BeiGene, Ltd.
Form 10-Q
August 10, 2016
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

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)

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 x No o

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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.

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

As of August 8, 2016, 427,919,031 ordinary shares, par value $0.0001 per share, were outstanding, of which 116,130,664 ordinary shares were held in the form of 8,933,128 American Depositary Shares, each representing 13 ordinary shares.

Table of Contents

BeiGene, Ltd.
Quarterly Report on Form 10-Q

TABLE OF CONTENTS

		Page
PART I. FINANCIAL INFORMATION		2
Item 1.	Financial Statements	2
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	33
Item 4.	Controls and Procedures	34
PART II. OTHER INFORMATION		35
Item 1.	Legal Proceedings	35
Item 1A.	Risk Factors	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	104
Item 3.	Defaults Upon Senior Securities	105
Item 4.	Mine Safety Disclosures	105
Item 5.	Other Information	105
Item 6.	Exhibits	105
SIGNATURES		106

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. **Financial Statements**

BEIGENE, LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	As of December 31, 2015 $ (audited)	As of June 30, 2016 $ (unaudited)
Assets			
Current assets:			
Cash and cash equivalents		17,869	58,084
Short-term investments	3	82,617	168,535
Prepaid expenses and other current assets		5,783	6,135
Total current assets		106,269	232,754
Property and equipment, net	4	6,612	9,752
Other non-current assets		3,883	8,724
Total non-current assets		10,495	18,476
Total assets		116,764	251,230
Liabilities and shareholders deficit			
Current liabilities:			
Accounts payable		8,980	6,071
Advances from customers		1,070	
Accrued expenses and other payables	6	8,351	14,226
Senior Promissory Note	9	14,598	
Warrant and option liabilities	7	2,173	
Tax payable			168
Total current liabilities		35,172	20,465
Non-current liabilities:			
Long-term bank loan	8	6,188	10,553
Deferred rental		980	
Other long-term liabilities		105	165
Total non-current liabilities		7,273	10,718
Total liabilities		42,445	31,183
Commitments and contingencies	18		
Convertible preferred shares	10	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)			

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)			
Total mezzanine equity		176,084	
Shareholders deficit:			
Ordinary shares (par value of US$0.0001 per share; 9,500,000,000 shares authorized; 427,919,031 shares issued and outstanding as of June 30, 2016 (December 31, 2015: 116,174,094 shares))		12	43
Additional paid-in capital		18,227	385,787
Accumulated other comprehensive loss	15	(1,809)	(1,463)
Accumulated deficit		(118,195)	(164,320)
Total shareholders (deficit) equity	16	(101,765)	220,047
Total liabilities, mezzanine equity and shareholders (deficit) equity		116,764	251,230

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

Table of Contents

BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Note	Three Months Ended June 30,		Six Months Ended June 30,	
		2015	2016	2015	2016
		$	$	$	$
Revenue					
Collaboration revenue		1,380	393	2,759	1,070
Total revenue		1,380	393	2,759	1,070
Operating expenses:					
Research and development		(6,737)	(21,117)	(16,796)	(38,994)
General and administrative		(1,208)	(3,904)	(2,340)	(7,038)
Total operating expenses		(7,945)	(25,021)	(19,136)	(46,032)
Loss from operations		(6,565)	(24,628)	(16,377)	(44,962)
Interest income		409	262	526	756
Interest expense		(273)	(141)	(540)	(345)
Changes in fair value of financial instruments	7	(14)		(202)	(1,514)
Disposal loss on available-for-sale securities		(44)	(228)	(57)	(940)
Other income		809	748	809	1,063
Other expense		37	(2)	(12)	(4)
Loss before income tax expense		(5,641)	(23,989)	(15,853)	(45,946)
Income tax expense	5		(135)		(179)
Net loss		(5,641)	(24,124)	(15,853)	(46,125)
Loss per share	13				
Basic and diluted		(0.05)	(0.06)	(0.15)	(0.13)
Weighted-average number of ordinary shares used in net loss per share calculation	13				
Basic and diluted		108,544,901	427,746,711	108,520,761	360,894,390
Loss per ADS					
Basic and diluted		(0.68)	(0.73)	(1.90)	(1.66)

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

Table of Contents

BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016
	$	$	$	$
Net loss	(5,641)	(24,124)	(15,853)	(46,125)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	(32)	(486)	(81)	(390)
Unrealized holding (loss) gain, net	(365)	275	(421)	736
Comprehensive loss	(6,038)	(24,335)	(16,355)	(45,779)

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

Table of Contents

BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

(Unaudited)

	Note	Six Months Ended June 30, 2015 $	2016 $
Operating activities			
Net loss		(15,853)	(46,125)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation expenses	4	725	931
Share-based compensation expenses	14	3,224	3,899
Loss on disposal of property and equipment		2	
Changes in fair value of financial instruments		202	1,514
Disposal loss on available-for-sale securities		57	940
Interest expense		540	93
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		(742)	(1,982)
Other non-current assets		(29)	(321)
Accounts payable		1,164	(3,075)
Advances from customers		(2,761)	(1,070)
Accrued expenses and other payables		297	5,871
Tax payable			168
Other long-term liabilities		(28)	60
Net cash used in operating activities		(13,202)	(39,097)
Investing activities			
Purchases of property and equipment		(1,028)	(8,758)
Purchase of available-for-sale securities		(90,115)	(176,993)
Proceeds from disposal of available-for-sale securities		18,678	90,546
Proceeds from disposal of property and equipment		3	
Net cash used in investing activities		(72,462)	(95,205)
Financing activities			
Proceeds from issuance of ordinary shares, net of initial public offering costs			167,931
Proceeds from issuance of preferred shares		97,350	
Payment of convertible preferred shares issuance cost		(75)	
Repayment of short-term loan		(322)	
Proceeds from long-term loan			4,521
Proceeds from exercise of warrants			2,118
Net cash provided by financing activities		96,953	174,570
Effect of foreign exchange rate changes, net		(31)	(53)
Net increase in cash and cash equivalents		11,258	40,215
Cash and cash equivalents at beginning of period		13,898	17,869

Cash and cash equivalents at end of period	25,156	58,084
Supplemental cash flow disclosures:		
Income taxes paid		25
Interest expense paid	7	242
Non-cash activities:		
Conversion of Senior Promissory Note		14,693
Conversion of deferred rental		980
Conversion of convertible preferred shares		176,084
Conversion of warrant and option liabilities		3,687
Initial public offering costs accrued in accrued expenses and other payables		166
Acquisitions of equipment included in accounts payable	36	78

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

Table of Contents

BEIGENE, LTD.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

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.

On February 8, 2016, the Company completed its initial public offering (IPO) on the NASDAQ Global Select Market. 6,600,000 ADSs representing 85,800,000 ordinary shares were sold at $24.00 per ADS, or $1.85 per share (the IPO Price). 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 $166,197. The deferred IPO costs were recorded as a reduction of the proceeds received from the IPO in the shareholders equity.

As at June 30, 2016, the Company s wholly-owned 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 Islands	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

2. Summary of significant accounting policies

Basis of presentation and principles of consolidation

The accompanying condensed consolidated balance sheet as of June 30, 2016, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June

Table of Contents

30, 2015 and 2016, the condensed consolidated statements of cash flows for the six months ended June 30, 2015 and 2016, and the related footnote disclosures are unaudited. The accompanying unaudited interim financial statements were prepared in accordance with U.S. generally accepted accounting principles (GAAP), including guidance with respect to interim financial information and in conformity with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for annual financial statements. These financial statements should be read in conjunction with the consolidated financial statements and related footnotes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2015.

The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all normal recurring adjustments, necessary to present a fair statement of the results for the interim periods presented. Results of the operations for the three and six months ended June 30, 2016 are not necessarily indicative of the results expected for the full fiscal year or for any future annual or interim period.

The condensed consolidated financial statements include the financial statements of the Company and its subsidiaries, which are all wholly-owned by the Company. All significant intercompany transactions and balances between the Company and its subsidiaries are eliminated upon consolidation.

Use of estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, identifying separate accounting units and estimating the best estimate selling price of each deliverable in the Company s revenue arrangements, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets and the fair value of the financial instruments. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

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. Cash equivalents which consist primarily of money market funds are stated at fair value.

Fair value measurements

Fair value of financial instruments

Financial instruments of the Company primarily include cash and cash equivalents, short-term investments, long-term bank loan, accounts payable, Senior Promissory Note, convertible preferred shares, and warrant and option liabilities. As of December 31, 2015 and June 30, 2016, the carrying values of cash and cash equivalents, and accounts payable approximated their fair values due to the short-term maturity of these instruments. The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets. 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 instruments 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. Prior to the

Table of Contents

exercise dates, the Company determined the fair values of the warrant and option liabilities with the assistance of an independent third party valuation firm. On the exercise dates, the Company determined the fair values of the warrant and option liabilities using the intrinsic value, which equals to the difference between the share price at the IPO closing date and the exercise price, as the exercise dates were immediately prior to or very close to the IPO closing date.

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.

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, 2015 and June 30, 2016:

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 7)			1,388

Warrants in connection with the convertible promissory notes (note 7) 785

As of June 30, 2016	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	12,455		
Municipal Bonds	3,002		
U.S. Treasury securities	153,078		
Cash equivalents			
Money market funds	32,321		

Table of Contents

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, 2015. The option and warrants have been exercised as of June 30, 2016. The Company determined the exercise date fair value of the warrants and option using significant other observable inputs (Level 2).

The following tables present a reconciliation of the option and warrant liabilities for the six months ended June 30, 2016.

	Warrant and Option Liabilities $
Balance as of December 31, 2015	2,173
Recognized	
Unrealized loss	1,514
Settlement	(3,687)
Balance as of June 30, 2016	
The amount of total unrealized loss for the six months ended June 30, 2016 included in losses	1,514

Realized and unrealized gain or loss for the three and six months ended June 30, 2015 and 2016 was recorded as Changes in fair value of financial instruments in the condensed consolidated statements of operations.

Recent accounting pronouncements

In August 2015, the FASB issued Accounting Standards Update (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 ASU No. 2014-09, *Revenue from Contracts with Customers,* (ASU 2014-09), 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. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers Principal versus Agent Considerations* (ASU 2016-08), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers Identifying Performance Obligations and Licensing* (ASU 2016-10), which clarify guidance related to identifying performance obligations and licensing implementation guidance contained in ASU No. 2014-09. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers Narrow-Scope Improvements and Practical Expedients* (ASU 2016-12), which addresses narrow-scope improvements to the guidance on collectability, non-cash consideration, and completed contracts at transition and provides practical expedients for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers. The effective date for the amendment in ASU 2016-08, ASU 2016-10 and ASU 2016-12 are the same as the effective date of ASU No. 2014-09. The Company is currently evaluating the method of adoption to be utilized and it cannot currently estimate the financial statement impact of adoption.

In February, 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires lessees to recognize assets and liabilities related to lease arrangements longer than 12 months on the balance sheet. This standard also requires additional disclosures by lessees and contains targeted changes to accounting by lessors. The updated guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. The recognition, measurement, and presentation of expenses and

Table of Contents

cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09). The amendments in ASU 2016-09 simplify several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public business entities, ASU 2016-09 is effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. The Company is currently evaluating the method of adoption to be utilized and it cannot currently estimate the financial statement impact of adoption.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments Credit Losses* (ASU 2016-13). The amendments in ASU 2016-13 update guidance on reporting credit losses for assets held at amortized cost basis and available-for-sale debt securities. These amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. For public business entities that are U.S. SEC filers, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is currently evaluating the method of adoption to be utilized and it cannot currently estimate the financial statement impact of adoption.

Table of Contents

3. Short-term investments

Short-term investments as of December 31, 2015 consisted 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

Short-term investments as of June 30, 2016 consisted 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	12,755		300	12,455
U.S. treasury securities	153,225	57	204	153,078
Municipal Bonds	3,024		22	3,002
Total	169,004	57	526	168,535

Contractual maturities of all debt securities as of June 30, 2016 were within one year. The Company does not intend to sell the debt securities 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 debt securities to be other-than-temporarily impaired at June 30, 2016.

4. Property and equipment

Property and equipment consisted of the following as of December 31, 2015 and June 30, 2016:

	As of	
	December 31, 2015 $	June 30, 2016 $
Office equipment	213	225
Electronic equipment	424	582
Laboratory equipment	5,919	6,942

Computer software	186	215
Leasehold improvements	5,954	6,280
Property and equipment, at cost	12,696	14,244
Less accumulated depreciation and amortization	(6,084)	(6,845)
Construction in progress		2,353
Property and equipment, net	6,612	9,752

Depreciation expenses for the three and six months ended June 30, 2015 were $373 and $725, respectively. Depreciation expenses for the three and six months ended June 30, 2016 were $492 and $931, respectively.

5. Income taxes

Income tax expense was $135 and $179, respectively, for the three and six months ended June 30, 2016 compared with nil for both the three and six months ended June 30, 2015. Current year income tax expense was attributable to BeiGene USA, Inc., a wholly owned subsidiary, which was established in July 2015 and provided general management services and strategic advisory services to the Company. The

Table of Contents

Company and its other subsidiaries were in a cumulative loss position for the three and six months ended June 30, 2015 and 2016.

The Company recorded a full valuation allowance against deferred tax assets for all periods presented. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

6. Accrued expenses and other payables

	As of	
	December 31, 2015 $	**June 30, 2016 $**
Payroll payables	275	168
Accrued operating expenses	5,513	10,371
Other payables	2,563	3,687
Total accrued expenses and other payables	8,351	14,226

7. Warrant and option liabilities

	As of	
	December 31, 2015 $	**June 30, 2016 $**
Option to purchase shares by rental deferral	1,388	
Warrants in connection with the promissory notes	785	
Total	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. Prior to the Company s IPO, the Company determined the fair value of the Option with the assistance of an independent third party valuation firm. On February 8, 2016, immediately prior to the Company s IPO, the landlord exercised the Option to purchase 1,451,586 ordinary shares of the Company. As the exercise date was the IPO closing date, the exercise date fair value of $1.750 was determined based on the intrinsic value, which equals to the difference between the share price at the IPO closing date and the exercise price. During the three and six months ended June 30, 2015, the Company recognized a loss from the increase in fair value of the Option of $6 and $112, respectively. During the three and six months ended June 30, 2016, the Company recognized a loss from the increase in fair value of the Option of nil and $1,151, respectively.

Warrants in connection with the 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 preferred shares up to 10% of the convertible promissory notes principal amount concurrently for an aggregate principal amount of $2,410. The warrants were freestanding instruments and were recorded as liabilities in accordance with ASC480. The warrants were initially recognized at fair value with subsequent changes in fair value recorded in losses. In January and February, 2016, the warrants issued in connection with the promissory notes were exercised for 621,637 Preferred Shares, which shares were converted into 621,637 ordinary shares. As the exercise dates were very close to the IPO closing date, the respective exercise date fair value of $1.750 per share was determined based on the intrinsic value, which equals to the difference between the share price at the IPO closing date and the exercise price.

Table of Contents

For the three and six months ended June 30, 2015, the Company recognized loss from the increase in fair value of $8 and $90, respectively. For the three and six months ended June 30, 2016, the Company recognized loss from the increase in fair value of nil and $363, respectively.

8. 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. As of June 30, 2016, the Company has drawn down $10,533 which is secured by BeiGene Suzhou s future equipment purchases and the Company s rights to a PRC patent on a drug candidate. The loan amounts of $9,443 and $1,090 are repayable on September 30, 2018 and 2019, respectively. Interest expense recognized for the three and six months ended June 30, 2016 amounted to $142 and $250, respectively.

9. Senior Promissory Note

On January 26, 2016, the Company entered into a note amendment and exchange agreement with Merck Sharp & Dohme Research GmbH (MSD), pursuant to which, the maturity date of the Senior Promissory Note was extended to May 2, 2016 from February 2, 2016. In addition, if the IPO occurred 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) would 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. The amendments and subsequent extinguishment of the Senior Promissory Note did not result in any gain or loss since the conversion rate was set at the IPO Price.

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 IPO Price of $1.85 per ordinary share.

10. 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 a 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.

Table of Contents

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.

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. Upon conversion of the Preferred Shares, 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) entities affiliated with Baker Bros. Advisors LP (collectively, Baker Bros.) 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

Table of Contents

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 were not redeemable, and it was not probable that the Preferred Shares would become redeemable because the likelihood of a Liquidation Transaction was remote. Therefore, no adjustment has been made to the initial carrying amount of the Preferred Shares.

On February 8, 2016, in connection with the completion of the IPO, all outstanding Preferred Shares were converted into 199,990,641 ordinary shares.

11. Related party balances and transactions

During the three and six months ended June 30, 2015, a shareholder provided consulting services to the Company at a fee of $25 and $50, respectively. During the three and six months ended June 30, 2016, a shareholder, who is also a director, provided consulting services to the Company at a fee of $25 and $50, respectively.

12. Research and development collaborative arrangements

The Company did not enter into any new collaborative arrangements during the three or six months ended June 30, 2015 and 2016.

The following table summarizes total collaboration revenue recognized for the three and six months ended June 30, 2015 and 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016
	$	$	$	$

License revenue				
Research and development revenue	1,380	393	2,759	1,070
Total	1,380	393	2,759	1,070

The Company recorded advances from customers related to the collaboration of approximately $1,070 and nil at December 31, 2015 and June 30, 2016, respectively.

Table of Contents

13. Loss per share

Loss per share was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015 $	2016 $	2015 $	2016 $
Numerator:				
Net loss attributable to ordinary shareholders for computing basic and diluted loss per ordinary share	(5,641)	(24,124)	(15,853)	(46,125)
Denominator:				
Weighted average number of ordinary shares outstanding for computing basic and diluted loss per ordinary share	108,544,901	427,746,711	108,520,761	360,894,390
Basic and diluted loss per share	(0.05)	(0.06)	(0.15)	(0.13)

For the three and six months ended June 30, 2015 and 2016, 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, share options, restricted shares, 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 three months ended June 30, 2015 and the six months ended June 30, 2015 and 2016. The effects of all share options and restricted shares were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive during the three months ended June 30, 2016.

14. Share-based compensation

2016 share option and incentive plan

On January 14, 2016, in connection with the IPO, the board of directors and shareholders of the Company approved a new equity compensation plan, the 2016 Share Option and Incentive Plan, or 2016 Plan, which became effective on February 2, 2016. The Company 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 the board of directors or the compensation committee. This number is subject to adjustment in the event of a share split, share dividend or other change in the Company s capitalization. In addition, shares not needed to fulfill any obligations under the 2011 Plan will also be available for issuance under the 2016 Plan.

In January 2016, the Company granted 2,417,152 options with an exercise price of $1.85 per ordinary share under the 2011 Plan.

On February 8, 2016, the Company granted 460,626 options with an exercise price of $2.43 per ordinary share under the 2016 Plan.

On May 3, 2016, the Company granted 2,376,000 options with an exercise price of $2.05 per ordinary share and 475,000 restricted ordinary shares under the 2016 Plan.

Table of Contents

Generally, options have a contractual term of 10 years and vest over a three- to five-year period, with the first tranche vesting one calendar year after the grant date or the service relationship start date and the remainder of the awards vesting on a monthly basis thereafter.

The restricted ordinary shares vest evenly over a four-year period on a yearly basis.

Modification

Upon the completion of the Company s IPO on February 8, 2016 (Date of the Change in Employment Status), a consultant (the Consultant) became a member of the Company s board of directors and his compensation is now treated as employee compensation. The fair value of the options granted by the Company to the Consultant has been re-measured as of 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 total share-based compensation expense recognized for the three and six months ended June 30, 2015 and 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016
	$	$	$	$
Research and development	890	744	3,185	3,043
General and administrative	20	541	39	856
Total	910	1,285	3,224	3,899

15. Accumulated other comprehensive loss

The movement of accumulated other comprehensive loss was as follows:

	Foreign Currency Translation Adjustments	Unrealized Gains (Losses)	Total
	$	$	$
Balance as of December 31, 2015	(602)	(1,207)	(1,809)
Other comprehensive income before reclassifications	(390)	(204)	(594)
Amounts reclassified from accumulated other comprehensive loss		940	940
Net-current period other comprehensive loss	(390)	736	346
Balance as of June 30, 2016	(992)	(471)	(1,463)

16. Shareholders equity

Conversion of preferred shares and Senior Promissory Note

Upon completion of the IPO, all outstanding Preferred Shares were converted into 199,990,641 ordinary shares and the related carrying value of $176,084 was reclassified from mezzanine equity to shareholders equity. The outstanding unpaid principal and interest of the Senior Promissory Note were converted into 7,942,314 ordinary shares, computed at the initial public offering price of $1.85 per ordinary share and the related carrying value of $14,693 was reclassified from current liability to shareholders equity.

Table of Contents

Exercise of the option and warrants

In January and February 2016, certain warrants in connection with the convertible promissory notes and short term notes were exercised to purchase 621,637 Preferred Shares, which shares were converted into 621,637 ordinary shares. On the IPO closing date, (i) the Company s landlord exercised its option to purchase 1,451,586 ordinary shares of the Company; (ii) Baker Bros. exercised their warrants to purchase 2,592,593 ordinary shares at an exercise price of $0.68 per share; and (iii) a senior executive exercised warrants to purchase 57,777 Preferred Shares at an exercise price of $0.68 per share, which were converted into 57,777 ordinary shares. Upon the exercise of the aforementioned option and warrants, except for Baker Bros. warrants, which were initially classified in equity, the related carrying value totaling $3,687 was reclassified from current liabilities to shareholders equity.

17. Restricted net assets

As a result of PRC laws and regulations, the Company s PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company. As of December 31, 2015 and June 30, 2016, amounts restricted were the net assets of the Company s PRC subsidiaries, which amounted to $3,383 and $3,573, respectively.

18. Commitments and contingencies

Operating lease commitments

The Company leases office facilities under non-cancelable operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases, and the terms of the leases do not contain rent escalation, contingent rent, renewal, or purchase options.

There are no restrictions placed upon the Company by entering into these leases. Total expenses under these operating leases were $263 and $551 for the three and six months ended June 30, 2015, respectively. Total expenses under these operating leases were $309 and $625 for the three and six months ended June 30, 2016, respectively.

Future minimum payments under non-cancelable operating leases consist of the following as of June 30, 2016

	$
Six months ending December 31, 2016	1,007
Year ending December 31, 2017	1,787
Year ending December 31, 2018	1,555

Year ending December 31, 2019	1,273
Year ending December 31, 2020	1,396
Year ending December 31, 2021 and thereafter	166
Total	**7,184**

Capital commitments

The Company had capital commitments amounting to $12,451 for the acquisition of property, plant and equipment as of June 30, 2016.

19. Subsequent Events

New option grants

Subsequent to June 30, 2016, the Company in aggregate granted 15,832,527 options to employees and 3,322,080 options to consultants with an exercise price per ordinary share equal to 1/13 of the closing price of the Company s American Depositary Shares quoted on the NASDAQ Stock Exchange on the applicable grant date under the 2016 plan.

Table of Contents

Item 2. 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 in conjunction with our condensed consolidated financial statements (unaudited) and related notes included in the section of this Quarterly Report on Form 10-Q, or this Quarterly Report, titled Item 1 Financial Statements. This Quarterly Report contains forward-looking statements that are based on management s beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: aim, anticipate, believe, continue, could, estimate, expect, goal, intend, may, ongoing, plan, potential, predict, project, negative of these terms or other similar expressions, although not all forward-looking statements contain these words. These forward-looking statements, include, but are not limited to, statements regarding: 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, or CFDA; our reliance on the success of our clinical-stage drug candidates BGB-3111, BGB-A317, BGB-290 and BGB-283 and certain other drug candidates, as monotherapies and in combination; 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; 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 II Item 1A Risk Factors. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in Part II Item 1A Risk Factors of this Quarterly Report. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Unless the context requires otherwise, in this Quarterly Report, the terms BeiGene, the Company, we, us and our refer to BeiGene, Ltd. and its subsidiaries, on a consolidated basis.

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

Table of Contents

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. BGB-3111 received orphan drug designation from the U.S. Food and Drug Administration for chronic lymphocytic leukemia, mantle cell lymphoma and Waldenström s macroglobulinemia. 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 next18 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 note and a 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. 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, and additionally received $37 million from the Merck KGaA Collaboration to fund our operations. On February 8, 2016, we completed our initial public offering and received net proceeds of $166.2 million, after deducting underwriting discounts and offering expenses. 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. As of June 30, 2016, we had an accumulated deficit of $164.3 million. In the future, we may generate revenue from product sales, collaboration agreements, strategic alliances and licensing arrangements, or a combination of these. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue investment in our cancer biology platform;

- continue preclinical and clinical development of our programs;

- continue investment in our manufacturing facilities;

- hire additional research, development and business personnel;

Table of Contents

- maintain, expand and protect our intellectual property portfolio; and

- incur additional costs associated with operating as a public company.

We expect that any revenue we generate will fluctuate from quarter to quarter and year to year as a result of the timing and amount of license fees, milestones, reimbursement of costs incurred and other payments and product sales, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval of them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Cash used in operations were $13.2 million and $39.1 million, respectively, for the six months ended June 30, 2015 and 2016. As of June 30, 2016, we had cash, cash equivalents and short-term investments of $226.6 million, compared with $100.5 million as of December 31, 2015.

Components of operating results

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 payments in 2014 and $4 million in milestone payments 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 gene 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

Table of Contents

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, 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 of our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC, on March 30, 2016, or Annual Report.

We recognized $1.4 million and $2.8 million of collaboration revenue from the Merck KGaA Collaboration for the three and six months ended June 30, 2015, respectively. We recognized $0.4 million and $1.1 million of collaboration revenue from the Merck KGaA Collaboration for the three and six months ended June 30, 2016, 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 three and six months ended June 30, 2015 and 2016, substantially all of our revenue was 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.

Operating 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;

Table of Contents

- costs associated with preclinical activities and development activities;

- costs associated with regulatory operations; and

- other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in research and development activities.

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

- BGB-3111, a potent and selective small molecule inhibitor of BTK;

- BGB-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

Table of Contents

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 candidates 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, 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 income, net

Interest income

Interest income consists primarily of interest generated from our short-term investments in treasury securities, municipal bonds and corporate fixed income bonds.

Interest expense

Interest expense consists primarily of interest on our Senior Promissory Note and long-term bank loan.

In 2011, we issued $10 million 8% Senior Promissory Note to MSD. 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.

On September 2, 2015, BeiGene Suzhou entered into a loan agreement with Suzhou Industrial Park and China Construction Bank, to borrow $18.9 million at a 7% fixed annual interest rate. As of June 30, 2016, we have drawn down $10.5 million, which is secured by BeiGene Suzhou s future equipment purchases and our rights to a PRC patent on a drug candidate. The loan amounts of $9.4 million and $1.1 million are repayable on September 30, 2018 and 2019, respectively.

Table of Contents

Results of operations

The following table summarizes our results of operations for the three and six months ended June 30, 2015 and 2016:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2015	2016	Change	2015	2016	Change
	in thousands					
Collaboration revenue	$ 1,380	$ 393	$ (987)	$ 2,759	$ 1,070	$ (1,689)
Operating expenses:						
Research and development	(6,737)	(21,117)	(14,380)	(16,796)	(38,994)	(22,198)
General and administrative	(1,208)	(3,904)	(2,696)	(2,340)	(7,038)	(4,698)
Total operating expenses	(7,945)	(25,021)	(17,076)	(19,136)	(46,032)	(26,896)
Loss from operations	(6,565)	(24,628)	(18,063)	(16,377)	(44,962)	(28,585)
Net interest income (expense)	136	121	(15)	(14)	411	425
Changes in fair value of financial instruments	(14)		14	(202)	(1,514)	(1,312)
Disposal loss on available-for-sale securities	(44)	(228)	(184)	(57)	(940)	(883)
Net other income (expense)	846	746	(100)	797	1,059	262
Loss before income tax expense	(5,641)	(23,989)	(18,348)	(15,853)	(45,946)	(30,093)
Income tax expense		(135)	(135)		(179)	(179)
Net loss	$ (5,641)	$ (24,124)	$ (18,483)	$ (15,853)	$ (46,125)	$ (30,272)

Comparison of the three months ended June 30, 2015 and June 30, 2016

Revenue

Revenue from the Merck KGaA Collaboration decreased by $1.0 million to $0.4 million for the three months ended June 30, 2016 from $1.4 million for the three months ended June 30, 2015. The decrease was primarily attributable to revenue that was no longer being recognized for BGB-290 for the second quarter in 2016 after we repurchased its ex-PRC right from Merck KGaA in October 2015.

Research and development expense

Research and development expense increased by $14.4 million to $21.1 million for the three months ended June 30, 2016 from $6.7 million for the three months ended June 30, 2015. The following table summarizes our research and development expense by program and stage of development for the three months ended June 30, 2015 and 2016, respectively:

	Three Months Ended June 30,	
	2015	2016
	(in thousands)	
External cost of clinical-stage programs	$ 1,628	$ 12,589
External cost of preclinical-stage programs	1,238	1,355
Internal research and development expenses	3,871	7,173
Total research and development expenses	$ 6,737	$ 21,117

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

Table of Contents

Increases of approximately $4.5 million, $4.4 million, $1.4 million and $0.7 million, respectively, for BGB-3111, BGB-A317, 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:

- $2.6 million increase of employee salary and benefits, which was primarily attributable to hiring of more development personnel during the three months ended June 30, 2016;

- $0.4 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our pipeline;

- $0.5 million increase of facilities, reagents, rental fee and other expenses; and

- Offset by $0.2 million decrease of stock option expenses ($0.7 million in the three months ended June 30, 2016 compared to $0.9 million in the three months ended June 30, 2015).

General and administrative expense

General and administrative expense increased by $2.7 million to $3.9 million for the three months ended June 30, 2016 from $1.2 million for the three months ended June 30, 2015. The increase was primarily attributable to the following:

- $0.9 million increase of professional fees for audit, legal and consulting services, mainly in connection with the preparation of our periodic reports, consulting activities and patent prosecution activities;

- $0.7 million increase of employee salary and benefits, which was primarily attributable to hiring of more personnel during the three months ended June 30, 2016;

- $0.5 million increase of stock option expense ($0.5 million in the three months ended June 30, 2016 compared to $20,000 in the three months ended June 30, 2015), which was mainly attributable to options and restricted shares granted to certain employees; and

- $0.6 million increase of travel, office, leasing and other administrative expenses, mainly in connection with the global expansion of our company.

Interest income and expense, net

Interest income (net) decreased by $15,000 to $121,000 for the three months ended June 30, 2016 from $136,000 for the three months ended June 30, 2015. The decrease in interest income (net) was primarily attributable to decrease of interest income, mainly generated from short-term investments in treasury securities, municipal bonds and fixed income bonds.

Changes in fair value of financial instruments

Loss from changes in fair value of financial instruments was nil for the three months ended June 30, 2016, compared with $14,000 for the three months ended June 30, 2015. The decrease in loss from changes in fair value of financial instruments was primarily attributable to the exercise of warrants and options in January and February 2016.

Disposal loss on available-for-sale securities

The $0.2 million disposal loss on available-for-sale securities was recorded for the three months ended June 30, 2016 following the disposal of the available-for-sale securities.

Table of Contents

Other income, net

Other income (net) decreased by $0.1 million to $0.7 million for the three months ended June 30, 2016 from $0.8 million for the three months ended June 30, 2015. Other income primarily consisted of government grants received.

Income tax expense

Income tax expense was $0.1 million for the three months ended June 30, 2016 compared with nil for the three months ended June 30, 2015. Current-year income tax expense was attributable to BeiGene USA, Inc., a wholly owned subsidiary, which was established in July 2015 and provided general management services and strategic advisory services to BeiGene, Ltd. BeiGene, Ltd. and its other subsidiaries were in a cumulative loss position for the three months ended June 30, 2015 and 2016.

Comparison of the six months ended June 30, 2015 and June 30, 2016

Revenue

Revenue from the Merck KGaA Collaboration decreased by $1.7 million to $1.1 million for the six months ended June 30, 2016 from $2.8 million for the six months ended June 30, 2015. The decrease was primarily attributable to revenue that was no longer being recognized for BGB-290 for the six months ended June 30, 2016 after we repurchased its ex-PRC right from Merck KGaA in October 2015.

Research and development expense

Research and development expense increased by $22.2 million to $39.0 million for the six months ended June 30, 2016 from $16.8 million for the six months ended June 30, 2015. The following table summarizes our research and development expense by program and stage of development for the six months ended June 30, 2015 and 2016, respectively:

	Six Months Ended June 30,	
	2015	2016
	(in thousands)	

External cost of clinical-stage programs	$	5,808	$	22,069
External cost of preclinical-stage programs		1,771		1,887
Internal research and development expenses		9,217		15,038
Total research and development expenses	$	16,796	$	38,994

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 $7.0 million, $6.4 million, $1.5 million and $1.4 million, respectively, for BGB-3111, BGB-A317, 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:

- $3.9 million increase of employee salary and benefits, which was primarily attributable to hiring of more development personnel during the six months ended June 30, 2016;

- $0.8 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our pipeline;

- $1.3 million increase of facilities, reagents, rental fee and other expenses; and

- Offset by $0.2 million decrease of stock option expenses ($3.0 million in the six months ended June 30, 2016 compared to $3.2 million in the six months ended June 30, 2015).

Table of Contents

General and administrative expense

General and administrative expense increased by $4.7 million to $7.0 million for the six months ended June 30, 2016 from $2.3 million for the six months ended June 30, 2015. The increase was primarily attributable to the following:

- $1.6 million increase of professional fees for audit, legal and consulting services, mainly in connection with the preparation of our periodic reports, consulting activities and patent prosecution activities;

- $1.5 million increase of employee salary and benefits, which was primarily attributable to hiring of more personnel during the six months ended June 30, 2016;

- $0.8 million increase of stock option expense ($856,000 in the six months ended June 30, 2016 compared to $39,000 in the six months ended June 30, 2015), which was mainly attributable to options and restricted shares granted to certain employees; and

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

Interest income and expense, net

Interest income (net) increased by $425,000 to $411,000 for the six months ended June 30, 2016 from interest expense (net) of $14,000 for the six months ended June 30, 2015. The increase in interest income (net) was primarily attributable to the following:

- $0.2 million increase of interest income which was primarily generated from short-term investments in treasury securities, municipal bonds and fixed income bonds; and

- $0.2 million decrease of interest expense which was primarily attributable to the conversion of the Senior Promissory Note in connection with our initial public offering.

Changes in fair value of financial instruments

Loss from changes in fair value of financial instruments increased by $1.3 million to $1.5 million for the six months ended June 30, 2016 from $0.2 million for the six months ended June 30, 2015. The increase in loss from changes in fair value of financial instruments was primarily attributable to the fair value change of warrants and options.

Disposal loss on available-for-sale securities

The $0.9 million disposal loss on available-for-sale securities was recorded for the six months ended June 30, 2016 following the disposal of the available-for-sale securities.

Other income, net

Other income (net) increased by $0.3 million to $1.1 million for the six months ended June 30, 2016 from $0.8 million for the six months ended June 30, 2015. Other income primarily consisted of government grants received.

Income tax expense

Income tax expense was $0.2 million for the six months ended June 30, 2016 compared with nil for the six months ended June 30, 2015. Current-year income tax expense was attributable to BeiGene USA, Inc., a wholly owned subsidiary, which was established in July 2015 and provided general management services and strategic advisory services to BeiGene, Ltd. BeiGene, Ltd. and its other subsidiaries were in a cumulative loss position for the six months ended June 30, 2015 and 2016.

Table of Contents

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 $5.6 million and $15.9 million, respectively, for the three and six months ended June 30, 2015, and $24.1 million and $46.1 million, respectively, for the three and six months ended June 30, 2016. As of June 30, 2016, we had an accumulated deficit of $164.3 million. Our primary use of cash is to fund research and development costs. Our operating activities used $13.2 million and $39.1 million of cash flows during the six months ended June 30, 2015 and 2016, 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. On February 8, 2016, we completed our initial public offering and received net proceeds of $166.2 million, after deducting underwriting discounts and offering expenses. At June 30, 2016, we had cash, cash equivalents and short-term investments of $226.6 million.

The following table provides information regarding our cash flows for the six months ended June 30, 2015 and 2016:

	Six Months Ended June 30,	
	2015	2016
	(in thousands)	
Net cash used in operating activities	$ (13,202)	$ (39,097)
Net cash used in investing activities	(72,462)	(95,205)
Net cash provided by financing activities	96,953	174,570
Net effect of foreign exchange rate changes	(31)	(53)
Net increase in cash and cash equivalents	$ 11,258	$ 40,215

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 six months ended June 30, 2016, operating activities used $39.1 million of cash, which resulted principally from our net loss of $46.1 million, adjusting for non-cash charges of $7.2 million and interest expense of $0.1 million, and by cash used in our operating assets and liabilities of $0.3 million. Our net non-cash charges during the six months ended June 30, 2016 primarily consisted of a $0.9 million depreciation charge, a $3.9 million share-based compensation expense, a $0.9 million disposal loss on available-for-sale securities and a $1.5 million loss from changes in the fair value of financial instruments.

During the six months ended June 30, 2015, our operating activities used $13.2 million of cash, which resulted principally from our net loss of $15.9 million, adjusted for non-cash charges of $4.2 million and interest expense of $0.5 million, and by cash used in our operating assets and liabilities of $2.0 million. Our net non-cash charges during the six months ended June 30, 2015 primarily consisted of $0.7 million of depreciation expense, $3.2 million of share-based compensation expense, and a $0.2 million loss from changes in fair value of financial instruments.

Net cash used in investing activities

Net cash used in investing activities was $95.2 million for the six months ended June 30, 2016 compared to $72.5 million for the six months ended June 30, 2015. The increase in cash used in investing activities was primarily due to $86.4 million net purchase of available-for-sale securities and $8.8 million paid to purchase property and equipment.

Table of Contents

Net cash provided by financing activities

Net cash provided by financing activities was $174.6 million for the six months ended June 30, 2016 compared to $97.0 million for the six months ended June 30, 2015. The increase was primarily due to proceeds of $167.9 million from issuance of ordinary shares, net of initial public offering costs, proceeds of $4.5 million from long term loan and proceeds of $2.1 million from exercise of warrants.

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 June 30, 2016, 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 as monotherapies and in combination, fund new and ongoing research and development activities and working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

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

- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our drug candidates to progress through clinical development successfully;
- the initiation, progress, timings, costs and results of non-clinical studies and clinical trials for our other programs and potential drug candidates;

- the number and characteristics of the drug candidate we pursue;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- the extent to which we acquire or in-license other products and technologies; and

- our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of holders of ADSs or ordinary shares. 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 the ownership interest of holders of ADSs or ordinary shares. If we raise additional

Table of Contents

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 June 30, 2016:

	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	$ 7,184	$ 1,831	$ 3,086	$ 2,256	$ 11
Long-term debt obligation	$ 10,553		$ 9,463	1,090	
Capital commitments	$ 12,451	$ 12,451			
Total	$ 30,188	$ 14,282	$ 12,549	$ 3,346	$ 11

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.

On April 10, 2016, we entered into a Lease Agreement with Suzhou Industrial Park Biotech Development Co., Ltd. for an approximately 11,000 square meter facility for research and manufacturing use in Suzhou, China. The lease commenced on April 18, 2016 and will expire on July 17, 2021. The initial rent, the payment of which commenced on July 18, 2016, is RMB 280,650 per month, plus service charges of RMB 65,485 per month and other fees for use of the premises, including water costs and electricity. The service charges will remain unchanged for the first three years and the increasing range thereafter will not exceed 5% of the previous yearly service charges. Suzhou Industrial Park will pay our full monthly rent for the first three years and 50% of the monthly rent for the following two years. The lease contains customary covenants, insurance and indemnification obligations, and termination provisions.

Long-term debt obligation

On September 2, 2015, BeiGene Suzhou entered into a loan agreement with Suzhou Industrial Park and China Construction Bank, to borrow $18.9 million at a 7% fixed annual interest rate. As of June 30, 2016, we have drawn down $10.5 million, which is secured by BeiGene Suzhou s future equipment purchases and our rights to a PRC patent on a drug candidate. The loan amounts of $9.4 million and $1.1 million are repayable on September 30, 2018 and 2019, respectively. As of June 30, 2016, the outstanding unpaid principal and interest of this bank loan was $10.6 million.

Capital commitments

We had capital commitments amounting to $12.5 million for the acquisition of property, plant and equipment as of June 30, 2016.

Table of Contents

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 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.

There have been no material changes to our critical accounting policies from those described in the section titled Part II Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report.

Recent accounting pronouncements

See Note 2 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding new accounting pronouncements.

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 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, known as the auditor

Table of Contents

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.

Item 3. 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 $17.9 million and $58.1 million and short-term investments of $82.6 million and $168.5 million at December 31, 2015 and June 30, 2016, respectively. At June 30, 2016, 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 June 30, 2016, 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 will continually monitor the credit worthiness of these institutions.

The primary objectives of our investment activities are to preserve principal, 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 depreciation of approximately 4.4% in the year ended December 31, 2015, and depreciation of approximately 1.7% in the six months ended June 30, 2016. 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

Table of Contents

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.

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.

Item 4. 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 June 30, 2016. 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 June 30, 2016, 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 condensed 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 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.

Table of Contents

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 appropriate accounting 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 GAAP and SEC rules and regulations;

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

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

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. 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 JOBS Act. We are in the process of improving the internal control over financial reporting required to comply with this obligation. 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.

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 June 30, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. **Legal Proceedings.**

From time to time, we may become involved in litigation relating 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.

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 Quarterly Report, including our financial statements and the related notes and Part I Item 2 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.

Table of Contents

*The risk factors denoted with a * are newly added or have been materially updated from our Annual Report.*

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. We reported a net loss of $5.6 million and $15.9 million, respectively, for the three and six months ended June 30, 2015, and $24.1 million and $46.1 million, respectively, for the three and six months ended June 30, 2016. As of June 30, 2016, we had a deficit accumulated of $164.3 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates, and begin to commercialize approved drugs, if any. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, our ability to generate revenues and the timing and amount of milestones and other required payments to third parties in connection with our potential future arrangements with third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain

Table of Contents

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.

Table of Contents

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. Our operating activities used $13.2 million and $39.1 million of net cash during the six months ended June 30, 2015 and 2016, respectively. We expect to continue to spend substantial amounts on drug discovery advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

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

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;

Table of Contents

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

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

- our ability to successfully commercialize our drug candidates;

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

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

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

- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;

- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

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

- the costs of operating as a public company;

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

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

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

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of the ADSs may not support capital raising transactions such as an additional public or private offering of the ADSs or other securities. In addition, our ability to raise additional capital may be dependent upon the ADSs being quoted on the NASDAQ or upon obtaining shareholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on the NASDAQ or that we will be able to obtain shareholder approval if it is necessary. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or drug candidates or to grant licenses on terms that may not be favorable to us.

We believe that the net proceeds from 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

Table of Contents

unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of the ADSs or our ordinary shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of the ADSs to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

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

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

Table of Contents

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 $17.9 million and $58.1 million and short-term investments of $82.6 million and $168.5 million at December 31, 2015 and June 30, 2016, respectively. At June 30, 2016, our short-term investments mainly consisted of high credit quality corporate fixed income bonds and U.S. Treasury securities. On February 8, 2016, we completed our initial public offering of the ADSs and received net proceeds of $166.2 million, after deducting underwriting discount and offering expenses. We may invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper and money market instruments, which may not yield a favorable return to our shareholders. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. Our primary exposure to market risk relates to fluctuations in the interest rates of the PRC and the United States. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

Risks related to clinical development of our drug candidates

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

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

Table of Contents

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

- protecting our rights in our intellectual property;

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

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

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

- competition with other drug candidates and drugs; and

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

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

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

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

candidates, our business could be materially harmed.

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

Table of Contents

drug candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

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

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

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

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial s primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;

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

- our ability to obtain and maintain patient consents;

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

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

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

Table of Contents

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

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. For example, as of January 2016 we voluntarily decided to temporarily suspend new patient accrual to our dose-escalation trial for BGB-283 in China to allow evaluation of pharmacokinetics, safety and efficacy after we found more frequent observation of thrombocytopenia in the China trial as compared to the Australia / New Zealand trial. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

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

Before obtaining regulatory approval for the sale of our drug candidates, such as BGB-3111, BGB-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;

Table of Contents

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

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

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

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

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

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

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

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

- not obtain regulatory approval at all;

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

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

- be subject to additional post-marketing testing requirements;

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

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

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

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

Table of Contents

necessary to gain approval may change during the course of a drug candidate s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug candidate, and it is possible that none of our existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

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

- disagreement with the design or implementation of our clinical trials;

- failure to demonstrate that a drug candidate is safe and effective or that a biologic drug candidate is safe, pure, and potent for its proposed indication;

- failure of clinical trial results to meet the level of statistical significance required for approval;

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

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

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

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

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

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

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:

Table of Contents

- 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;

- 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;

Table of Contents

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

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

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

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

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

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

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

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

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the drug candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our drug candidates. Companion diagnostics are subject to regulation by the FDA, CFDA, EMA and other comparable regulatory authorities and require separate regulatory approval or clearance prior to commercialization. We do not develop companion diagnostics internally, and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval or clearance for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval or clearance of the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval or clearance of the companion diagnostics could delay or prevent approval of our drug candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. A failure of such companion diagnostics to gain market acceptance would have an adverse effect on our ability to derive revenues from sales of our drugs. In addition, the

Table of Contents

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,

Table of Contents

EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events.

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

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

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

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

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

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

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

designation from the FDA for chronic lymphocytic leukemia, mantle cell lymphoma and Waldenström s macroglobulinemia in 2016.

Generally, if a drug with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EMA, from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States

Table of Contents

and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

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

Manufacturers and manufacturers facilities are required to comply with extensive FDA, CFDA, EMA and comparable regulatory authority, requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to current Good Manufacturing 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;

Table of Contents

- fines, untitled or warning letters, or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

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

- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA, CFDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA, CFDA, EMA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

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

Risks related to commercialization of our drug candidates

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

We currently do not have any drug candidates that have gained regulatory approval for sale in the United States, European Union, China or any other country, and we cannot guarantee that we will ever have marketable drugs. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without first obtaining regulatory approval to market each drug from the FDA, CFDA, EMA and comparable regulatory authorities. BGB-3111, BGB-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.

Table of Contents

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

Specifically, in China, the CFDA categorizes domestically-manufactured innovative drug applications as Category 1 and imported innovative drug applications as Category 3. To date, most of local companies domestically-manufactured drug applications are filed in Category 1 if the drug has not already been approved by the FDA or EMA. Most multinational pharmaceutical companies drug registration applications are filed in Category 3. These two categories have distinct approval pathways, as described in the section of our Annual Report titled Item 1 Business Regulatory Framework and Structural Advantages of Being a China-Based Research and Development Organization. We believe the local drug registration pathway, Category 1, is a faster and more efficient path to approval in the Chinese market than Category 3. Companies are required to obtain Clinical Trial Application approval before conducting clinical trials in China. This registration pathway has a fast track review and approval mechanism if the drug candidate is on a national priority list. 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

Table of Contents

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 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 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.

Table of Contents

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;
- 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

Table of Contents

- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

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

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

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

Table of Contents

obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and or slow our regulatory approval.

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

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

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

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

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

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

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

In addition, a drug product approved under an NDA, such as BGB-3111, BGB-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.

Table of Contents

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

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

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

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

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

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

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

authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

Table of Contents

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

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

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

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;

- cost-effective; and

- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each

Table of Contents

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 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

Table of Contents

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

Table of Contents

changed, or what the impact of such changes on the regulatory approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA s approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician 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

Table of Contents

Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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

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

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable 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.

Table of Contents

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

Non-U.S. markets are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

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

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

- differing regulatory requirements for drug approvals and marketing internationally;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;

- potentially reduced protection for intellectual property rights;

- potential third-party patent rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements;

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

- compliance with tax, employment, immigration and labor laws for employees traveling abroad;

- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;

- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;

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

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

- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act;

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

- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

Table of Contents

Risks related to our intellectual property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States, the PRC and other countries with respect to our proprietary technology and drug candidates. As of August 8, 2016, we own six issued U.S. patents and nine pending U.S. patent applications as well as corresponding patents and patent applications internationally. In addition, we own six pending international patent applications under the Patent Cooperation Treaty, or PCT, which we plan to file nationally in the United States and other jurisdictions. With respect to any issued patents in the United States and Europe, we may be entitled to obtain a patent term extension to extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. We have sought to protect our proprietary position by filing patent applications in the United States, the PRC and other countries related to novel technologies and drug candidates that we consider are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the 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 *interpartes* 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

Table of Contents

identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

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

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength than do those in the United States. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as U.S. federal and state laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drugs made using our inventions in and into the United States or non-U.S. jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the United States. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

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

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

Table of Contents

and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent rights or other intellectual property rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent rights or other intellectual property rights do not cover the technology in question. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we initiate legal proceedings against a third party to enforce our patent, or any patents that may issue in the future from our patent applications, that relates to one of our drug candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as inventors or co-inventors. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose rights such as exclusive ownership of, or right to use, our patent rights or other intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including *inter partes* review, post-grant review, interference and *ex parte* reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, or oppositions and other comparable proceedings in non-U.S.

Table of Contents

jurisdictions. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to prevent us from commercializing such drug candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Third parties who bring successful claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement or misappropriation against us, we may have to pay substantial damages, including treble damages and attorneys fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. We cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms, and we may fail to obtain any of these licenses on commercially reasonable terms, if at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Specifically, we are aware of three U.S. patents owned by Ono Pharmaceutical Co., or Ono, and licensed to Bristol-Myers Squibb Co., or BMS, that are relevant to our BGB-A317 drug candidate. These patents are expected to expire in 2023, 2023 and 2024, respectively. In patent infringement actions filed in Delaware Federal District court, BMS and Ono are alleging that Merck & Co. s KEYTRUDA product, a humanized anti-PD-1 antibody is infringing these U.S. patents. Although Merck has challenged the validity of these patents, the litigation is at an early stage and the outcome is uncertain. Merck also filed an opposition proceeding challenging a corresponding European patent at the European Patent Office, or EPO. The EPO s Opposition Division disagreed with Merck s arguments and maintained the European patent in the form in which it was granted. Merck has appealed the decision. If the validity of the relevant claims in these U.S. patents is upheld and our BGB-A317 drug candidate is approved for sale in the United States before the expiration of these patents, then we will need a license from BMS in order to commercialize our BGB-A317 drug candidate in the United States prior to their expiration. In addition, depending upon circumstances, we may need a license for jurisdictions outside the United States where we wish to commercialize BGB-A317 before the expiration of a corresponding patent covering BGB-

Table of Contents

A317. There can be no assurance that we will be able to obtain such a license, which could materially and adversely affect our business.

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

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical personnel, management personnel, or both from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of the ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

Table of Contents

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

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

In most countries in which we file, including the United States, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords, is limited. Even if patents covering our drug candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. If patents are issued on our currently pending patent applications, the resulting patents will be expected to expire on dates ranging from 2031 to 2035, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patent or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

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

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by

the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme

Table of Contents

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

Table of Contents

area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications, including the rights to prosecute patent applications and to enforce patents. Certain of these license agreements impose and, for a variety of purposes, we may enter into additional licensing and funding arrangements with third parties that also may impose, diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties on net product sales of our drug candidates once commercialized, pay a percentage of sublicensing revenues, make other specified payments relating to our drug candidates or pay license maintenance and other fees. We also have diligence and clinical development obligations under certain of these agreements that we are required to satisfy. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Risks related to our reliance on third parties

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, CFDA, EMA and other comparable regulatory authorities for all of our drugs in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, CFDA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority,

such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP

Table of Contents

regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially influence our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

We expect to rely on third parties to manufacture at least a portion of our drug candidate supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our drug candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we currently have a facility that may be used as our clinical-scale manufacturing and processing facility, we intend to at least partially rely on outside vendors to manufacture supplies and process our drug candidates. We have not yet caused our drug candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our drug candidates. 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.

Table of Contents

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

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

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

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drugs.

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

- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects.

- 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

Table of Contents

to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

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

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

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

We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. For example, in 2013, we entered into collaboration agreements with Merck KGaA pursuant to which we have agreed to license the ex-China rights of BGB-283 to Merck KGaA as discussed further in the section of our Annual Report titled Item 1 Business Collaboration with Merck KGaA. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and

Table of Contents

third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates;

- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and

- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

Table of Contents

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 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 June 30, 2016, we had over 250 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;

Table of Contents

- managing our internal development efforts effectively, including the clinical and FDA or other comparable regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our drug candidates and begin commercializing those drugs in the United States, our potential exposure under U.S. laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as 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.

Table of Contents

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 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 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 GAAP and SEC rules and regulations;

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

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

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

Table of Contents

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;
- 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;

Table of Contents

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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

Although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act, or FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery laws of other jurisdictions, particularly China. As our business has expanded, the applicability of the FCPA and other anti-bribery laws to our operations has increased. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

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

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

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

We and third parties, such as our CRO, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We also store certain low level radioactive waste at our facilities until the materials can be properly disposed of. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Table of Contents

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

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

Our operations, and those of our third-party research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We partially rely on third-party manufacturers

to produce and process our drug candidates. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. A large portion of our operations is located in a single facility in Changping, Beijing, PRC. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss,

Table of Contents

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 hold $5 million in product liability coverage in the aggregate, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future

Table of Contents

corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

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

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

Because we intend to market drugs, if approved, globally, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

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

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

- unexpected changes in laws and regulatory requirements in local jurisdictions;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;

- inadequate intellectual property protection in certain countries;

- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges;

- the effects of applicable local tax regimes and potentially adverse tax consequences; and

- significant adverse changes in local currency exchange rates.

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

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

Table of Contents

be materially and adversely affected by the global economic downturn and the slowdown of the U.S. or Chinese economy.

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

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

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

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

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

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

Table of Contents

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

- achieving adequate or clinical-grade materials that meet FDA, CFDA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;

- shortages of qualified personnel, raw materials or key contractors; and

- ongoing compliance with cGMP regulations and other requirements of the FDA, CFDA, EMA or other comparable regulatory agencies.

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

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

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

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

In addition to the similar manufacturing risks described in Risks related to our reliance on third parties, if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA, CFDA, EMA or and other comparable regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our

product sales if and when we are able to successfully commercialize one or more of our drug candidates.

Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages;

Table of Contents

- damage to or destruction of either facility due to natural disasters;
- regional power shortages;
- product tampering; or
- terrorist activities.

Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property and equipment in the amount of up to RMB 84 million. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

Risks related to our doing business in the PRC

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

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

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

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

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

Table of Contents

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

Table of Contents

implementation. The draft Foreign Investment Law, if enacted as proposed, may materially impact the viability of our current corporate governance if we, in the future, have PRC shareholders.

Among other things, the draft Foreign Investment Law expands the definition of foreign investment and introduces the principle of actual control in determining whether a company is considered a foreign-invested enterprise, or an FIE. The draft Foreign Investment Law specifically provides that entities established in China but controlled by foreign investors will be treated as FIEs, whereas an entity set up in a foreign jurisdiction would nonetheless be, upon market entry clearance by the Ministry of Commerce or its local counterparts, treated as a PRC domestic investor provided that the entity is controlled by PRC entities and/or citizens. In this connection, control is broadly defined in the draft law to cover the following summarized categories: (1) holding 50% 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.

Table of Contents

We believe that four of our shareholders, each of whom owns our ordinary shares as a result of exercising share options, are PRC residents under SAFE Circular 37. These four shareholders have undertaken to (i) apply to register with local SAFE branch or its delegated commercial bank as soon as possible after exercising their options, and (ii) indemnify and hold harmless us and our subsidiaries against any loss suffered arising from their failure to complete the registration. We do not have control over the four shareholders and our other beneficial owners and cannot assure you that all of our PRC-resident beneficial owners have complied with, and will in the future comply with, SAFE Circular 37 and subsequent implementation rules. The failure of PRC-resident beneficial owners to register or amend their SAFE registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future PRC-resident beneficial owners of our company to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our PRC subsidiaries to fines and legal sanctions. Furthermore, SAFE Circular 37 is unclear how this regulation, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant PRC government authorities, and we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiaries and limit our PRC subsidiaries ability to distribute dividends to us. These risks could in the future have a material adverse effect on our business, financial condition and results of operations.

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

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

Table of Contents

may also limit our ability to make payments under our equity incentive plans or receive dividends or sales proceeds related thereto, or our ability to contribute additional capital into our wholly-foreign owned enterprises in China and limit our wholly-foreign owned enterprises ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law.

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

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

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

Under PRC laws, rules and regulations, each of our subsidiaries incorporated in China is required to set aside a portion of its net income each year to fund certain statutory reserves. These reserves, together with the registered equity, are not distributable as cash dividends. As a result of these laws, rules and regulations, our subsidiaries incorporated in China are restricted in their ability to transfer a portion of their respective net assets to their shareholders as dividends. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each operating subsidiary. As of June 30, 2016, these restricted assets totaled RMB 23.7 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.

Table of Contents

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

Under the EIT Law an enterprise established outside China with de facto management bodies within China is considered a resident enterprise, meaning that it is treated in a manner similar to a Chinese enterprise for EIT purposes. The implementing rules of the EIT Law define de facto management bodies as management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: senior management personnel and departments that are responsible for daily production, operation and management; financial and personnel decision-making bodies; key properties, accounting books, company seal, and minutes of board meetings and shareholders meetings; and half or more of senior management or directors having voting rights. On July 27, 2011, the SAT issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration. In 2014, the SAT, released the Announcement of the SAT on Issues Concerning the Recognition of Chinese-Controlled Enterprises Incorporated Overseas as Resident Enterprises on the Basis of Their Actual Management Bodies and supplemented some provisions on the administrative procedures for the recognition of resident enterprise, while the standards used to classify resident enterprises in Circular 82 remain unchanged.

Although BeiGene, Ltd. does not have a PRC enterprise or enterprise group as our primary controlling shareholder and is therefore not a Chinese-controlled offshore incorporated enterprise within the meaning of Circular 82, in the absence of guidance specifically applicable to us, we have applied the guidance set forth in Circular 82 to evaluate the tax residence status of BeiGene, Ltd. and its subsidiaries organized outside the PRC.

We are not aware of any offshore holding company with a corporate structure similar to ours that has been deemed a PRC resident enterprise by the PRC tax authorities. Accordingly, we do not believe our company or any of our overseas subsidiaries should be treated as a PRC resident enterprise.

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

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

If we are deemed a PRC resident enterprise as described under We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and be subject to PRC tax on our worldwide taxable income at a rate of 25%, dividends paid on our ordinary shares or ADSs, and any gain realized from the transfer of our ordinary shares or ADSs, may be treated as income derived from sources within the PRC. As a result, dividends paid to non-PRC resident enterprise ADS holders or shareholders may be subject to PRC withholding tax at a rate of 10% (or 20% in the case of

non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprises ADS holders or shareholders from the transfer of our ordinary shares or ADSs may be subject to PRC tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders). It is unclear whether if we or any of our subsidiaries established outside China are considered a PRC resident enterprise, holders of the ADSs or ordinary

Table of Contents

shares would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas. If dividends payable to our non-PRC investors, or gains from the transfer of the ADSs or ordinary shares by such investors are subject to PRC tax, the value of your investment in the ADSs or ordinary shares may decline significantly.

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

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7, which replaced or supplemented certain previous rules under the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises, or Circular 698, issued by the SAT, on December 10, 2009. Pursuant to this Bulletin, an indirect transfer of PRC taxable assets, including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a reasonable commercial purpose of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be reported on with the enterprise income tax filing of the PRC establishment or place of business being transferred, and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC enterprise income tax at the rate of 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC enterprise income tax pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. As such, the sale of the ADSs or ordinary shares on a public stock exchange will not be subject to PRC enterprise income tax pursuant to Bulletin 7. However, the sale of our ordinary shares or ADSs by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Bulletin 7.

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

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

93

Table of Contents

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.

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 the 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.

Table of Contents

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

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

If our independent registered public accounting firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to 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.

Table of Contents

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

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

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

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

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

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

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

- the results of our testing and clinical trials;

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

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

- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- 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;

Table of Contents

- 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.

As of August 8, 2016, the holders of approximately 281,354,176 ordinary shares, or 65.8%, 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.

Table of Contents

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

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

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

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

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

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

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

The trading market for the ADSs 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

Table of Contents

United States. In particular, the Cayman Islands has a less developed body of securities law than the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

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

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

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

We are incorporated in the Cayman Islands and currently conduct substantially all of our operations outside the United States through our subsidiaries. Some of our directors and executive officers reside outside the United States and a substantial portion of their assets are located outside of the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the Cayman Islands or in China in the event that you believe that your rights have been infringed under the securities laws of the United States or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and China may render you unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

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

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

Table of Contents

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

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

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

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

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

Our amended and restated memorandum and articles of association provide that any shareholder bringing an unsuccessful action against us may be obligated to reimburse us for any costs we have incurred in connection with such unsuccessful action.

Our amended and restated memorandum and articles of association provide that under certain circumstances the fees, costs, and expenses that we incur in connection with actions or proceedings brought by any person or entity, which we refer to as claiming parties, may be shifted to such person or entity. If a claiming party asserts any claim; initiates any proceeding; or joins, offers substantial assistance to, or has a direct financial interest in any claim or proceeding against us (including any proceeding purportedly filed on behalf of us or any shareholder), and such claiming party (or the third party that received substantial assistance from a claiming party or in whose claim or proceeding such claiming party has a direct financial interest) is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails, then such claiming party may, to the fullest extent permissible by law, be obligated jointly and severally to reimburse us for all fees, costs, and expenses, including but not limited to all reasonable attorneys fees and other litigation expenses, that we may incur in connection with such claim, suit, action, or proceeding.

Fee-shifting articles are relatively new and untested in both the Cayman Islands and the United States. The case law and potential legislative action on fee-shifting articles are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such articles. For example, it is unclear whether our ability to invoke our fee-shifting article in connection with claims under the federal securities laws, including claims related to 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

Table of Contents

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, 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.

Table of Contents

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

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

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 66.4% of our outstanding ordinary shares as of August 8, 2016. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our company, which could have the dual

effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and reducing the price of the ADSs. These actions may be taken even if they are opposed by our other shareholders, including the holders of the ADSs. In addition, these persons could divert business opportunities away from us to themselves or others.

Table of Contents

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 ADSs or ordinary shares. A U.S. shareholder who makes an effective QEF election generally must

Table of Contents

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 become one in the future. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of proceeds

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 statement 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 $166.2 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses of approximately $16.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

Table of Contents

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.

Item 3. **Defaults Upon Senior Securities.**

None.

Item 4. **Mine Safety Disclosures.**

Not applicable.

Item 5. **Other Information.**

Not applicable.

Item 6. **Exhibits.**

See the Exhibit Index on the page immediately following the signature page to this Quarterly Report for a list of the exhibits filed as part of this Quarterly Report, which Exhibit Index is incorporated herein by reference.

Table of Contents

SIGNATURES

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

BEIGENE, LTD.

Date: August 10, 2016

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

Date: August 10, 2016

By: /s/ Howard Liang
Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
3.1	Fourth Amended and Restated Memorandum and Articles of Incorporation of the Registrant, as currently in effect	8-K	02/11/2016	3.1	
4.1	Deposit Agreement dated February 5, 2016 by and among the Registrant, the Depositary and holders of the American Depositary Receipts	8-K	02/11/2016	4.1	
4.2	Amendment No. 1 to Deposit Agreement, dated April 11, 2016, by and among the Registrant, Citibank, N.A. and holders of the American Depositary Receipts	8-K	04/11/2016	4.1	
4.3	Form of American Depositary Receipt (included in Exhibit 4.2)	8-K	04/11/2016	4.2	
4.4	Specimen Certificate for Ordinary Shares	S-1	12/09/2015	4.3	
4.5	Second Amended and Restated Investors Rights Agreement, dated as of April 21, 2015, by and among the Registrant and certain shareholders named therein	S-1	10/16/2015	4.4	
4.6	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	S-1	01/27/2016	10.21	
4.7	Letter Agreement, dated as of July 11, 2016, between the Registrant and Citibank, N.A.				X
10.1	Lease Agreement, dated as of April 10, 2016, between the Registrant and Suzhou Industrial Park Biotech Development Co., Ltd (English Translation)	10-Q	05/12/2016	10.5	
10.2	Separation Agreement and Release, dated as of April 28, 2016, by and between the Registrant and RuiRong Yuan	10-Q	05/12/2016	10.6	
10.3	Employment Agreement, dated as of April 28, 2016, by and between BeiGene USA, Inc. and Ji Li				X
10.4#	Supplemental Agreement to the Entrusted Loan Contract, dated as of June 11, 2016, by and between BeiGene (Suzhou) Co., Ltd.; Suzhou Industrial Park Biotech Development Co., Ltd.; and China Construction Bank Suzhou Industrial Park Branch				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X

Table of Contents

101	The following materials from Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, formatted in eXtensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Loss; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to the Condensed Consolidated Financial Statements.	X

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

* Furnished herewith.

Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Quarterly Report on Form 10-Q and have been filed separately with the U.S. Securities and Exchange Commission.