaA Collaboration decreased by $4.2 million to $8.8 million for the year ended December 31, 2015 from $13.0 million for the year ended December 31, 2014. The decrease was mainly attributable to the difference between revenues recognized in 2014 for payments received for dosing of 5th patient of BGB-283 and BGB-290 in ex-PRC trials and a payment received in 2015 for dosing of the 5th patient of BGB-283 in PRC trials.

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Research and Development Expense

Research and development expense increased by $36.4 million to $58.3 million for the year ended December 31, 2015 from $21.9 million for the year ended December 31, 2014. The following table summarizes our research and development expense by program and stage of development for the year ended December 31, 2014 and 2015, respectively:

	Year Ended December 31,	
	2014	2015
	(in thousands)	
External cost of clinical-stage programs	$ 10,107	$ 30,806
External cost of preclinical-stage programs	296	3,514
Internal research and development expenses	11,459	23,930
Total research and development expenses	$ 21,862	$ 58,250

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

- Increases of approximately $7.8 million, $5.8 million, $6.4 million, and $0.7 million respectively for BGB-290, BGB-A317, BGB-3111, and BGB-283, including the recognized expenses associated with the repurchase of ex-PRC rights to BGB-290.

The increase in internal research and development expense was primarily attributable to the expansion of our development organization and our pipeline, and included the following:

- $7.7 million for increased compensation expenses, which was primarily attributable to the hiring of more development personnel during the year ended December 31, 2015 and increased share option expense ($9.6 million in 2015 increased from $4.0 million in 2014); and

- $4.7 million for increased facilities, reagents, consulting fee and other expenses.

General and Administrative Expense

General and administrative expense increased by $0.4 million to $7.3 million for the year ended December 31, 2015 from

$6.9 million for the year ended December 31, 2014. The increase was primarily attributable to the following:

- $0.7 million increase of professional fees, in connection with the Series A-2 preferred share financing and initial public offering;

- $0.9 million increase of employee salary and benefits, which was primarily attributable to hiring of more personnel during the year ended December 31, 2015;

- $2.0 million decrease in stock option expense ($0.6 million in 2015 compared to $2.6 million in 2014) primarily attributable to the contractual discount in the exchange price of a loan advanced by a senior executive to the company into Series A preferred shares which was treated as a compensation expense in 2014; and

- $0.8 million increase of travel, office, leasing and other administrative expenses, mainly in connection with the global expansion of the company.

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Interest Income and Expense, Net

Interest expense (net) decreased by $4.1 million from $3.5 million for the year ended December 31, 2014, resulting in net interest income of $0.6 million for the year ended December 31, 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 $0.9 million to $1.9 million for the year ended December 31, 2015 from $2.8 million for the year ended December 31, 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 year ended December 31, 2014 before conversion to Series A preferred shares in October 2014, offset by the fair value increase of our ordinary shares underlying the warrants and option we issued.

Disposal Loss on Available-for-Sale Securities

The $314,000 disposal loss on available-for-sale securities was recorded for the year ended December 31, 2015 following the disposal of the available-for-sale securities.

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 $624,000 to $1.2 million for the year ended December 31, 2015 from $600,000 for the year ended December 31, 2014. Other income primarily consisted of government grants received and foreign exchange gains recognized.

Comparison of the Years Ended December 31, 2013 and 2014

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

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

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Revenue

We recognized $11.1 million and $13.0 million of collaboration revenue from the Merck KGaA Collaboration for the years ended December 31, 2013 and 2014, 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, 2013 and December 31, 2014, respectively:

	Year Ended December 31,	
	2013	2014
	(in thousands)	
External cost of clinical-stage programs	$ 5,462	$ 10,107
External cost of preclinical-stage programs	1,316	296
Internal research and development expenses	6,685	11,459
Total research and development expenses	$ 13,463	$ 21,862

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

- Increases of approximately $2.3 million, $1.5 million, $0.8 million and $0.1 million respectively for BGB-A317, BGB-3111, BGB-290 and BGB-283.

The increase in internal research and development expense was primarily attributable to the expansion of our development organization and our pipeline, and included the following:

- $4.6 million for increased compensation expenses, due to the hiring of more development personnel during the year ended December 31, 2014,and the grants of new share options to certain employees; and

- $0.2 million for increased facility, reagent, consulting and other expenses.

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 was primarily attributable to additional external legal and accounting service costs in connection with protection of our intellectual property rights and preparation for our initial public offering and increased compensation expense, and included the following:

- $1.2 million increase of professional fees and other expenses, mainly in connection with preparation for our initial public offering and patent applications;

- $2.6 million increase in compensation expenses, including: (1) increase of $2.5 million in stock option expense ($2.6 million in 2014 as compared to $0.1 million in 2013 which was mainly related to the contractual discount in the exchange price of a loan advanced by a senior executive to the company into Series A preferred shares which was treated as a compensation expense in 2014 and the grants of restricted shares to certain employees during 2014; and (2) increase of $0.1 million in employee salary and benefits, mainly due to hiring of more personnel during 2014.

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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.

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 $7.9 million, $18.5 million and $57.1 million for the years ended December 31, 2013, 2014 and 2015, respectively. As of December 31, 2015, we had an accumulated deficit of $118.2 million. Our primary use of cash is to fund research and development costs. Our operating activities provided $4.1 million, used $8.7 million, and used $39.8 million of cash flows during the years ended December 31, 2013, 2014 and 2015, 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 $37 million. At December 31, 2015, we had cash, cash equivalents and short-term investments of $100.5 million.

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

	Year Ended December 31,		
	2013	2014	2015
		(in thousands)	
Net cash provided/(used in) by operating activities	$ 4,073	$ (8,694)	$ (39,843)
Net cash (used in) investing activities	(250)	(33,641)	(58,906)
Net cash (used in)/provided by financing activities	(482)	52,165	103,205
Net effect of foreign exchange rate changes	(41)	142	(485)
Net increase in cash and cash equivalents	$ 3,300	$ 9,972	$ 3,971

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 year ended December 31, 2015, operating activities used $39.8 million of cash, which resulted principally from our net loss of $57.1 million, adjusting for non-cash charges of $13.9 million and interest expense of $1.1 million, and by cash provided in our operating assets and liabilities of $2.3 million. Our net non-cash charges during the year ended December 31, 2015 primarily consisted of a $1.5 million depreciation charge, $10.2 million of share-based compensation expense and a $1.8 million loss from changes in the fair value of financial instruments.

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

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$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 $58.9 million for the year ended December 31, 2015 compared to $33.6 million for the year ended December 31, 2014. The increase in cash used in investing activities was primarily due to a net purchase of $53.6 million worth of short-term investments and $5.3 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 $0.3 million 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 $103.2 million for the year ended December 31, 2015 compared to $52.2 million for the year ended December 31, 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 $6.2 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 $0.5 million 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 a $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. As a newly public company, we will 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 December 31, 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-A317, BGB-290 and BGB-283, 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;

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- 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.

Contractual Obligations and Commitments

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2015:

		Payments Due by Period			
	Total	Less Than 1 Year	1 3 Years	3 5 Years	More Than 5 Years
			(in thousands)		
Contractual obligations					
Operating lease commitments	$ 5,398	$ 1,258	$ 2,118	$ 1,870	$ 152
Senior promissory note	14,598	14,598			
Total	$ 19,996	$ 15,856	$ 2,118	$ 1,870	$ 152

Operating Lease Commitments

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.

Senior Promissory Note

The senior promissory note issued to MSD in 2011 bears an interest of 8% compounding per annum and has a term of five years. As of December 31, 2015, the outstanding unpaid principal and interest of the senior promissory note was $14.6 million. In February 2016, in connection with the closing of our initial public offering, the outstanding unpaid principal and interest of the senior promissory note was automatically exchanged into 7,942,314 of our ordinary shares.

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Other Business Agreements

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.

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 accounting principles generally accepted in the United States of America, or 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.

We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements.

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,

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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. To date, none of the products have been approved. Hence, no revenue has been recognized related to 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 (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 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 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

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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 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.

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.

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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:

	Year Ended December 31,		
	2013	2014	2015
Risk-free interest rate	1.4% 3.0%	1.9% 2.6%	1.5% 2.4%
Expected exercise multiple	2.2 2.8	2.2 2.8	2.2 2.8
Expected volatility	102% 107%	99% 104%	94% 106%
Expected dividend yield	0%	0%	0
Contractual life	10 years	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 operations, 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:

	Year Ended December 31,		
	2013	2014	2015
		(in thousands)	
Research and development	$ (79)	$ 4,030	$ 9,593
General and administration	55	2,607	618
Total	$ 24	$ 6,637	$ 10,211

As of December 31, 2015, there was $15.63 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 2.32 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

Because a public trading market for the ADSs has been established in connection with the completion of our initial public offering, it is no longer 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.

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Previously, we were 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 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.

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 operations. 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 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.

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We have measured the warrant and option liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of December 31, 2014 and 2015. The significant unobservable inputs used in the fair value measurement and the corresponding impacts to the fair values are presented below:

			Estimation	
Financial Instrument	**Valuation Techniques**	**Unobservable Inputs**	**2014**	**2015**
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	$665,213
		Volatility for invested capital value allocation	72%	83%
		Volatility for Black-Scholes option pricing model	72% 101%	69% 83%
		Discount for lack of marketability (DLOM)	17%	11%
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	$665,213
		Volatility for invested capital value allocation	72%	83%
		Volatility for Black-Scholes option pricing model	72% 104%	69% 83%
		DLOM	17%	11%

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.

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Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. The guidance requires an entity to evaluate whether there are conditions or events, in the aggregate, 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 and to provide related footnote disclosures in certain circumstances. The guidance is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early application is permitted. The adoption of this guidance is not expected to have a significant impact on our consolidated financial statements.

In April 2015, the FASB issued ASU 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. In August 2015, ASU No. 2015-15 *Imputation of Interest* was issued to address presentation and subsequent measurement of debt issuance costs related to line-of-credit arrangements. Given the absence of authoritative guidance within ASU 2015-03 for debt issuance costs related to line-of-credit arrangements, the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The adoption of this guidance is not expected to have a significant impact on our consolidated financial statements.

In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers-Deferral of the effective date*, or ASU 2015-14. The amendments in ASU 2015-14 defer the effective date of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers issued in May 2014. According to the amendments in ASU 2015-14, the new revenue guidance ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the method of adoption to be utilized and we cannot currently estimate the financial statement impact of adoption.

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 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 our initial public 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.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest and 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. We had cash and cash equivalents of $3.9 million, $13.9 million and $17.9 million and short term investments of $0, $30.5 million and $82.6 million at December 31, 2013, 2014 and 2015, respectively. At December 31, 2015, our cash and cash equivalents were deposited with various major reputable financial institutions located in the PRC and international financial institutions outside of the PRC. The deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. We believe that these financial institutions are of high credit quality, and we continually monitor the credit worthiness of these financial institutions. At December 31, 2015 our short-term investments consisted primarily of high credit quality corporate fixed income bonds and U.S. Treasury securities. We believe that the corporate bonds and the U.S. Treasury securities are of high credit quality and continually monitors the credit worthiness of these institutions.

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.

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. dollar, but a portion of our operating transactions and assets and liabilities are in other currencies, such as RMB, 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.

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB 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 RMB is permitted to fluctuate within a

narrow and managed band against a basket of certain foreign currencies. For the RMB against U.S. dollars, there was appreciation of approximately 2.9% in the year ended December 31, 2013, depreciation of approximately 2.4% in the year ended December 31, 2014 and depreciation of approximately 4.4% in the year ended December 31, 2015. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for capital expenditures and working capital and other business purpose, appreciation of RMB against U.S. dollars would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of U.S. dollars against RMB would have a negative effect on the U.S. dollar amount available to us.

In addition, a significant depreciation of the RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our earnings or losses.

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Currency Convertibility Risk

A majority of our expenses and a significant portion of our 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, or PBOC. However, the unification of exchange rates does not imply that the RMB may be readily convertible into U.S. 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 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.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the year ended December 31, 2015.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this item are appended to this Annual Report. An index of those financial statements is in Part IV Item 15 Exhibits, Financial Statement Schedules.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. The term disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Material Weakness and Remediation of Material Weakness

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

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.

The SEC, as required by Section 404 of the Sarbanes-Oxley Act, adopted rules requiring companies that file reports with the SEC to include a management report on such company s internal control over financial reporting in its annual report. In addition, our independent registered public accounting firm may be required to attest to our internal control over financial reporting. This Annual Report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by SEC rules applicable to newly public companies. Management will be required to provide an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2016. Our independent registered public accounting firm will first be required to attest to the effectiveness of our internal control over financial reporting for our Annual Report on Form 10-K for the first year we are no longer an emerging growth company under the Jumpstart Our Business Startups Act of 2012. We believe we will have adequate resources and expertise, both internal and external, in place to meet this requirement. However, there is no guarantee that our efforts will result in management s ability to conclude, or, if required, our independent registered public accounting firm to attest, that our internal control over financial reporting is effective as of December 31, 2016.

Management s Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management s assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

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Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for emerging growth companies.

Item 9B. Other Information

Not applicable.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth the name, age and position of each of our directors and executive officers as of March 25, 2016:

Name	Age	Position(s)
Executive Officers:		
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.	52	Senior Vice President, Head of Clinical Development
Wendy Yan	50	Senior Vice President, Head of Regulatory Affairs
Non-Management Directors:		
Timothy Chen(1)	59	Director
Donald W. Glazer(2)	71	Director
Michael Goller(2)	41	Director
Ranjeev Krishana(1)	42	Director
Thomas Malley(3)	47	Director
Ke Tang(3)	35	Director
Xiaodong Wang, Ph.D.	52	Director
Qingqing Yi(1)(3)	44	Director

(1) Member of the Compensation Committee.
(2) Member of the Nominating and Corporate Governance 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 serve 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. has served as our Chief Financial Officer and Chief Strategy Officer since July 2015. 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

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Securities, where he covered major and specialty pharmaceuticals. Before 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. has served as our Chief Medical Officer and President of Global Clinical Research and Development since November 2015. 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. from 2004 to 2011, and as a research scientist in cancer genomics at Tularik Inc. (acquired by Amgen Inc. in 2004) from 1998 to 2004. 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

Timothy Chen has served as a member of our board of directors since February 2016. Mr. Chen has served as the Corporate Vice President of Hon Hai Technology Group and President of Asia Pacific Telecom since January 2016. He was the President of Telstra International Group from November 2012 to December 2015. He has also served as Chairman of the board of Autohome Inc. since 2012. Previously, Mr. Chen was a partner of a China Opportunities Fund within GL Capital Group from 2010 to 2012. He was the CEO of National Basketball Association China from 2007 to 2010, the Corporate Vice President of Microsoft and the CEO of its Greater China region from 2003 to 2007, the Corporate Vice President of Motorola and the Chairman and President of Motorola (China) Electronics from 2001 to 2003. Before Microsoft, he was the CEO of 21CN Cybernet, a company listed on the Hong Kong Stock Exchange, from 2000 to 2001. Prior to 2000, Mr. Chen spent eight years in China with

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Motorola, including serving as the General Manager responsible for the sales and marketing for the Greater China Cellular Infrastructure Division. He also spent nine years with AT&T Bell Laboratories in the United States. Mr. Chen holds an MBA degree from the University of Chicago, a master s degree in both computer science and mathematics from Ohio State University, and a bachelor s degree from Chiao Tung University. We believe that Mr. Chen s extensive business expertise in Asia and globally qualify him to serve as a member of our board of directors.

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 serve on our board of directors include his extensive leadership, executive, managerial, business, and corporate legal experience.

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 Master s 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.

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.

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

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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.

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 since 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.

Xiaodong Wang, Ph.D. is our Founder and has served as the Chairman of our scientific advisory board since 2011. Dr. Wang became a member of our board of directors in February 2016. 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.

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.

Ji Li served as a member of our board of directors from January 2015 to February 2, 2016, on which date he resigned from our board of directors prior to the effectiveness of the registration statement for our initial public offering. Mr. Li s decision to resign from our board of directors was not the result of any disagreement with us on any matter relating to our operations, policies or practices.

Composition of Our Board of Directors

Our board of directors currently consists of nine members, all of whom were elected pursuant to the board composition provisions of our voting agreement, which agreement terminated upon the closing of our initial public offering. Currently, there are no 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 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-

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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.

In accordance with the terms of our amended and restated memorandum and articles of association, our board of directors are 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 are John V. Oyler, Timothy Chen and Ke Tang;
- Our Class II directors are Donald W. Glazer, Michael Goller and Thomas Malley; and
- Our Class III directors are Ranjeev Krishana, Xiaodong Wang and Qingqing Yi.

Our amended and restated memorandum and articles of association 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.

Director Nominations by Shareholders

Any shareholder wishing to recommend a director candidate for consideration by the nominating and corporate governance committee should provide the following information within the timeframe set forth by our memorandum and articles of association and SEC rules to BeiGene, Ltd., c/o Mourant Ozannes Corporate Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY1-1108, Cayman Islands, Attention: Secretary: (a) the name and address of record of the shareholder; (b) a representation that the shareholder is a record holder of our securities or, if the shareholder is not a record holder, evidence of ownership in accordance with Rule 14a-8(b)(2) of the Exchange Act; (c) the candidate s name, age, business and residential address, educational background, current principal occupation or employment, and principal occupation or employment for the past five years; (d) a description of the qualifications and background of the candidate that addresses the criteria for board membership approved by our board of directors; (e) a description of all arrangements or understandings between the shareholder and the candidate; (f) the consent of the candidate (i) to be named in the proxy statement for our next shareholder meeting and (ii) to serve as a director if elected at that meeting; and (g) and any other information regarding the candidate that is required to be included in a proxy statement filed pursuant to SEC rules. The nominating and corporate governance committee may seek further information from or about the shareholder making the recommendation, the candidate, or any such other beneficial owner, including information about all business and other relationships between the candidate and the shareholder and between the candidate and any such other beneficial owner.

Audit Committee and Audit Committee Financial Experts

Thomas Malley, Ke Tang and Qingqing Yi currently serve on the audit committee, which is chaired by Thomas Malley. 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 Thomas Malley and Ke Tang as an audit committee financial expert, as defined under the applicable rules of the SEC. The audit committee functions pursuant to a written charter adopted by our board of directors, pursuant to which the audit committee is granted the responsibilities and authority necessary to comply with Rule 10A-3 of the Exchange Act. The full text of the audit committee charter is available under the Investors Corporate Governance section of our website, which is located at *www.beigene.com*.

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Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and certain officers and holders of more than 10% of our ordinary shares to file with the SEC initial reports of ownership of our ordinary shares and other equity securities on a Form 3 and reports of changes in such ownership on a Form 4 or Form 5. These Section 16 reporting persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. During the fiscal year ended December 31, 2015, we did not have any class of equity security registered under Section 12 of the Exchange Act, and accordingly, no reports were required to be filed pursuant to Section 16(a) by these Section 16 reporting persons with respect to our ordinary shares during that fiscal year.

Code of Ethics

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. A current copy of the code is posted under the Investors Corporate Governance section of our website, which is located at *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.

Item 11. Executive Compensation

Overview

Our compensation programs are designed to:

- attract and retain individuals with superior ability, technical, and managerial experience;

- align executive officers incentives with our corporate strategies, business objectives and the long-term interests of our shareholders; and

- increase the incentive to achieve key strategic performance measures by linking incentive award opportunities to the achievement of performance objectives and by providing a portion of total compensation for executive officers in the form of ownership in the company.

Our compensation committee is primarily responsible for developing and implementing our compensation policies and establishing and approving the compensation for all of our executive officers; with respect to the Chief Executive Officer and Chief Financial Officer, the compensation committee will review and make recommendations to the full board of directors for approval. The compensation committee oversees our compensation and benefit plans and policies, administers our equity incentive plans, reviews and approves annually all compensation decisions relating to our executive officers, and makes recommendations to the full board of directors on compensation for the Chief Executive Officer and Chief Financial Officer. The compensation committee considers recommendations from our Chief Executive Officer regarding the compensation of our executive officers other than the Chief Executive Officer and Chief Financial Officer. Our compensation committee has the authority under its charter to engage the services of a consulting firm or other outside advisor to assist it in designing our compensation programs and in making compensation decisions.

Executive Compensation Components

Our executive compensation consists of base salary, performance-based cash compensation, long-term incentive compensation in the form of share options, and broad-based benefits programs. We have no formula for allocating among different components of compensation. The compensation committee considers a number of factors in setting compensation for our executive officers, including company performance, as well as the executive s performance, experience, responsibilities and the compensation of executive officers in similar positions at comparable companies.

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Base Salary

Base salary is intended to provide compensation for day-to-day performance. The compensation committee believes that a competitive base salary is a necessary element of any compensation program that is designed to attract and retain talented and experienced executives. Base salaries for our named executive officers are intended to be competitive with those received by other individuals in similar positions at the companies with which we compete for talent. Base salaries are originally established at the time the executive is hired based on individual experience, skills and expected contributions, our understanding of what executives in similar positions at peer companies were paid, and also negotiations during the hiring process. The base salaries of our named executive officers are reviewed annually and may be adjusted to reflect market conditions and our executives performance during the prior year as well as the financial position of the company, or if there is a change in the scope of the officer s responsibilities. As of December 31, 2015, the base salaries of our named executive officers were as described in Summary Compensation Table 2015 below.

Performance-Based Cash Bonus

Our compensation committee has the authority to award annual performance-based cash bonuses to our executive officers and make recommendations to the full board of directors for approval of performance-based cash bonuses for the Chief Executive Officer and Chief Financial Officer. In 2016, the board of directors and compensation committee approved performance-based cash bonus for our named executive officers as described in Summary Compensation Table 2015 below. These payments were awarded in recognition of our named executive officer s performance in achieving certain corporate, clinical, and operational milestones.

Equity Incentive Compensation

Equity incentive grants to our named executive officers are made at the discretion of the compensation committee under the terms of our equity incentive plans except for equity incentive grants for the Chief Executive Officer and Chief Financial Officer, which are approved by the full board of directors. We believe that equity incentives subject to vesting over time or upon achievement of performance objectives, can be an effective vehicle for the long-term element of compensation, as these awards align individual and team performance with the achievement of our strategic and financial goals over time, and with shareholders interests. In 2015, the compensation committee made share option grants to our named executive officers as specified in the Outstanding Equity Awards at Fiscal Year-End Table 2015 below. Share options, which have exercise prices equal to at least the fair market value of our ordinary shares on the date of grant, reward executive officers only if the share price increases from the date of grant.

Employee Benefits

In addition to the primary elements of compensation described above, the named executive officers also participate in the same broad-based employee benefits programs available to all of our employees (which may vary based on the location of employment), including health insurance, pension benefits, employee housing fund, welfare benefits, life and disability insurance, dental insurance, and retirement plan. We do not provide special benefits to our named executive officers except as otherwise described in this Annual Report.

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Summary Compensation Table 2015

The following table presents information regarding the total compensation awarded to, earned by, and paid during the fiscal years ended December 31, 2015 and 2014 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 at the end of the year ended December 31, 2015. These individuals are our named executive officers for 2015.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
John V. Oyler	2015	344,705(2)(3)	172,352(4)	3,890,991	16,206(2)(5)	4,424,254
Founder, Chief Executive Officer and Chairman	2014	97,664(6)(7)	1,272,073(8)		17,770(7)(9)	1,387,507(10)
Howard Liang	2015	160,417(11)	48,650(4)	1,622,880		1,831,947
Chief Financial Officer and Chief Strategy Officer						
RuiRong Yuan	2015	66,667(12)	26,267(4)	2,266,619		2,359,553
Chief Medical Officer and President of Global Clinical Research and Development						

(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 Annual Report. 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 RMB was translated into dollars based on the noon buying rate of the Federal Reserve Bank of New York for RMB 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) The 2015 performance-based cash bonuses have been approved by the board of directors, and as such are included in the table above.

(5) Consists of $4,308 in employer-paid health insurance premiums and $11,898 attributable to the use of a company car.

(6) 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.

(7) Payment in RMB was translated into dollars based on the noon buying rate of the Federal Reserve Bank of New York for RMB of ¥1.00=$0.1612 at December 31, 2014.

(8) 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 company 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.

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(9) Consists of $4,019 in employer-paid health insurance premiums and $13,751 attributable to the use of a company car.

(10) 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.

(11) 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.

(12) 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 Named Executive Officers

We have entered into employment agreements with each of our named executive officers other than our Chief Executive Officer.

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

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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.

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.

	Option Awards				
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Equity Incentive Plan Awards; Number of Securities Underlying Unexercised Unearned Options (#)**	**Option Exercise Price ($)**	**Option Expiration Date**
John V. Oyler		11,400,500(1)		0.50	7/19/2025
Howard Liang		4,900,000(2)		0.50	7/1/2025
RuiRong Yuan		3,000,000(3)		0.50	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.

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.

Benefit Plans

Our full-time employees in the PRC, including certain of our named executive officers, 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 our PRC subsidiaries make contributions to the government for these benefits based on certain percentages of the employees salaries.

Our U.S. subsidiary expects to adopt a 401(k) retirement plan effective in April 2016 for all of its full-time employees in the United States, including certain of our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. Pursuant to the 401(k) plan, participants will be able to elect to defer their current compensation by up to the statutorily prescribed annual limit, with additional salary deferral amounts available to employees in the year the employee becomes 50 years of age and thereafter and have this amount contributed to the 401(k) plan. Our U.S. subsidiary intends to match 50% of employee contributions, limited to the first

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6% of compensation, with such employer-matching contributions to vest 50% after one year and be fully vested after the second anniversary of the employment date.

Rule 10b5-1 Plans

Our policy governing transactions in our securities by directors, officers and employees permits our officers, directors and certain other persons to enter into trading plans complying with Rule 10b5-1 under the Exchange Act. Generally, under these trading plans, the individual relinquishes control over the transactions once the trading plan is put into place. Accordingly, sales under these plans may occur at any time, including possibly before, simultaneously with, or immediately after significant events involving our company.

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 share options to two non-employee directors who are not affiliated with an institutional investor of the company. In addition, as further described in Item 13 Certain Relationships and Related Transactions, and Director Independence Consulting Arrangements, as of December 31, 2015, Donald W. Glazer held 44,444 unvested restricted shares, which were issued to him on November 24, 2010 as compensation for his consulting services to our company. These shares vested in early 2016.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during 2015 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.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information known to us regarding beneficial ownership of our share capital as of March 25, 2016 by:

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

- each of our named executive officers;

- each of our directors; and

- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC 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.

The table lists applicable percentage ownership based on 427,442,865 ordinary shares outstanding as of March 25, 2016 and also lists applicable percentage ownership. Options to purchase ordinary shares that are exercisable within 60 days of March 25, 2016 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person s ownership percentage. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

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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 of Beneficial Owner	Number of Ordinary Shares Beneficially Owned	Percentage of Ordinary Shares Beneficially Owned
5% or Greater Shareholders		
Entities affiliated with Baker Bros. Advisors LP(1)	105,199,597	24.6%
Entities affiliated with Hillhouse Capital Management, Ltd.(2)	39,726,779	9.3
Merck Sharp & Dohme Research GmbH(3)	31,589,038	7.4
Named Executive Officers and Directors		
John V. Oyler(4)	77,882,537	18.2
Howard Liang	65,000	*
RuiRong Yuan	130,000	*
Timothy Chen		
Donald W. Glazer(5)	7,632,000	1.8
Michael Goller		
Ranjeev Krishana		
Thomas Malley		
Ke Tang		
Xiaodong Wang(6)	17,066,559	4.0
Qingqing Yi		
All Directors and Executive Officers as a Group (13 persons)(7)	103,580,262	24.2%

(1) Based solely on a Schedule 13D filed by Baker Bros. Advisors LP, Baker Bros. Advisors (GP) LLC, Felix J. Baker and Julian C. Baker on February 9, 2016, consists of (i) 8,994,997 ordinary shares held by 667, L.P., (ii) 95,565,000 ordinary shares held by Baker Brothers Life Sciences, L.P. and (iii) 639,600 ordinary shares held by 14159 L.P. (collectively, Baker Funds), as of February 8, 2016. Baker Bros. Advisors LP is the investment advisor to Baker Funds and has sole voting and investment power with respect to the shares held by Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.

(2) Based solely on a Schedule 13D filed by Hillhouse Capital Management, Ltd. on February 18, 2016, consists of (i) 8,372,000 ordinary shares held by Gaoling Fund, L.P., (ii) 728,000 ordinary shares held by YHG Investment, L.P., and (iii) 30,626,779 ordinary shares held by BGN Holdings Limited, as of February 8, 2016. Hillhouse Capital Management, Ltd. acts as the sole general partner of YHG Investment, L.P. and the sole management company of Gaoling Fund L.P. and Hillhouse Fund II, L.P., which owns BGN Holdings Limited. Mr. Lei Zhang may be deemed to have controlling power over Hillhouse Capital Management, Ltd. Mr. Lei Zhang disclaims beneficial ownership of all of the shares held by Hillhouse Fund II, L.P., except to the extent of his pecuniary interest therein. The registered address of Hillhouse Capital Management Ltd. is Cayman Corporate Centre, 3rd Floor, 18 Fort Street, George Town, Grand Cayman.

(3) Based solely on a Schedule 13G filed by Merck & Co., Inc., Merck Sharp & Dohme Corp., and Merck Sharp & Dohme Research GmbH on February 12, 2016, consists of 31,589,038 ordinary shares as of February 8, 2016, held by Merck Sharp & Dohme Research GmbH, which is a wholly subsidiary of Merck Sharp & Dohme Corp., which is a wholly owned subsidiary of Merck & Co., Inc. The entities reported shared voting and dispositive power over the ordinary shares. The address for this entity is Weystrasse 20, CH-6000, Lucerne 6, Switzerland.

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(4) Consists of (i) 59,780,349 ordinary shares held directly by Mr. Oyler; (ii) 10,000,000 ordinary shares held for the benefit of Mr. Oyler in a Roth IRA PENSCO trust account; (iii) 102,188 ordinary shares held by The John Oyler Legacy Trust for the benefit of his minor child, for which Mr. Oyler disclaims beneficial ownership; and (iv) 8,000,000 ordinary shares held for the benefit of Mr. Oyler in a grantor retained annuity trust.

(5) 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.

(6) Consists of (i) 16,344,143 ordinary shares held directly by Dr. Wang; (ii) 507,885 shares issuable to Dr. Wang upon exercise of share options exercisable within 60 days after March 25, 2016; and (iii) 214,531 ordinary shares held in a UTMA account for Dr. Wang s minor child, for which Dr. Wang disclaims beneficial ownership.

(7) Includes 1,112,051 ordinary shares issuable upon exercise of options within 60 days of March 25, 2016.

Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2015.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Option, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)
Equity compensation plans approved by security holders		$	
Equity compensation plans not approved by security holders	44,109,990(1)	0.35	14,651,109(2)
Total	44,109,990	$ 0.35	14,651,109

(1) Includes 28,909,323 ordinary shares to be issued pursuant to outstanding awards under our 2011 Plan and 15,200,667 ordinary shares to be issued pursuant to outstanding awards granted outside of our 2011 Plan.

(2) As of December 31, 2015, there were 14,651,109 shares available for grant under our 2011 Plan.

In connection with our initial public offering, our board of directors and shareholders approved a new equity compensation plan, the 2016 Share Option and Incentive Plan, or the 2016 Plan. 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.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2015, 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.

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

Certain of the transactions described below were entered into prior to the adoption of this written policy but each such transaction was approved by our board of directors. Prior to our board of directors consideration of a transaction with a related person, the material facts as to the related person s relationship or interest in the transaction were disclosed to our board of directors, and the transaction was not approved by our board of directors unless a majority of the directors approved the transaction.

We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties. Compensation arrangements for our directors and named executive officers are described in the section of this Annual Report titled Item 11 Executive Compensation.

Sales and Purchases of Securities

Participation in Our Initial Public Offering

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

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

(1) See Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters for more information about the shares held by the above identified shareholders, directors and executive officers.

(2) Michael Goller and Ranjeev Krishana, members of our board of directors, are, respectively, a Managing Director and Head of International Investments of Baker Bros. Advisors LP, affiliates of which collectively hold more than 5% of our voting securities.

(3) Qingqing Yi, a member of our board of directors, is a Principal at Hillhouse Capital Group, affiliates of which collectively hold more than 5% of our voting securities.

(4) Dr. Liang, our Chief Financial Officer and Chief Strategy Officer, purchased the ADSs through the Directed Share Program.

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(5) Dr. Yuan, our Chief Medical Officer and President of Global Clinical Research and Development, purchased the ADSs through the Directed Share Program.

Series A-2 Preferred Share Financing

On April 21, 2015, we issued and sold an aggregate of 83,205,124 shares of our Series A-2 preferred shares for an aggregate consideration of $97,349,995.08 to certain investors, pursuant to the share purchase agreement entered into with these investors. All of these Series A-2 preferred shares were automatically converted into ordinary shares on a one-for-one basis at the closing of our initial public offering on February 8, 2016.

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

Name	Series A-2 Preferred Shares	Aggregate Purchase Price Paid
Entities affiliated with Baker Bros. Advisors LP(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, was a member of our board of directors prior to our initial public offering.

(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 for his consulting services, on November 24, 2010, in connection with the initial formation of our company, we issued 4,000,000 ordinary shares to Mr. Glazer at $0.0001 per share to vest over five years. Those shares are fully vested. We also reimburse Mr. Glazer for the out of pocket expenses incurred in connection with his consulting services.

Dr. Xiaodong Wang, our Founder, Chairman of the Scientific Advisory Board and director, has been providing scientific and strategic advisory services to us. Dr. Wang currently receives an annual fixed fee of $100,000. On June 29, 2015, we granted him an option to purchase 500,000 ordinary shares at an exercise price of $0.50 per share. On July 19, 2015, we granted him an option to purchase 3,800,167 ordinary shares at an exercise price of $0.50 per share. In March 2016, we granted him a cash bonus in the amount of $86,176.

Note Exchange

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. On February 8, 2016, the entire outstanding unpaid principal and interest of the MSD note as of February 2, 2016 (i.e., $14,693,281) was automatically exchanged into 7,942,314 of our ordinary shares at $1.85

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per share, the initial offering price per ordinary share calculated based on the initial public offering price per American Depositary Share divided by 13, the then ordinary share-to-ADS ratio.

Warrant Exercises

On February 8, 2016, in connection with the closing of our initial public offering, entities affiliated with Baker Bros. Advisors LP exercised their warrants to purchase 2,592,293 ordinary shares at an exercise price of $0.675 per share.

On February 8, 2016, in connection with the closing of our initial public offering, John V. Oyler exercised his warrants to purchase 57,777 Series A preferred shares at an exercise price of $0.675 per share, which shares were converted into 57,777 ordinary shares.

Employment Agreements

For more information regarding employment agreements with certain of our executive officers, see Item 11 Executive Compensation Employment Agreements with Our Named 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 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 entered into new agreements to indemnify our directors and executive officers. These agreements, among other things, indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or executive officer.

Agreements With Our Shareholders

In connection with our preferred share financings, we entered into (1) an investors rights agreement, (2) a right of first refusal and co-sale agreement and (3) a voting agreement, in each case, with the purchasers of our preferred shares and certain holders of our ordinary shares. The primary rights under each of these terminated upon the closing of our initial public offering, other than certain registration rights for certain holders of our ordinary shares.

Other Transactions

We have granted share options to our executive officers. For a description of these share options, see Item 11 Executive Compensation.

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-

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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. Our board of directors also determined that Messrs. Malley, Tang and Yi, who comprise our audit committee; Messrs. Yi, Chen and Krishana, who comprise our compensation committee; and Messrs. Glazer and Goller, who comprise our nominating and corporate governance committee, each satisfy the independence standards for such committees established by the SEC and the NASDAQ Listing Rules, as applicable. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital shares by each non-employee director. There are no family relationships among any of our directors or executive officers.

Item 14. Principal Accounting Fees and Services

Auditors Fees

The following table summarizes the fees of Ernst & Young Hua Ming LLP, our registered independent public accounting firm, billed to us for each of the last two fiscal years (in thousands).

Fee Category	2014	2015
Audit Fees(1)	$ 409	$ 753
Audit-related Fees		
Tax Fees(2)	18	17
All Other Fees		
Total Fees	$ 427	$ 770

(1) Audit fees consist of fees for the audit of our financial statements, the review of our interim financial statements and services associated with our registration statement on Form S-1.

(2) Tax fees consists of fees incurred for tax compliance, tax advice and tax planning and includes fees for tax return preparation and tax consulting.

Pre-approval Policies

In connection with our initial public offering, our board of directors has adopted policies and procedures for the pre-approval of audit and non-audit services by our audit committee for the purpose of maintaining the independence of our independent auditor. We may not engage our independent auditor to render any audit or non-audit service unless either the service is approved in advance by the audit committee, or the engagement to render the service is entered into pursuant to the audit committee s pre-approval policies and procedures.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

The financial statements listed in the Index to Consolidated Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K.

No financial statement schedules have been filed as part of this Annual Report because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

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BEIGENE, LTD.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2014 and 2015, and the related consolidated statements of operations, comprehensive loss, cash flows, and shareholders deficit for each of the three years in the period ended December 31, 2015. 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, 2014 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young Hua Ming LLP

Beijing, People s Republic of China

March 29, 2016

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BEIGENE, LTD.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands of U.S. Dollar ($), except for number of shares and per share data)

	Note	As of December 31, 2014 $	2015 $	Pro Forma Shareholders Equity at December 31, 2015 $ (unaudited)
Assets				
Current assets:				
Cash and cash equivalents		13,898	17,869	
Short-term investments	3	30,497	82,617	
Prepaid expenses and other current assets		2,793	5,783	
Total current assets		47,188	106,269	
Property and equipment, net	4	5,931	6,612	
Other non-current assets		502	3,883	
Total non-current assets		6,433	10,495	
Total assets		53,621	116,764	
Liabilities and shareholders deficit				
Current liabilities:				
Short-term bank loan	7	322		
Accounts payable		2,794	8,980	
Advances from customers		8,906	1,070	
Accrued expenses and other payables	6	1,002	8,351	
Senior Promissory Note	10		14,598	
Warrant and Option liabilities	8	347	2,173	
Total current liabilities		13,371	35,172	
Non-current liabilities:				
Senior Promissory Note	10	13,516		
Long-term bank loan	9		6,188	
Deferred rental		798	980	
Other long-term liabilities		168	105	
Total non-current liabilities		14,482	7,273	
Total liabilities		27,853	42,445	
Commitments and contingencies	20			
Convertible Preferred Shares	11	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 December 31, 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 December 31, 2015 (December 31, 2014: nil))				
Total mezzanine equity		78,809	176,084	
Shareholders deficit:				
		11	12	32

Ordinary shares (par value of US$0.0001 per share; 400,000,000 shares authorized; 116,174,094 shares issued and outstanding as of December 31, 2015 (December 31, 2014: 108,497,428 shares))				
Additional paid-in capital		7,941	18,227	208,889
Accumulated other comprehensive income (loss)	17	100	(1,809)	(1,809)
Accumulated deficit		(61,093)	(118,195)	(118,195)
Total shareholders (deficit) equity		(53,041)	(101,765)	88,917
Total liabilities, mezzanine equity and shareholders (deficit) equity		53,621	116,764	116,764

The accompanying notes are an integral part of these consolidated financial statements.

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BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands of U.S. Dollar ($), except for number of shares and per share data)

	Note	Year Ended December 31, 2013 $	2014 $	2015 $
Revenue				
Collaboration revenue	13	11,148	13,035	8,816
Total revenue		11,148	13,035	8,816
Operating expenses:				
Research and development		13,463	21,862	58,250
General and administrative		3,143	6,930	7,311
Total operating expenses		16,606	28,792	65,561
Loss from operations		(5,458)	(15,757)	(56,745)
Interest income		2	40	1,788
Interest expense (including interest expense incurred due to a related party amounting to $693, $831 and nil for the years ended December 31, 2013, 2014 and 2015, respectively)		(3,155)	(3,552)	(1,229)
Changes in fair value of financial instruments	8	133	(2,760)	(1,826)
Disposal loss on available-for-sale securities				(314)
Gain on debt extinguishment			2,883	
Other income		694	806	1,309
Other expense		(110)	(206)	(85)
Loss before income tax expense		(7,894)	(18,546)	(57,102)
Income tax expense				
Net loss		(7,894)	(18,546)	(57,102)
Less: net loss attributable to non-controlling interests		(400)	(268)	
Net loss attributable to ordinary shareholders		(7,494)	(18,278)	(57,102)
Loss per share	14			
Basic and diluted		(0.08)	(0.18)	(0.52)
Weighted-average number of ordinary shares used in net loss per share calculation	14			
Basic and diluted		91,484,521	99,857,623	110,597,263
Pro forma basic and diluted loss per share on an as-converted basis	15			(0.18)
Shares used in pro forma basic and diluted loss per share computation	15			318,530,218

The accompanying notes are an integral part of these consolidated financial statements.

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BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Amounts in thousands of U.S. Dollar ($), except for number of shares and per share data)

	Year Ended December 31,		
	2013	2014	2015
	$	$	$
Net Loss	(7,894)	(18,546)	(57,102)
Other comprehensive income/(loss), net of tax of nil:			
Foreign currency translation adjustments	176	(168)	(749)
Unrealized holding loss		(47)	(1,160)
Comprehensive loss	(7,718)	(18,761)	(59,011)
Less: comprehensive loss attributable to non-controlling interests	(392)	(274)	
Comprehensive loss attributable to ordinary shareholders	(7,326)	(18,487)	(59,011)

The accompanying notes are an integral part of these consolidated financial statements.

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BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands of U.S. Dollar ($), except for number of shares and per share data)

	Note	Year Ended December 31, 2013 $	2014 $	2015 $
Operating activities				
Net loss		(7,894)	(18,546)	(57,102)
Adjustments to reconcile net loss to net cash from operating activities:				
Depreciation expenses	4	1,592	1,557	1,545
Share-based compensation expenses	16	(24)	6,637	10,211
Changes in fair value of financial instruments		(133)	2,760	1,826
Gain on debt extinguishment			(2,883)	
Loss on disposal of property and equipment		21	53	5
Disposal loss on available-for-sale securities				314
Interest expense		2,766	3,265	1,095
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(277)	(2,285)	(2,990)
Other non-current assets		(100)	(190)	(565)
Accounts payable		(768)	731	6,186
Advances from customers		7,860	1,046	(7,836)
Accrued expenses and other payables		422	(761)	7,350
Tax payable				
Deferred rental		496	(20)	182
Other long-term liabilities		112	(58)	(64)
Net cash provided by (used in) operating activities		4,073	(8,694)	(39,843)
Investing activities				
Purchases of property and equipment		(264)	(654)	(5,314)
Purchase of available-for-sale securities			(30,646)	(119,291)
Proceeds from disposal of available-for-sale securities			102	65,698
Proceeds from disposal of property and equipment		14		1
Acquisition of non-controlling interest			(2,443)	
Net cash used in investing activities		(250)	(33,641)	(58,906)
Financing activities				
Proceeds from long-term loan	9			6,175
Proceeds from short-term loan	7		322	
Proceeds from issuance of convertible promissory notes			25	
Proceeds from issuance of secured guaranteed convertible promissory note			17,500	
Payment of convertible preferred shares issuance cost	11		(80)	(75)
Proceeds from issuance of convertible preferred shares	11		35,500	97,350
Proceeds from exercise of share options			80	77
Proceeds due to related parties	12	249	103	
Repayment of short-term loan				(322)
Repayment to related party	12	(731)	(1,285)	

Net cash (used in) provided by financing activities	(482)	52,165	103,205
Effect of foreign exchange rate changes, net	(41)	142	(485)
Net increase in cash and cash equivalents	3,300	9,972	3,971
Cash and cash equivalents at beginning of period	626	3,926	13,898
Cash and cash equivalents at end of period	3,926	13,898	17,869
Supplemental cash flow disclosures:			
Income taxes paid			
Interest expense paid	334	30	134
Non-cash activities:			
Repayment of subordinated convertible promissory note, convertible promissory notes and secured guaranteed convertible promissory note		33,730	
Repayment of due to related parties	134	8,204	
Acquisitions of equipment included in accounts payable		7	23

The accompanying notes are an integral part of these consolidated financial statements.

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BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS DEFICIT

(Amounts in thousands of U.S. Dollar ($), except for number of shares and per share data)

	Attributable to BeiGene, Ltd.							
	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated		Non-Controlling	
	Shares	Amount	Capital	Income/(Loss)	Deficit	Total	Interests	Total
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 16)	(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 16)	(116,671)							
Share-based compensation			4,797			4,797		4,797
Issuance of warrants in connection with the secured guaranteed convertible promissory note (note 11)			184			184		184
Repurchase of non-controlling interest			(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	108,497,428	11	7,941	100	(61,093)	(53,041)		(53,041)
Issuance of ordinary shares	7,676,666	1	75			76		76
Share-based compensation			10,211			10,211		10,211
Net loss					(57,102)	(57,102)		(57,102)
Other comprehensive loss				(1,909)		(1,909)		(1,909)
Balance at December 31, 2015	116,174,094	12	18,227	(1,809)	(118,195)	(101,765)		(101,765)

The accompanying notes are an integral part of these consolidated financial statements.

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BEIGENE, LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2013, 2014 AND 2015

(Amounts in thousands of U.S. Dollar ($), 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 its 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, 2015, the Company s subsidiaries are as follows:

Name of Company	Place of Incorporation	Date of Incorporation	Percentage of Ownership by the Company	Principal Activities
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 (Suzhou) Co., Ltd. (BeiGene (Suzhou))	PRC	April 9, 2015	100%	Medical and pharmaceutical research
BeiGene USA, Inc.	United States	July 8, 2015	100%	Clinical trial activities
BeiGene (Shanghai) Co., Ltd. (BeiGene (Shanghai))	PRC	September 11, 2015	100%	Medical and pharmaceutical research

*BeiGene Beijing became a wholly-owned subsidiary of the Company as of December 19, 2014.

2. Summary of significant accounting policies

Basis of presentation and principles of consolidation

The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and balances between the Company and its wholly-owned 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 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

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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.

2. Summary of significant accounting policies (Continued)

Functional Currency and Foreign Currency Translation

Functional Currency

The determination of the respective functional currency is based on the criteria of Accounting Standard Codification (ASC) 830, *Foreign Currency Matters*. The functional currency of the Company, BeiGene AUS Pty Ltd., BeiGene (Hong Kong) Co., Limited, BeiGene 101 Ltd and BeiGene USA, Inc. is the United States dollar ($ or U.S. dollar). The Company s PRC subsidiaries determined their functional currencies to be the Chinese Renminbi (RMB). The Company uses the U.S. dollar as its reporting currency.

Foreign Currency Translation

For subsidiaries whose functional currencies are not the U.S. dollar, 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 to U.S. dollar, the reporting currency, respectively. Translation differences are recorded in accumulated other comprehensive income/(loss), a component of shareholders equity/deficit. Transactions denominated in currencies other than the functional currency are translated 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 the Company has 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, 2014 and 2015.

Available-for-sale securities are stated at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income/loss. 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. 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.

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Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	Useful Life
Office Equipment	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, 2014 and 2015, 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, long-term bank loan, accounts payable, senior promissory note, convertible preferred shares, and warrant and option liabilities. As of December 31, 2014 and 2015, 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/loss. The long-term bank loan approximates its fair value due to the fact that the related interest rate approximates the rate currently offered by financial institutions for similar debt instrument of comparable maturities. 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 and 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.

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.

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Financial instruments measured at fair value on a recurring basis

The following tables set forth assets and liabilities measured at fair value on a recurring basis as of December 31, 2014 and 2015:

As of December 31, 2014	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 (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 8)			222

As of December 31, 2015	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 (note 3):			
Corporate fixed income bonds	69,255		
U.S. treasury securities	8,000		
Municipal Bonds	5,362		
Option to purchase shares by rental deferral (note 8)			1,388
Warrants in connection with the convertible promissory notes (note 8)			785

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 December 31, 2014 and 2015. 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	2015
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	$665,213
		Volatility for invested capital value allocation	72%	83%
		Volatility for Black-Scholes option pricing model	72% 101%	69%-83%

		Discount for lack of marketability (DLOM)	17%	11%
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	$145,300	$665,213
		Volatility for invested capital value allocation	72%	83%
		Volatility for Black-Scholes option pricing model	72% 104%	69%-83%
		DLOM	17%	11%

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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, 2014 and 2015.

	Warrant and Option Liabilities $
Balance as of December 31, 2012	183
Recognized during the year	
Unrealized gain	(133)
Settlement	
Balance as of December 31, 2013	50
Recognized during the year	37
Unrealized loss	260
Settlement	
Balance as of December 31, 2014	347
Recognized during the year	
Unrealized loss	1,826
Settlement	
Balance as of December 31, 2015	2,173
The amount of total gain for the year ended December 31, 2013 included in losses	133
The amount of total loss for the year ended December 31, 2014 included in losses	(260)
The amount of total loss for the year ended December 31, 2015 included in losses	(1,826)

Realized and unrealized gain or loss for the years ended December 31, 2013, 2014 and 2015 was recorded as Changes in fair value of financial instruments in the consolidated statements of comprehensive loss.

In 2011, the Company issued a subordinated convertible promissory note to Merck Sharp for an aggregate principal amount of $10,000.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 Changes in fair value of financial instruments in the consolidated statements of operations. In October 2014, the subordinated convertible promissory note was automatically converted into Series A Preferred Shares. Upon the conversion of the subordinated convertible promissory note in October 2014, the Company recognized a 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.

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,

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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) 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, none of the products have been approved. Hence, no revenue has been recognized related to 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

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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, 2014 and 2015.

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.

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.

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

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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 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.

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 operations. 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.

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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.

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 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 operations.

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. In addition, pursuant to the note amendment and

exchange agreement with Merck Sharp dated January 26, 2016, the Senior Promissory Note will automatically be converted into ordinary shares at the price per ordinary share in the IPO. Unaudited pro forma shareholders equity as of December 31, 2015, as adjusted for the reclassification of the convertible preferred shares from mezzanine equity to shareholders equity and the reclassification of the Senior Promissory Note from current liability 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, 2015, and assumes the automatic conversion of all of the Company s convertible preferred shares and Senior Promissory Note 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.

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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.

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, 2014 and 2015, $13,898 and $17,869 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, 2014 and 2015, the Company had debt security investments amounting to $30,497 and $82,617, 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, 2014 and 2015, 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 U.S. dollar 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 currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers invoices, shipping documents and signed contracts.

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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. For RMB against U.S. dollar, there was appreciation of approximately 2.9% in the year ended December 31, 2013, depreciation of 2.4% in the year ended December 31, 2014 and depreciation of 4.4% in the year ended December 31, 2015, respectively. It is difficult to predict how market forces or PRC or US government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that the Company needs to convert U.S. dollar into RMB for capital expenditures and working capital and other business purposes, appreciation of RMB against U.S. dollar would have an adverse effect on the RMB amount the Company would receive from the conversion. Conversely, if the Company decides to convert RMB into U.S. dollar for the purpose of making payments for dividends on ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of U.S. dollar against RMB would have a negative effect on the U.S. dollar amount available to the Company. In addition, a significant depreciation of the RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of the Company s earnings or losses.

Recent accounting pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. The guidance requires an entity to evaluate whether there are conditions or events, in the aggregate, 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 and to provide related footnote disclosures in certain circumstances. The guidance is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early application is permitted. The adoption of this guidance is not expected to have a significant impact on the Company s consolidated financial statements.

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. In August 2015, ASU No. 2015-15 *Imputation of Interest* was issued to address presentation and subsequent measurement of debt issuance costs related to line-of-credit arrangements. Given the absence of authoritative guidance within ASU 2015-03 for debt issuance costs related to

line-of-credit arrangements, the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The adoption of this guidance is not expected to have a significant impact on the Company s consolidated financial statements.

In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers-Deferral of the effective date* (ASU 2015-14). The amendments in ASU 2015-14 defer the effective date of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers issued in May 2014. According to the amendments in ASU 2015-14, the new revenue guidance ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is currently evaluating the method of adoption to be utilized and it cannot currently estimate the financial statement impact of adoption.

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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
Total	30,544		47	30,497

Short-term investments as of December 31, 2015 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	70,383		1,128	69,255
U.S. treasury securities	7,999	1		8,000
Municipal Bonds	5,441		79	5,362
Total	83,823	1	1,207	82,617

During the years ended December 31, 2013, 2014, and 2015, the net adjustment to unrealized holding loss on available-for-sale securities in other comprehensive loss totaled nil, $47 and $1,160, respectively. Contractual maturities of all debt securities as of December 31, 2015 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, 2015.

4. Property and equipment

Property and equipment consist of the following:

	As of December 31,	
	2014 $	2015 $
Office equipment	223	213

Electronic equipment	378	424
Laboratory equipment	4,635	5,919
Computer software	147	186
Leasehold improvements	5,385	5,954
	10,768	12,696
Less accumulated depreciation and amortization	(4,837)	(6,084)
Property and equipment, net	5,931	6,612

Depreciation expenses for the years ended December 31, 2013, 2014 and 2015 were $1,592, $1,557 and $1,545, respectively.

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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, 2014 and 2015, 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.

United States

BeiGene USA, Inc., incorporated in United States on July 8, 2015, is subject to corporate income tax at a rate of 35%.

PRC

BeiGene Beijing, BeiGene Suzhou and BeiGene Shanghai are subject to the statutory tax rate of 25% for the years ended December 31, 2013, 2014 and 2015 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.

Loss before income taxes consists of:

	Year Ended December 31,		
	2013	2014	2015
	$	$	$
Cayman	2,669	(5,487)	(29,913)
PRC	(6,276)	(5,808)	(5,253)
Australia	(4,035)	(7,684)	(21,906)
Others	(252)	433	(30)
	(7,894)	(18,546)	(57,102)

There is no provision for income taxes because the Company and substantially all of the subsidiaries are in a cumulative loss position for all the periods presented.

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The reconciliation of the actual income taxes to the amount of tax computed by applying the PRC statutory income tax rate to pre-tax income is as follows:

	Year Ended December 31,		
	2013	2014	2015
	$	$	$
Loss before tax	(7,894)	(18,546)	(57,102)
PRC statutory tax rate	25%	25%	25%
Expected taxation at PRC statutory tax rate	(1,974)	(4,636)	(14,275)
Foreign tax rate differential	(846)	1,082	6,397
Non-taxable income	(226)	(191)	(7)
Non-deductible expenses	98	115	584
Addition to valuation allowance	2,948	3,630	7,301
Taxation for the year			
Effective tax rate	0%	0%	0%

Significant components of deferred tax assets are as follows:

	As of December 31,	
	2014	2015
	$	$
Deferred tax assets, non-current portion:		
Net operating losses carryforward	9,656	16,957
Less valuation allowance	(9,656)	(16,957)
Total deferred tax assets		

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 .

As of December 31, 2015, the Company had net operating losses of approximately US$61,280 derived from entities in the PRC, Australia and United States, which can be carried forward to offset future net profit for income tax purposes. The net operating loss in PRC entities will expire, if unused, beginning January 1, 2017 through 2021. The net operating loss in Australia can be carried forward indefinitely if the loss utilization tests criteria are met. The net operating loss in United States will expire, if unused, in 2034 and 2036, respectively.

No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented. The Company s management did not expect the amount of unrecognized tax benefits would increase significantly in the next 12 months. In general, the PRC tax authorities have up to five years to conduct examinations of the Company s tax filings. Accordingly, the PRC subsidiaries tax years 2010 through 2015 and the Australia subsidiary s tax years indefinitely remain open to examination by the respective taxing authorities.

6. Accrued expenses and other payables

	As of December 31,	
	2014	2015
	$	$
Payroll payables	101	275
Accrued operating expenses	605	5,513
Other payables	296	2,563
	1,002	8,351

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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 of $18 and $7, and guarantee fee of $7 and nil, was recognized for the years ended December 31, 2014 and 2015, respectively. The short-term bank loan was fully repaid on April 3, 2015.

8. Warrant and option liabilities

	As of December 31,	
	2014 $	2015 $
Option to purchase shares by rental deferral	125	1,388
Warrants in connection with the convertible promissory notes	222	785
	347	2,173

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 is a freestanding instrument and is recorded as liability in accordance with ASC480, *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, 2015. During the years ended December 31, 2013, 2014 and 2015, the Company recognized a gain from the decrease in fair value of $83, a loss from the increase in fair value of $99 and a loss from the increase in the fair value of $1,263, respectively. The Company determined the fair value of the Option with the assistance of an independent third party valuation firm.

Warrants in connection with the convertible promissory notes

During the years ended December 31, 2012 and 2014, the Company entered into agreements with several investors to issue convertible promissory notes, and related warrants to purchase the Company s preference shares up to 10% of the convertible promissory notes principal amount concurrently for an aggregate principal amount of $2,410. The warrants are freestanding instruments and are recorded as liabilities in accordance with ASC480. The warrants are initially recognized at fair value with subsequent changes in fair value recorded in losses. For the years ended December 31, 2013, 2014 and 2015, the Company recognized a gain from the decrease in fair value of the warrants of $39, a loss from the increase in fair value of $127 and a loss from the increase in fair value of $563, respectively.

9. Long-term bank 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 December 31, 2015, the Company has drawn down $6,175 which is secured by BeiGene Suzhou s future equipment purchases and the Company s PRC patent on a product candidate. Interest expense recognized for the year ended December 31, 2015 amounted to $140.

10. 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 of 8% compounding per annum and has a

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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. 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, 2014 and 2015 amounted to $2,515, $3,516 and $4,598, respectively.

11. 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 previously issued subordinated convertible promissory note, convertible promissory notes, secured guaranteed convertible promissory notes, 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 been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or deemed liquidation event.

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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 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 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 holders of the ordinary shares 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 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 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 Preferred Shares and Series A-2 Preferred Shares, the most favorable conversion price used to measure the beneficial conversion feature were $0.68 and $1.17, respectively. No beneficial conversion feature was recognized for the Series A Preferred Shares and Series A-2 Preferred Shares as the fair value per ordinary share at the commitment date were $0.28 and $0.47, respectively, 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 $204,375 as of December 31, 2015.

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12. Related party balances and transactions

(a) The Company had the following related party transactions for the periods presented:

	Year Ended December 31,		
	2013	2014	2015
	$	$	$
Consulting service fee paid to shareholders(1)	100	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	177	(8,455)	100

(1) During the years ended December 31, 2013, 2014 and 2015, shareholders provided consulting services to the Company at a fee of $100, $100 and $100, respectively.

(2) During the years ended December 31, 2013, 2014 and 2015, senior executives advanced $249, $103 and nil, 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 was recognized in losses immediately. On 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. 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, 2014 and 2015, the Company recognized a gain from the decrease in fair value of the Warrants of $11, a loss from the increase in fair value of $34 and $80, 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.

(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. The difference of $1,840 was recognized in losses as a result of the settlement of indebtedness. 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, 2015.

13. Research and development collaborative arrangements

The Company has developed and controls certain technology and proprietary materials related to its proprietary BRAF inhibitor (BRAF or BGB-283) and poly (ADP-ribose) polymerase inhibitor (PARP or 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

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the Collaborative Arrangements, the Company granted to Merck KGaA the exclusive right to develop and commercialize the BRAF and PARP inhibitors worldwide except the PRC (Ex-PRC). The Company has retained the exclusive right to develop and commercialize the BRAF and PARP inhibitors in the PRC.

Under the terms of the BRAF Collaborative Arrangements, the Company received an upfront non-refundable payment and upfront Phase I research and development fees in 2013. Upon the dosing of the 5th 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 the dosing of the 5th 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 ranging from one to 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.

On October 1, 2015, the Company entered into a purchase of rights agreement with Merck KGaA, pursuant to which the Company purchased from Merck KGaA all its exclusive rights to develop and commercialize the PARP

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inhibitors in the Ex-PRC territories for a consideration of $10,000, and reduced 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. The repurchase consideration of $10,000 was charged to research and development expenses as incurred because the rights have no alternative future use. As Merck KGaA has no further rights in the Ex-PRC territories under the PARP Collaborative Agreements, the advances previously received from Merck KGaA amounting to $3,018 was offset against the aforementioned repurchase consideration.

Upon achievement of a 5th patient dosing development based target in the PRC territory under the BRAF Collaborative Arrangements on November 12, 2015, the Company recognized $4,000 of research and development revenue. No other development based targets have been achieved and none of the products have been approved. Hence, no revenue has been recognized related to 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.

License revenue was approximately $9,758, $6,679 and nil, while research and development revenue was approximately $1,382, $6,275 and $8,816 of the collaboration revenue from the Merck KGaA Collaboration for the years ended December 31, 2013, 2014 and 2015, respectively. The Company recorded advances from customers related to the collaboration of approximately $8,906 and $1,070 at December 31, 2014 and 2015, respectively.

Other revenue

The Company provided research and development services to other customers in the PRC amounting to $8, $81 and nil, respectively, for the years ended December 31, 2013, 2014 and 2015.

14. Loss per share

Loss per share was calculated as follows:

	Year Ended December 31		
	2013	2014	2015
	$	$	$
Numerator:			
Net loss attributable to ordinary shareholders for computing basic and diluted loss per ordinary share	(7,494)	(18,278)	(57,102)
Denominator:			
Weighted average number of ordinary shares outstanding for computing basic and diluted loss per ordinary share	91,484,521	99,857,623	110,597,263
Basic and diluted loss per share	(0.08)	(0.18)	(0.52)

For the years ended December 31, 2013, 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 notes, 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, 2014 and 2015.

15. 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 Preferred Shares as of December 31, 2015, into 199,990,641 ordinary shares and the automatic conversion of the Senior Promissory Note

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into 7,942,314 ordinary shares 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 conversions of the Company s Preferred Shares and the Senior Promissory Note 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:

	Year Ended December 31, 2015 $ (unaudited)
Numerator:	
Net loss attributable to ordinary shareholders	(57,102)
Denominator:	
Weighted average number of ordinary shares used in net loss per share attributable to ordinary shareholders basic and diluted	110,597,263
Add: adjustment to reflect assumed effect of automatic conversion of preferred shares	199,990,641
Add: adjustment to reflect assumed effect of automatic conversion of the Senior Promissory Note	7,942,314
Pro forma weighted average number of shares outstanding basic and diluted	318,530,218
Pro forma net loss per share attributable to ordinary shareholders basic and diluted	(0.18)

The effects of all convertible preferred shares, stock options, restricted stock, subordinated convertible promissory note, warrants, convertible promissory notes, the secured guaranteed convertible promissory notes, warrants 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 year ended December 31, 2015.

16. 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, October 6, 2014 and April 17, 2015, 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, 30,560,432 ordinary shares and 43,560,432 ordinary shares, respectively. The options granted under the Plan 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, 3,766,000 and 15,663,600 options to employees, as well as 1,401,000, 125,000 and 1,950,000 options to non-employees, during the years ended December 31, 2013, 2014 and 2015, respectively.

The Company granted nil, nil, and 11,400,500 options to employees and nil, nil, and 3,800,167 options to non-employees outside of the Plan during the years ended December 31, 2013, 2014 and 2015, respectively.

As of December 31, 2015, share-based awards to purchase 44,109,990 ordinary shares were outstanding and share-based awards to purchase 14,651,109 ordinary shares were available for future grant under the Plan.

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Modification

On October 1, 2015 (Modification Date), a consultant (the Consultant) surrendered 1,000,000 options in exchange for a reduction of the vesting period (Modified Option Agreement). The fair value of the options immediately after the modification was higher than that immediately before the modification. The total incremental compensation cost for the modification of $81 was recognized on Modification Date. Subsequently, on November 1, 2015 (Date of the Change in Employment Status), the Consultant became an employee of the Company. Under the terms of the Modified Option Agreement, the individual retains the same vesting terms; hence, there is no modification to account for. The fair value of the options 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.

There were no other modifications to the Company s share option arrangements for the periods presented.

The following table summarizes the Company s employee share option activities under the share option plan:

	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, 2014	19,585,489	0.02	0.02	7.74	
Granted*	27,064,100	0.49	0.28		
Exercised**	(7,757,383)	0.01	0.02		12,496
Forfeited	(1,976,885)	0.38	0.10		
Outstanding at December 31, 2015	36,915,321	0.35	0.20	8.71	
Exercisable as of December 31, 2015	6,236,030	0.05		1.57	9,806
Vested or expected to vest at December 31, 2015	17,892,965	0.03		6.69	28,556

*Includes options granted outside the Plan.

**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, 2014 and 2015 was nil, $737 and $12,496, respectively.

The total weighted average grant-date fair value of the equity awards granted during the years ended December 31, 2013, 2014 and 2015 were $0.01, $0.01 and $0.28 per option, respectively. The total fair value of the equity awards vested during the years ended December 31, 2013, 2014 and 2015 were $55, $87 and $72, respectively.

As of December 31, 2015, there were $8,278 of total unrecognized employee 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 1.64 years. Total unrecognized compensation cost may be adjusted for future changes in estimated forfeitures.

The following table summarizes the Company s non-employee share option activities under the share option plan:

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	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, 2014	2,194,502	0.08	0.02	7.58	
Granted*	5,750,167	0.47	0.35		
Exercised					
Forfeited	(750,000)				
Outstanding at December 31, 2015	7,194,669	0.37	0.08	8.63	
Exercisable as of December 31, 2015	1,452,702	0.12		6.19	2,174
Vested or expected to vest at December 31, 2015	3,004,502	0.14		7.27	4,443

*Includes options granted outside the Plan.

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, 2014 and 2015 was nil, $278 and nil, respectively.

The total weighted average grant-date fair value of the equity awards granted during the years ended December 31, 2013, 2014 and 2015 were $0.01, $0.01 and $0.35 per option, respectively. The total fair value of the equity awards vested during the years ended December 31, 2013, 2014 and 2015 were $2, $251 and $578, respectively.

As of December 31, 2015, there was $7,353 of total unrecognized non-employee 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 3.09 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 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. Prior to the completion of the Company s initial public offering, the Company s management was 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	2015
Fair value of ordinary share	0.01	0.30	1.62
Risk-free interest rate	1.4%~3.0%	1.9%~2.6%	1.5%-2.4%
Expected exercise multiple	2.2~2.8	2.2~2.8	2.2~2.8
Expected volatility	102%~107%	99%~104%	94%~106%
Expected dividend yield	0%	0%	0%
Contractual life	10 years	10 years	10 years

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Restricted stock

The following table summarizes the Company s employee restricted stock activities:

	Numbers of Shares	Weighted Average Grant Date Fair Value $
Outstanding at December 31, 2014	577,778	0.05
Granted		
Vested	(533,333)	0.05
Forfeited		
Outstanding at December 31, 2015	44,445	0.05
Expected to vest at December 31, 2015	44,445	0.05

The following table summarizes the Company s non-employee restricted stock activities:

	Numbers of Shares	Weighted Average Grant Date Fair Value $
Outstanding at December 31, 2014	1,516,667	0.05
Granted		
Vested	(1,516,667)	0.05
Forfeited		
Outstanding at December 31, 2015		
Expected to vest at December 31, 2015		

As of December 31, 2015, there was $0 of total unrecognized share-based compensation expenses, net of estimated forfeitures, related to unvested restricted shares.

The following table summarizes total compensation cost recognized for the years ended December 31, 2013, 2014 and 2015:

	Year Ended December 31,		
	2013 $	2014 $	2015 $
Research and development	(79)	4,030	9,593
General and administrative	55	2,607	618
Total	(24)	6,637	10,211

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.

17. Accumulated other comprehensive income

The movement of accumulated other comprehensive income is as follows:

	Foreign Currency Translation Adjustments $	Unrealized Losses $	Total $
Balance as of December 31, 2013	309		**309**
Other comprehensive loss	(162)	(47)	(209)
Balance as of December 31, 2014	**147**	**(47)**	**100**
Other comprehensive income before reclassifications	(749)	(1,474)	(2,223)
Amounts reclassified from accumulated other comprehensive income		314	314
Net-current period other comprehensive income	(749)	(1,160)	(1,909)
Balance as of December 31, 2015	(602)	(1,207)	(1,809)

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18. Restricted net assets

The Company s ability to pay dividends may depend on the Company receiving distributions of funds from its PRC subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by the Company s PRC subsidiaries 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 subsidiaries.

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 subsidiaries were established as domestic invested enterprises and therefore were subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2013, 2014 and 2015, no appropriation to statutory reserves was made because the PRC subsidiaries had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Company s PRC subsidiaries are 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 subsidiaries from transferring funds to the Company in the form of dividends, loans and advances. As of December 31, 2014 and 2015, amounts restricted are the net assets of the Company s PRC subsidiaries, which amounted to $1,827 and $3,383, respectively.

19. 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 subsidiaries 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, $1,030 and $1,443 for the years ended December 31, 2013, 2014 and 2015, respectively. Employee benefits for the remaining wholly owned subsidiaries were immaterial.

20. 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.

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There are no restrictions placed upon the Company by entering into these leases. Total expenses under these operating leases were $939, $940 and $1,136 for the years ended December 31, 2013, 2014 and 2015, respectively.

Future minimum payments under non-cancelable operating leases consist of the following as of December 31, 2015:

	$
Year ending December 31:	
2016	1,258
2017	1,061
2018	1,057
2019	945
2020 and thereafter	1,077
	5,398

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21. Selected Quarterly Financial Data (Unaudited)

The following table summarizes the unaudited statements of operations for each quarter of 2014 and 2015 (in thousands except share and per share amounts). The unaudited quarterly information has been prepared on a basis consistent with the audited financial statements and includes all adjustments that the Company considers necessary for a fair presentation of the information shown. The operating results for any fiscal quarter are not necessarily indicative of the operating results for a full fiscal year or for any future period and there can be no assurances that any trend reflected in such results will continue in the future.

	Quarter Ended			
	March 31	**June 30**	**September 30**	**December 31**
2014				
Revenue	770	4,388	6,496	1,381
Profit/(loss) from operations	(3,792)	208	(5,720)	(6,453)
Net loss	(4,635)	(365)	(9,808)	(3,738)
Net loss attributable to ordinary shareholders	(4,497)	(271)	(9,759)	(3,751)
Basic and diluted net loss per share(1)	(0.05)	(0.00)	(0.10)	(0.03)

	Quarter Ended			
	March 31	**June 30**	**September 30**	**December 31**
2015				
Revenue	1,379	1,380	1,380	4,677
Loss from operations	(9,812)	(6,565)	(13,992)	(26,376)
Net loss	(10,212)	(5,641)	(13,999)	(27,250)
Net loss attributable to ordinary shareholders	(10,212)	(5,641)	(13,999)	(27,250)
Basic and diluted net loss per share(1)	(0.09)	(0.05)	(0.13)	(0.23)

(1) Per common share amounts for the quarters and full years have been calculated separately. Accordingly, the sum of quarterly amounts may not equal the annual amount because of differences in the weighted average common shares outstanding during each period, principally due to the effect of share issuances by the Company during the year.

22. Subsequent Events

Exercise of the Option and Warrants

In February 2016, the landlord exercised its option to purchase the Company s ordinary shares. In January and February 2016, certain warrants issued in connection with the promissory notes were exercised.

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Amendment and Conversion of Senior Promissory Note

On January 26, 2016, the Company entered into a note amendment and exchange agreement with Merck Sharp, pursuant to which, the maturity date of the Senior Promissory Note was extended 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 the 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.

On February 8, 2016, the outstanding unpaid principal and interest of the Senior Promissory Note were exchanged into 7,942,314 ordinary shares, computed at the initial public offering price of $1.85 per ordinary shares.

Closing of initial public offering

On February 8, 2016, the Company completed its IPO on the NASDAQ Global Select Market. 6,600,000 ADS representing 85,800,000 ordinary shares were sold at $24.00 per ADS, or $1.85 per share. Additionally, the underwriters exercised their options to purchase an additional 12,870,000 ordinary shares in the form of 990,000 ADSs. Net proceeds from the IPO including underwriter options after deducting underwriting discount and offering expenses were approximately $166,552. The deferred IPO costs were recorded as a reduction of the proceeds received from the IPO in the shareholders equity.

Upon completion of the IPO, all outstanding Series A and Series A-2 Preferred Shares and the outstanding unpaid principal and interest of the Senior Promissory Note were converted into 199,990,641 and 7,942,314 ordinary shares, respectively.

2016 Share Option and Incentive Plan

In connection with the IPO, the board of directors and shareholders approved a new equity compensation plan, the 2016 Share Option and Incentive Plan.

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SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 30, 2016

BEIGENE, LTD.

By: /s/ John V. Oyler
John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints John V. Oyler and Howard Liang, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities indicated below and on the dates indicated:

Signature	Title	Date
/s/ John V. Oyler John V. Oyler	Chief Executive Officer and Chairman (Principal Executive Officer)	March 30, 2016
/s/ Howard Liang Howard Liang	Chief Financial Officer and Chief Strategy Officer (Principal Financial and Accounting Officer)	March 30, 2016
/s/ Timothy Chen Timothy Chen	Director	March 30, 2016
/s/ Donald W. Glazer Donald W. Glazer	Director	March 30, 2016
/s/ Michael Goller Michael Goller	Director	March 30, 2016
/s/ Ranjeev Krishana	Director	March 30, 2016

Ranjeev Krishana		
/s/ Thomas Malley Thomas Malley	Director	March 30, 2016
/s/ Ke Tang Ke Tang	Director	March 30, 2016

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/s/ Xiaodong Wang Xiaodong Wang	Director	March 30, 2016
/s/ Qingqing Yi Qingqing Yi	Director	March 30, 2016

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Exhibit Index

Exhibit No.	Description
3.1	Fourth Amended and Restated Memorandum and Articles of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant s Current Report on Form 8-K (File No. 001-37686) filed on February 11, 2016)
4.1	Deposit Agreement dated February 5, 2016 by and among the Company, the Depositary and holders of the American Depositary Receipts (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K (File No. 001-37686) filed on February 11, 2016)
4.2	Form of American Depositary Receipt (included in Exhibit 4.1)
4.3	Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on December 9, 2015)
4.4	Second Amended and Restated Investors Rights Agreement, dated as of April 21, 2015, by and among the Registrant and certain shareholders named therein (incorporated by reference to Exhibit 4.4 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
4.5	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated January 26, 2016, by and among the Registrant and certain shareholders named therein (incorporated by reference to Exhibit 10.21 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on January 27, 2016)
10.1	BeiGene, Ltd. 2011 Option Plan, as amended and form of option agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.2	2016 Share Option and Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on January 19, 2016)
10.3	Form of Indemnification Agreement, entered into between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.3 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on January 19, 2016)
10.4	Lease dated February 1, 2011 by and between BeiGene (Beijing) Co., Ltd. and Beijing Xintaike Medical Device Co., Ltd. (English translation) (incorporated by reference to Exhibit 10.4 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.5#	Amended and Restated License Agreement for BRAF in Ex-PRC, dated December 10, 2013, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.5 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.6#	Amended and Restated License Agreement for BRAF in PRC, dated December 10, 2013, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.6 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.7#	License Agreement for PARP in Ex-PRC, dated October 28, 2013, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.7 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)

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10.8#	License Agreement for PARP in PRC, dated October 28, 2013, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.8 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.9#	Purchase of Rights Agreement, dated October 1, 2015, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.14 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.10#	Option Agreement, dated October 1, 2015, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.15 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.11#	Amendment Agreement, dated October 1, 2015, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.16 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.12	Second Amendment Agreement, dated December 3, 2015, by and between the Registrant and Merck KGaA (incorporated by reference to Exhibit 10.18 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on December 9, 2015)
10.13	Employment Agreement, dated July 13, 2015, by and between BeiGene USA, Inc. and Howard Liang (incorporated by reference to Exhibit 10.9 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.14	Employment Agreement, dated October 5, 2015, by and between BeiGene USA, Inc. and RuiRong Yuan (incorporated by reference to Exhibit 10.17 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on December 9, 2015)
10.15	Employment Contract, dated July 7, 2014, by and between BeiGene (Beijing) Co., Ltd. and Jason Yang (incorporated by reference to Exhibit 10.10 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.16	Employment Contract, dated July 1, 2014, by and between BeiGene (Beijing) Co., Ltd. and Wendy Yan (incorporated by reference to Exhibit 10.11 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.17	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.19 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on January 19, 2016)
10.18	Senior Promissory Note, dated February 2, 2011, by the Registrant in favor of Essex Chemie AG (incorporated by reference to Exhibit 10.12 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
10.19	Note Amendment and Exchange Agreement, dated January 26, 2016, by and between the Registrant and Merck Sharp & Dohme Research GmbH (incorporated by reference to Exhibit 10.20 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on January 27, 2016)
10.20#	Entrusted Loan Contract, dated September 2, 2015, by and between BeiGene (Suzhou) Co., Ltd.; Suzhou Industrial Park Biotech Development Co., Ltd.; and China Construction Bank (English translation) (incorporated by reference to Exhibit 10.13 of the Registrant s Registration Statement on Form S-1 (File No. 333-207459) filed on October 16, 2015)
21.1	List of Subsidiaries of the Registrant
23.1	Consent of Ernst & Young Hua Ming LLP
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of

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	2002
31.2	Certification of Principle Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principle Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Indicates a management contract or any compensatory plan, contract or arrangement.

Confidential treatment has been granted by the U.S. Securities and Exchange Commission as to certain portions of this exhibit omitted and filed separately.

* Furnished herewith.