BeiGene, Ltd.
Form 10-Q
November 13, 2017
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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	KY1-1108
(Address of principal executive offices)	(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 No

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 No

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

Large accelerated filer		Accelerated Filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

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

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

As of November 8, 2017, 591,072,330 ordinary shares, par value $0.0001 per share, were outstanding, of which 377,568,555 ordinary shares were held in the form of 29,043,735 American Depositary Shares, each representing 13 ordinary shares.

Table of Contents

BeiGene, Ltd.

Quarterly Report on Form 10-Q

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BEIGENE, LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	As of September 30, 2017 $ (unaudited)	December 31, 2016 $ (audited)
Assets			
Current assets:			
Cash and cash equivalents		208,510	87,514
Short-term investments	5	548,925	280,660
Accounts receivable		10,521	—
Unbilled receivable		170,950	—
Inventories	6	5,712	—
Prepaid expenses and other current assets		17,712	6,225
Total current assets		962,330	374,399
Property and equipment, net	7	55,322	25,977
Land use right, net	8	12,251	—
Intangible assets, net	9	7,437	—
Goodwill	9	1,984	—
Deferred tax assets	10	7,684	768
Other non-current assets		2,051	4,669
Total non-current assets		86,729	31,414
Total assets		1,049,059	405,813
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		35,168	11,957
Accrued expenses and other payables	11	46,991	22,297
Deferred revenue, current portion		9,132	—
Tax payable	10	2,852	804
Current portion of long-term bank loan	14	9,018	—
Total current liabilities		103,161	35,058
Non-current liabilities:			
Long-term bank loan	14	9,018	17,284
Shareholder loan	15	140,311	—
Deferred revenue, non-current portion		29,477	
Deferred tax liabilities	10	1,859	—
Other long-term liabilities		744	564
Total non-current liabilities		181,409	17,848

Total liabilities		284,570	52,906
Commitments and contingencies	24		
Equity:			
Ordinary shares (par value of US$0.0001 per share; 9,500,000,000 shares authorized; 589,772,330 shares issued and outstanding as of September 30, 2017 (December 31, 2016: 9,500,000,000 shares authorized; 515,833,609 shares issued and outstanding))		59	52
Additional paid-in capital		981,237	591,213
Accumulated other comprehensive income /(loss)	20	38	(946)
Accumulated deficit		(231,194)	(237,412)
Total BeiGene, Ltd. shareholders' equity		750,140	352,907
Noncontrolling interest	21	14,349	—
Total equity	22	764,489	352,907
Total liabilities and equity		1,049,059	405,813

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. Dollars ("$"), except for number of shares and per share data)

(Unaudited)

	Note	Three Months Ended September 30,		Nine Months Ended September 30,	
		2017	2016	2017	2016
		$	$	$	$
Revenue					
Product revenue, net	17	8,822	—	8,822	—
Collaboration revenue	3	211,391	—	211,391	1,070
Total revenues		220,213	—	220,213	1,070
Expenses					
Cost of sales - product		(1,944)	—	(1,944)	—
Research and development		(87,660)	(30,106)	(177,678)	(69,100)
Selling, general and administrative		(15,641)	(4,722)	(35,187)	(11,760)
Amortization of intangible assets		(63)	—	(63)	—
Total expenses		(105,308)	(34,828)	(214,872)	(80,860)
Income /(loss) from operations		114,905	(34,828)	5,341	(79,790)
Interest (expense)/income, net		(1,785)	(75)	(3,581)	336
Changes in fair value of financial instruments	12	—	—	—	(1,514)
(Loss)/gain on sale of available-for-sale securities		—	(137)	10	(1,077)
Other income/(expense), net		1,103	(327)	1,531	732
Income/(loss) before income tax expense		114,223	(35,367)	3,301	(81,313)
Income tax benefit /(expense)	10	3,061	(127)	2,680	(306)
Net income /(loss)		117,284	(35,494)	5,981	(81,619)
Less: Net loss attributable to noncontrolling interest		(102)	—	(237)	—
Net income /(loss) attributable to BeiGene, Ltd.		117,386	(35,494)	6,218	(81,619)
Net income/(loss) per share attributable to BeiGene, Ltd.	18				
Basic (in dollars per share)		0.21	(0.08)	0.01	(0.21)
Diluted (in dollars per share)		0.20	(0.08)	0.01	(0.21)
Weighted-average shares used in net income/(loss) per share calculation	18				
Basic (in shares)		547,546,656	428,137,509	527,329,985	383,472,372
Diluted (in shares)		600,612,680	428,137,509	561,237,818	383,472,372
Net income /(loss) per American Depositary Share ("ADS")					
Basic (in dollars per ADS)		2.79	(1.08)	0.15	(2.77)

Diluted (in dollars per ADS)	2.54	(1.08)	0.14	(2.77)

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

Table of Contents

BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	$	$	$	$
Net income /(1oss)	117,284	(35,494)	5,981	(81,619)
Other comprehensive income /(loss), net of tax of nil:				
Foreign currency translation adjustments	341	377	985	(13)
Unrealized holding gain, net	51	121	58	857
Comprehensive income /(loss)	117,676	(34,996)	7,024	(80,775)
Less: Comprehensive loss attributable to noncontrolling interests	(70)	—	(178)	—
Comprehensive income /(loss) attributable to BeiGene, Ltd.	117,746	(34,996)	7,202	(80,775)

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. Dollars ("$"), except for number of shares and per share data)

(Unaudited)

	Note	Nine Months Ended September 30, 2017	2016
		$	$
Operating activities			
Net income /(loss)		5,981	(81,619)
Adjustments to reconcile net income/(loss) to net cash used in operating activities:			
Depreciation and amortization expense		2,704	1,436
Share-based compensation expense	19	26,401	6,678
Changes in fair value of financial instruments		—	1,514
Loss on disposal of property and equipment		85	—
Non-cash interest expense		4,796	118
Deferred income tax benefits		(5,871)	—
Other non-cash expenses		(10)	1,077
Changes in operating assets and liabilities:			
Accounts receivable		(10,521)	—
Unbilled receivable		(170,950)	—
Inventories		(5,712)	—
Prepaid expenses and other current assets		(10,967)	(2,183)
Other non-current assets		(635)	(1,281)
Accounts payable		21,420	(1,839)
Advances from customers		—	(1,070)
Accrued expenses and other payables		22,371	13,360
Tax payable		1,122	294
Deferred revenue		38,609	—
Other long-term liabilities		180	142
Net cash used in operating activities		(80,997)	(63,373)
Investing activities			
Purchases of property and equipment		(27,441)	(15,440)
Payment for the acquisition of land use right		(12,354)	—
Cash acquired in business combination, net of cash paid	4	19,916	—
Purchase of available-for-sale securities		(464,065)	(193,996)
Proceeds from sale or maturity of available-for-sale securities		245,928	158,307
Investment in time deposits		(50,061)	—
Net cash used in investing activities		(288,077)	(51,129)
Financing activities			
Proceeds from public offering, net of underwriter discount		189,191	169,409
Payment of public offering cost		(674)	(1,478)
Proceeds from sale of ordinary shares, net of cost		149,928	—
Proceeds from long-term loan		—	12,161

Proceeds from short-term loan	13	2,470	—
Repayment of short-term loan	13	(2,470)	—
Capital contribution from noncontrolling interest	21	14,527	—
Proceeds from shareholder loan	15	132,757	—
Proceeds from exercise of warrants and options		—	2,115
Proceeds from option exercises		1,579	3
Net cash provided by financing activities		487,308	182,210
Effect of foreign exchange rate changes, net		2,762	(45)
Net increase in cash and cash equivalents		120,996	67,663
Cash and cash equivalents at beginning of period		87,514	17,869
Cash and cash equivalents at end of period		208,510	85,532
Supplemental cash flow disclosures:			
Income taxes paid		1,429	25
Interest expense paid		940	510
Non-cash activities:			
Discount provided on sale of ordinary shares for business combination	4	23,606	—
Conversion of Senior Promissory Note		—	14,693
Conversion of deferred rental		—	980
Conversion of convertible preferred shares		—	176,084
Exercise of warrants and options		—	3,687
Initial public offering costs accrued in accrued expenses and other payables		—	166
Acquisitions of equipment included in accounts payable		1,482	319

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 (“$”) and Renminbi (“RMB”), except for number of shares and per share data)

(Unaudited)

1. Organization

BeiGene, Ltd. (the “Company”) is a globally focused, commercial-stage biopharmaceutical company dedicated to becoming a leader in the discovery, development and commercialization 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. The Company completed its initial public offering (“IPO”) on the NASDAQ Global Select Market on February 8, 2016 and has completed subsequent follow-on public offerings and a sale of ordinary shares to Celgene Switzerland LLC (“Celgene Switzerland”) in a business development transaction, as described in Note 22, Shareholders’ Equity.

As at September 30, 2017, the Company’s subsidiaries are as follows:

Name of Company	Place of Incorporation	Date of Incorporation	Percentage of Ownership by the Company	Principal Activities
BeiGene (Hong Kong) Co., Limited.("BeiGene HK")	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	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.("BeiGene (USA)")	United States	July 8, 2015	100 %	Clinical trial activities
BeiGene (Shanghai) Co., Ltd. (“BeiGene (Shanghai)”)	PRC	September 11, 2015	100 %	Medical and pharmaceutical research

BeiGene Biologics Co., Ltd. ("BeiGene Biologics")	PRC	January 25, 2017	95	%	Biologics manufacturing
BeiGene Guangzhou Biologics Manufacturing Co., Ltd. ("BeiGene Guangzhou Factory")	PRC	March 3, 2017	95	%	Biologics manufacturing
BeiGene (Guangzhou) Co., Ltd.	PRC	July 11, 2017	100	%	Medical and pharmaceutical research
BeiGene Pharmaceutical (Shanghai) Co., Ltd. (BeiGene Pharmaceutical (Shanghai))*	PRC	December 15, 2009	100	%	Medical and pharmaceutical consulting, marketing and promotional services
BeiGene Switzerland GmbH	Switzerland	September 6, 2017	100	%	Clinical trial activities and commercial
BeiGene Ireland Limited	Republic of Ireland	August 11, 2017	100	%	Clinical trial activities

* On August 31, 2017, BeiGene HK acquired 100% of the equity interest of Celgene Pharmaceutical (Shanghai) Co., Ltd., which has been renamed BeiGene Pharmaceutical (Shanghai) Co., Ltd.

Manufacturing facility in Guangzhou

On March 7, 2017, BeiGene HK, a wholly owned subsidiary of the Company, and Guangzhou GET Technology Development Co., Ltd. (“GET”), entered into a definitive agreement to establish a commercial scale biologics manufacturing facility in Guangzhou, Guangdong Province, PRC.

On March 7, 2017, BeiGene HK and GET entered into an Equity Joint Venture Contract (the “JV Agreement”). Under the terms of the JV Agreement, BeiGene HK agreed to make an initial cash capital contribution of RMB200,000 and a subsequent contribution of one or more biologics assets in exchange for a 95% equity interest in BeiGene Biologics. GET agreed to provide a cash capital contribution of RMB100,000 to BeiGene Biologics, representing a 5% equity interest in BeiGene Biologics. In addition, on March 7, 2017, BeiGene Biologics entered into a contract with GET, under which GET agreed to provide a RMB900,000 loan (the “Shareholder Loan”) to BeiGene Biologics (see footnote 15). BeiGene Biologics is working to establish a biologics manufacturing facility in Guangzhou, through a wholly-owned subsidiary, the BeiGene Guangzhou Factory, to manufacture biologics for the Company and its subsidiaries.

Table of Contents

On April 11, 2017, BeiGene HK, GET and BeiGene Biologics amended the JV agreement and the capital contribution agreement, among other things, to adjust the capital contribution schedules and adjust the initial term of the governing bodies and a certain management position. On April 13, 2017 and May 4, 2017, BeiGene HK made cash capital contributions of RMB137,830 and RMB2,415, respectively, into BeiGene Biologics. The remainder of the cash capital contribution from BeiGene HK to BeiGene Biologics will be paid by April 10, 2020. On April 14, 2017, GET made cash capital contributions of RMB100,000 into BeiGene Biologics. On April 14, 2017, BeiGene Biologics drew down the Shareholder Loan of RMB900,000 from GET (as further described in Note 15). As of September 30, 2017, the Company and GET held 95% and 5% equity interests in BeiGene Biologics, respectively.

As of September 30, 2017, the Company's cash and cash equivalents included $91,577 of cash held by BeiGene Biologics to be used to build the commercial scale biologics facility and to fund research and development of the Company's biologics drug candidates in China.

2. Summary of significant accounting policies

Basis of presentation and principles of consolidation

The accompanying condensed consolidated balance sheet as of September 30, 2017, the condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2017 and 2016, the condensed consolidated statements of cash flows for the nine months ended September 30, 2017 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, 2016 ("Annual Report").

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 nine months ended September 30, 2017 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. All significant intercompany transactions and balances between the Company and its subsidiaries are eliminated upon consolidation.

Noncontrolling interests are recognized to reflect the portion of the equity of subsidiaries which are not attributable, directly or indirectly, to the controlling shareholders. The Company consolidates BeiGene Biologics under the voting model and recognizes GET's equity interest as a noncontrolling interest in its consolidated financial statements.

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, estimating sales rebates and returns allowance to arrive at net product revenues, identifying separate accounting units and estimating the best estimate of selling price of each deliverable in the Company's revenue arrangements, estimating the fair value of net assets acquired in business combinations, assessing the impairment of long-lived assets, share-based compensation expenses, inventory, realizability of deferred tax assets and the fair value of financial instruments. Management bases the estimates on historical experience, known trends 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.

Table of Contents

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.

Accounts receivable

Trade accounts receivable are recorded at their invoiced amounts, net of allowances for doubtful accounts. An allowance for doubtful accounts is recorded when the collection of the full amount is no longer probable. In evaluating the collectability of receivable balances, the Company considers specific evidence including aging of the receivable, the customer's payment history, its current creditworthiness and current economic trends. Accounts receivable are written off after all collection efforts have ceased. No allowance for doubtful accounts was recorded as of September 30, 2017. The Company regularly reviews the adequacy and appropriateness of an allowance for doubtful accounts.

As of September 30, 2017 the Company had $10,521 in accounts receivable as a result of the sale of the Company's approved cancer therapies in the PRC, which are in-licensed from Celgene Coporation ("Celgene"), to the Company's distributors.

Inventory

Inventories are stated at the lower of cost and net realizable value, with cost determined on a weighted-average basis. The Company periodically analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded in the consolidated statements of operations.

Land use right, net

The land use right represents lease prepayments to the local Bureau of Land and Resources in Guangzhou. The land use right is carried at cost less accumulated amortization. Amortization is provided to write off the cost of lease prepayments on a straight-line basis over the shorter of the estimated usage periods or the terms of the land use, which is currently 50 years.

Business combination

The Company accounts for its business combinations using the acquisition method of accounting in accordance with ASC topic 805 ("ASC 805"): Business Combinations. The acquisition method of accounting requires all of the following steps: (i) identifying the acquirer, (ii) determining the acquisition date, (iii) recognizing and measuring the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree and (iv) recognizing and measuring goodwill or a gain from a bargain purchase. The consideration transferred in a business combination is measured as the aggregate of the fair values at the date of exchange of the assets given, liabilities incurred, and equity instruments issued as well as the contingent considerations and all contractual contingencies as of the acquisition date. The costs directly attributable to the acquisition are expensed as incurred. Identifiable assets, liabilities and contingent liabilities acquired or assumed are measured separately at their fair value as of the acquisition date, irrespective of the extent of any noncontrolling interests. The excess of (i) the total of cost of acquisition, fair value of the noncontrolling interests and acquisition date fair value of any previously held equity

interest in the acquiree over (ii) the fair value of the identifiable net assets of the acquiree, is recorded as goodwill. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognized directly in the consolidated statements of operations as a gain.

Table of Contents

The Company allocates the fair value of purchase consideration to the tangible assets acquired, liabilities assumed and intangible assets acquired based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of these identifiable assets and liabilities is recorded as goodwill. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Significant estimates in valuing certain intangible assets may include, but are not limited to, future expected cash flows from acquired assets, timing and probability of success of clinical events and regulatory approvals, and assumptions on useful lives and discount rates. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

Goodwill and other intangible assets

Goodwill is as asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. The Company allocates the cost of an acquired entity to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The excess of the purchase price for acquisitions over the fair value of the net assets acquired, including other intangible assets, is recorded as goodwill. Goodwill is not amortized, but is tested for impairment at least annually or more frequently if events or changes in circumstances would indicate a potential impairment.

For its goodwill impairment analysis, the Company operates with a single reporting unit. The Company tests goodwill for impairment on the last day of each fiscal year and whenever events or changes in circumstances indicate that the carrying amount of the reporting unit may exceed its fair value. The Company first assesses the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount, including goodwill, and performs a quantitative assessment if it is determined that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. Under the quantitative test, if the carrying amount of the reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit. The Company has an unconditional option to bypass the qualitative assessment and proceed directly to performing the quantitative goodwill impairment test.

Intangible assets acquired through business acquisitions are recognized as assets separate from goodwill and are measured at fair value upon acquisition. Acquired identifiable intangible assets consist of the distribution rights with respect to approved cancer therapies licensed from Celgene, ABRAXANE®, REVLIMID®, and VIDAZA®, and its investigational agent CC-122 and are amortized on a straight-line basis over the estimated useful lives of the assets, which are 10 years.

Intangible assets with finite useful lives are tested for impairment when events or circumstances occur that could indicate that the carrying amount of an asset may not be recoverable. When these events occur, the Group evaluates the recoverability of the intangible assets by comparing the carrying amount of the assets to the future undiscounted cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected undiscounted cash flows is less than the carrying amount of the assets, the Group recognizes an impairment loss based on the excess of the carrying amount of the assets over their fair value. Fair value is generally determined by discounting the cash flows expected to be generated by the assets, when the market prices are not readily available.

Revenue recognition

Product revenue

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has transferred to the customer, the price is fixed or determinable,

collection from the customer has been reasonably assured, all performance obligations have been met, and returns and allowances can be reasonably estimated. Product sales are recorded net of estimated rebates , estimated product returns and other deductions. Provisions for estimated reductions to revenue are provided for in the same period the related sales are recorded and are based on the sales terms, historical experience and trend analysis.

Table of Contents

Rebates are offered to distributors, consistent with pharmaceutical industry practices. The Company records a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include the level of distributor inventories, sales volumes and contract pricing and estimated acceptance of government pricing or reimbursement amounts (such as provincial acceptance of the National Reimbursement Drug List (“NRDL”) pricing in the PRC). The Company regularly reviews the information related to these estimates and adjust the provision accordingly.

The Company bases its sales returns allowance on estimated distributor inventories, customer demand as reported by third party sources, and actual returns history, as well as other factors, as appropriate. If the historical data the Company uses to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Any changes from the historical trend rates are considered in determining the current sales return allowance.

Collaboration revenue

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

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

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

Product development, royalties and commercial event payments, collectively referred to as target payments, under collaborative arrangements are triggered either by the results of our research and development efforts, achievement of regulatory goals or by specified sales results by a third-party collaborator. Under ASC 605-28, Milestone Method of Revenue Recognition, an accounting policy election can be made to recognize a payment that is contingent upon the

achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The Company elected not to adopt the milestone method of revenue recognition under ASC 605-28.

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

Table of Contents

revenue upon achievement of the respective development target. Royalties based on reported sales of licensed products will be recognized as collaboration revenue based on contract terms when reported sales are reliably measurable and collectability is reasonably assured. Targets related to commercial activities may be triggered upon events such as first commercial sale of a product or when sales first achieve a defined level. Since these targets would be achieved after the completion of our development activities, the Company would account for the commercial event targets in the same manner as royalties, with collaboration revenue recognized upon achievement of the target.

Fair value measurements

Fair value of financial instruments

Financial instruments of the Company primarily include cash and cash equivalents, short-term investments, accounts receivable, long-term bank loan, Shareholder Loan and accounts payable. As of September 30, 2017 and December 31, 2016, the carrying values of cash and cash equivalents, accounts receivable and accounts payable approximated their fair values due to the short-term maturity of these instruments. The short-term investments represented the available-for-sale debt securities and time deposits. The available-for-sale debt securities are recorded at fair value based on quoted prices in active markets with unrealized gain or loss recorded in other comprehensive income or loss. The long-term bank loan and Shareholder Loan approximate their fair values due to the fact that the related interest rates approximate the rates currently offered by financial institutions for similar debt instruments of comparable maturities. The warrants issued prior to the IPO relating to the convertible promissory notes and the option to purchase shares by rental deferral were exercised in January 2016 and February 2016. The Company determined the exercise date fair value of the warrants and option 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.

Table of Contents

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 September 30, 2017 and December 31, 2016:

As of September 30, 2017	Quoted Price in Active Market for Identical Assets (Level 1) $	Significant Other Observable Inputs (Level 2) $	Significant Unobservable Inputs (Level 3) $
Short-term investment (note 5):			
U.S. Treasury securities	498,864	—	—
Time deposits	50,061	—	—
Cash equivalents:			
Money market funds	51,928	—	—
Total	600,853	—	—

As of December 31, 2016	Quoted Price in Active Market for Identical Assets (Level 1) $	Significant Other Observable Inputs (Level 2) $	Significant Unobservable Inputs (Level 3) $
Short-term investment (note 5):			
U.S. Treasury securities	280,660	—	—
Cash equivalents:			
Money market funds	44,052	—	—
Total	324,712	—	—

Recent accounting pronouncements

In August 2015, the Financial Accounting Standards Board (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 in 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 anticipates adopting the new standard under the modified retrospective approach, effective January 1, 2018. The Company is continuing to assess the potential impact that ASC 606 may have on its financial position and results of operations as it relates to its collaboration agreements with Celgene and Merck KGaA, Darmstadt Germany. The Company expects that certain of its accounting conclusions will require further judgment. Further, the Company is continuing to analyze the potential impacts of the adoption of the new standard on its condensed consolidated financial

Table of Contents

statements and related disclosures. While the Company is still in the process of evaluating the impact of adoption on its existing collaboration agreements, the Company currently believes that the impact of adoption of the new standard to its financial statements will not be material. The Company will also continue to monitor additional modifications, clarifications or interpretations undertaken by the FASB that may impact its current conclusions, and will expand its analysis to include any new revenue arrangements initiated prior to 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 cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. The Company is currently evaluating the financial statement impact of adoption.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The Company will adopt ASU 2016-16 in its first quarter of 2018 utilizing the modified retrospective adoption method. The ultimate impact of adopting ASU 2016-16 will depend on the balance of intellectual property transferred between its subsidiaries as of the adoption date. The Company will recognize incremental deferred income tax expense thereafter as these deferred tax assets are utilized.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations: Clarifying the Definition of a Business. The new standard requires an entity to evaluate if substantially all the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets; if so, the set would not be considered a business. The new standard also requires a business to include at least one substantive process and narrows the definition of outputs. The new standard is effective for interim and annual periods beginning on January 1, 2018, and may be adopted earlier. The Company elected to early adopt the updated guidance. The standard is applied prospectively to any transaction occurring on or after the adoption date. The Company evaluated the acquisition of 100% of the equity interests of Celgene Pharmaceutical (Shanghai) Co., Ltd. (“Celgene Shanghai”) under the new guidance, and determined that the transaction represents a business combination, as disclosed further in Note 4.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other: Simplifying the Test for Goodwill Impairment. This ASU simplifies the test for goodwill impairment by removing Step 2 from the goodwill impairment test. Companies will now perform the goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount, recognizing an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value not to exceed the total amount of goodwill allocated to that reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The amendments in this update are effective for goodwill impairment tests in fiscal years beginning after December 15, 2019, with early adoption permitted for goodwill impairment tests performed after January 1, 2017. The Company elected to early adopt this ASU, and there was no material impact to the Company’s consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation: Scope of Modification Accounting. This standard provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation-Stock Compensation, to a change to the terms or conditions of a share-based payment award. The updated guidance is effective for interim and annual periods beginning after December 15, 2017, and early adoption is permitted. This ASU is not expected to have a material impact on the Company’s consolidated financial statements.

3. Research and development collaborative arrangements

To date, the Company's collaboration revenue has consisted of 1) upfront license fees from its collaboration agreement with Celgene on the Company's investigational anti-programmed cell death protein1 ("PD-1") inhibitor,

Table of Contents

BGB-A317 and 2) upfront license fees, reimbursed research and development expenses and milestone payments from its collaboration agreement with Merck KGaA, Darmstadt Germany on BGB-290 and BGB-283.

Celgene and Celgene Switzerland

On July 5, 2017, the Company entered into a license agreement with Celgene Switzerland pursuant to which the Company granted to the Celgene parties an exclusive right to develop and commercialize the Company's PD-1 inhibitor, BGB-A317, in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia (the "PD-1 License Agreement"). In connection with the closing of the transactions on August 31, 2017, the Company, Celgene and Celgene Switzerland amended and restated the PD-1 License Agreement (the "A&R PD-1 License Agreement") to, among other things, clarify the parties' responsibilities relating to the conducting and funding of certain global registration clinical trials and clarify the scope of the regulatory materials transferred by BeiGene to Celgene.

Under the terms of the A&R PD-1 License Agreement, Celgene agreed to pay the Company $263,000 in upfront non-refundable license fees, of which $92,050 was paid in the third quarter of 2017 and the remaining $170,950 is due in December 2017. In addition, subsequent to the completion of the research and development phase of the collaboration, the Company may be eligible to receive product development milestone payments based on the successful achievement of development and regulatory goals, commercial milestone payments based on the successful achievement of commercialization goals, and royalty payments based on a predetermined percentage of Celgene and Celgene Switzerland's aggregate annual net sales of all products in their territory for a period not to exceed the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity or 12 years from the date of the first commercial sale on a product-by-product and country-by-country basis. The Company allocated the $13,000 of upfront fees to the fair value of assets related to the Company's acquisition of Celgene Shanghai, a wholly-owned subsidiary of Celgene Holdings East Corporation established under the laws of China, that was completed contemporaneously with the A&R PD-1 License Agreement.

In addition to the exclusive right to develop and commercialize BGB-A317, the terms of the A&R PD-1 License Agreement provide Celgene with the right to collaborate with the Company on the development of BGB-A317 for specified indications, including required participation on a joint development committee and a joint steering committee as well as a joint commercialization committee upon achievement of commercialization. The joint development and joint steering committees are formed by an equal number of representatives from the Company and Celgene and are responsible for reviewing and approving the development plan and budget for the development of BGB-A317 for clinical studies associated with specified indications. Celgene will reimburse the Company for certain research and development costs at a cost plus agreed upon markup for the development of BGB-A317 related to the clinical trials that Celgene opts into, as outlined in the development plan.

Under ASC 605, the Company identified the following deliverables of the collaboration agreement with stand-alone value, which are accounted for as separate units of accounting: (a) the license provided to Celgene for the exclusive right to develop and commercialize BGB-A317, in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia ("the license"); and (b) the research and development services provided to Celgene to develop BGB-A317 within specified indications ("R&D services"). For each deliverable, the Company determined the BESP and allocated the non-contingent consideration of $250,000 to the units of accounting using the relative selling price method. The consideration allocated to the license was recognized upon transfer of the license to Celgene at contract inception and the consideration allocated to the R&D services will be recognized over the term of the respective clinical studies for the specified indications.

For the payments associated with the defined developmental, regulatory, and commercialization goals, the Company determined that upon achievement of the developmental, regulatory, and commercialization goals, such payments will

be allocated to the separate deliverables using the initial allocation based on the relative selling price method. Further, the sales-based milestones and royalty payments will be recognized when reported sales are reliably measurable and collectability is reasonably assured.

Table of Contents

For the three and nine months ended September 30, 2017, the Company recognized $211,391 as license revenue within collaboration revenue in the Company's condensed consolidated statements of operations. The consideration allocated to the R&D services, $38,609, is recorded as deferred revenue in balance sheet as of September 30, 2017 and will be recognized over the term of the respective clinical studies for the specified indications.

Merck KGaA, Darmstadt Germany

In March 2017, the Company regained the worldwide rights to BGB-283 after Merck KGaA, Darmstadt Germany informed the Company that it would not exercise a continuation option under the parties' collaboration agreement, and thus, that agreement has terminated in its entirety, except for certain provisions that will survive the termination.

Revenue recognized in the three and nine months ended September 30, 2016, was related to Phase 1 research and development fees from the Company's BRAF inhibitor, in accordance with the collaboration agreement with Merck KGaA Darmstadt Germany. Phase 1 services were completed by mid-2016 and as a result, all of the advance payments received from the collaboration have been recognized. For the three and nine months ended September 30, 2017, the company did not recognize any research and development revenue, and for the three and nine months ended September 30, 2016, the Company recognized nil and $1,070, respectively, as research and development revenue within collaboration revenue in the Company's condensed consolidated statements of operations.

The following table summarizes the components of total collaboration revenue recognized for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	$	$	$	$
License revenue	211,391	—	211,391	—
Research and development revenue	—	—	—	1,070
Total	211,391	—	211,391	1,070

4. Business Combination

On August 31, 2017, BeiGene HK acquired 100% of the equity interests of Celgene Shanghai, a wholly-owned subsidiary of Celgene Holdings East Corporation established under the laws of the PRC. Celgene Shanghai is in the business of, among other things, providing marketing and promotional services in connection with certain pharmaceutical products manufactured by Celgene. The name of Celgene Shanghai has been changed to BeiGene Pharmaceutical (Shanghai).

On July 5, 2017, BeiGene and a wholly-owned subsidiary of Celgene, Celgene Logistics Sàrl ("Celgene Logistics"), entered into a license agreement pursuant to which BeiGene has been granted the right to exclusively distribute and promote Celgene's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®, and its investigational agent CC-122 in clinical development (the "Distribution Rights"), in China excluding Hong Kong, Macau and Taiwan (the "Chinese License Agreement"). The China License Agreement became effective on August 31, 2017 contemporaneously with the closing of the acquisition of Celgene Shanghai and the A&R PD-1 License Agreement.

The Company evaluated the acquisition of the Celgene Shanghai equity and the distribution rights acquired under ASU No. 2017-01, Business Combinations: Clarifying the Definition of a Business. Because substantially all of the value of the acquisition did not relate to a similar group of assets and the business contained both inputs and processes necessary to manage products and provide economic benefits directly to its owners, it was determined that the acquisition represents a business combination. Therefore, the transaction has been accounted for using the acquisition method of accounting. This method requires that assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date.

Table of Contents

Share Subscription Agreement

On August 31, 2017, the Company closed the sale of 32,746,416 of its ordinary shares to Celgene Switzerland for an aggregate cash price of $150,000, or $4.58 per ordinary share, or $59.55 per ADS, pursuant to the Share Subscription Agreement dated July 5, 2017 by and between BeiGene and Celgene Switzerland (the "Share Subscription Agreement"). See Note 22 for further description of the Share Subscription Agreement.

Determination of Purchase Price

The purchase price of Celgene Shanghai is calculated as $28,138, and is comprised of cash consideration of $4,532 and non-cash consideration of $23,606, related to the discount on ordinary shares issued to Celgene in connection with the Share Subscription Agreement. The discount was a result of the increase in fair value of the Company's shares between the fixed price of $59.55 per ADS in the Share Subscription Agreement and the fair value per ADS as of August 31, 2017. The following summarizes the purchase price in the business combination (in thousands).

	Purchase Price
Cash paid to acquire Celgene Shanghai	$ 4,532
Discount on Share Subscription Agreement	23,606
Total purchase price	$ 28,138

Purchase Price Allocation

The following table summarized the estimated fair values of assets acquired and liabilities assumed (in thousands):

		Amount
Cash and cash equivalents	$	24,448
Other current assets		518
Property and equipment, net		204
Intangible assets		7,500
Deferred tax asset		1,069
Total identifiable assets		33,739
Current liabilities		(5,710)
Deferred tax liability		(1,875)
Total liabilities assumed		(7,585)
Goodwill		1,984
Total fair value of consideration transferred	$	28,138

The Company's accounting for this acquisition is preliminary. The fair value estimates for the assets acquired and liabilities assumed are subject to change as additional information becomes available concerning the fair value and tax basis of the assets acquired and liabilities assumed. Any additional adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from the date of acquisition. The goodwill resulting from the business combination is primarily attributable to the assembled workforce of the acquired business. The goodwill attributable to the business combination is not deductible for tax purposes.

Table of Contents

The following summarizes the business combination as presented on the statement of cash flows (in thousands):

Investing activities	
Cash acquired	$ 24,448
Cash paid to acquire Celgene Shanghai	(4,532)
Cash acquired in business combination, net of cash paid	$ 19,916
Non-cash activities	
Discount provided on sale of ordinary shares for business combination	$ (23,606)

5. Short-term investments

Short-term investments as of September 30, 2017 consisted of the following available-for-sale debt securities and time deposits:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
	$	$	$	$
U.S. Treasury securities	498,905	—	41	498,864
Time deposits	50,061	—	—	50,061
Total	548,966	—	41	548,925

Short-term investments as of December 31, 2016 consisted of the following available-for-sale debt securities:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
	$	$	$	$
U.S. Treasury securities	280,757	—	97	280,660
Total	280,757	—	97	280,660

Contractual maturities of all debt securities as of September 30, 2017 were within one year. The Company does not consider the investment in U.S. Treasury securities to be other-than-temporarily impaired at September 30, 2017. The cost of securities sold is based on the specific identification method.

6. Inventories

The Company’s inventory balance of $5,712 as of September 30, 2017 consisted entirely of finished goods product purchased from Celgene for distribution in the PRC.

Table of Contents

7. Property and equipment

Property and equipment consisted of the following:

	As of September 30, 2017 $	December 31, 2016 $
Laboratory equipment	14,612	7,536
Manufacturing equipment	13,380	—
Leasehold improvements	12,758	9,446
Electronic equipment	1,234	647
Office equipment	1,135	449
Computer software	713	317
Property and equipment, at cost	43,832	18,395
Less accumulated depreciation	(12,535)	(7,473)
Construction in progress	24,025	15,055
Property and equipment, net	55,322	25,977

Construction in progress as of September 30, 2017 of $24,025 primarily relates to the buildout of the Guangzhou manufacturing facility. Construction in progress as of December 31, 2016 primarily related to the BeiGene Suzhou manufacturing and laboratory facility that was put into service in the third quarter of 2017. In the three months ended September 30, 2017, assets totaling $21,400 related to the Suzhou facilities were transferred to laboratory equipment, manufacturing equipment and leasehold improvements from construction in progress. Depreciation expense for the three and nine months ended September 30, 2017 was $1,237 and $2,641, respectively. Depreciation expense for the three and nine months ended September 30, 2016 was $505 and $1,436, respectively.

8. Land use right, net

The land use right represents the land acquired for the purpose of constructing and operating the biologics manufacturing facility in Guangzhou. In 2017, the Company acquired the land use right from the local Bureau of Land and Resources in Guangzhou. The land use right is amortized over the remaining term of the right. The land use right asset as of September 30, 2017 and December 31, 2016 is summarized as follows:

	As of September 30, 2017 $	December 31, 2016 $
Land use right, cost	12,354	—
Accumulated amortization	(103)	—

Land use right, net	12,251	—

Amortization expense of the land use right for the three and nine months ended September 30, 2017 was $103, which was charged to construction in process. Amortization expense of the land use right for the three and nine months ended September 30, 2016 was nil.

As of September 30, 2017, expected amortization expense for the land use right is approximately $62 for the remainder of 2017, $247 in 2018, $247 in 2019, $247 in 2020, $247 in 2021 and $11,201 in 2022 and thereafter.

Table of Contents

9. Intangible assets and Goodwill

Intangible assets outstanding as of September 30, 2017 and December 31, 2016 are summarized as follows:

	September 30, 2017			December 31, 2016		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Product distribution rights	7,500	(63)	7,437	—	—	—
Total finite-lived intangible assets	7,500	(63)	7,437	—	—	—

Product distribution rights consist of distribution rights on the approved cancer therapies licensed from Celgene, ABRAXANE®, REVLIMID®, and VIDAZA®, and its investigational agent CC-122 acquired as part of the Celgene transaction.

Amortization expense for the three and nine months ended September 30, 2017 was $63 and $63, respectively.

As of September 30, 2017, expected amortization expense for the unamortized finite-lived intangible assets is approximately $188 for the remainder of 2017, $750 in 2018, $750 in 2019, $750 in 2020, $750 in 2021, and $4,249 in 2022 and thereafter.

Goodwill

The changes in the carrying amount of goodwill in the nine months ended September 30, 2017 were as follows:

	$
Balance as of December 31, 2016	—
Goodwill related to acquisition of the Celgene Shanghai business	1,984
Foreign currency translation adjustments	—
Balance as of September 30, 2017	1,984

10. Income taxes

Income tax benefit was $3,061 and $2,680, respectively, for the three and nine months ended September 30, 2017. Income tax expense was $127 and $306, respectively, for the three and nine months ended September 30, 2016. The income tax benefit for the three months ended September 30, 2017 was primarily attributable to the effect of estimated realized research and development tax credits and the U.S. Orphan Drug Credit.

As of September 30, 2017, the Company had a net liability for unrecognized tax benefits included in the balance sheet of $634. We recognize interest and, if applicable, penalties related to unrecognized tax benefits in the provision for

income taxes. We believe we have appropriately provided for all tax uncertainties.

The Company recorded a full valuation allowance against deferred tax assets related to net operating losses and other deductible temporary differences in all of its subsidiaries, except for BeiGene (USA) and BeiGene Pharmaceutical (Shanghai). As of September 30, 2017, deferred tax assets of $7,684 were primarily related to deductible temporary differences on share-based compensation expense, depreciation and accruals and deferred tax liabilities of $1,859 were primarily related to deductible temporary differences on intangible assets acquired in the business combination. In the nine months ended September 30, 2017, income tax benefit was comprised of a deferred tax benefit of $5,871 and tax expense of $3,191. Taxes payable totaled $2,852 and $804 as of September 30, 2017 and December 31, 2016, respectively.

Table of Contents

The Company conducts business in a number of tax jurisdictions and, as such, are required to file income tax returns in multiple jurisdictions globally. The years 2015 and 2016 remain open for examination by the United States Internal Revenue Service and the years 2010 through 2016 remain open for examination in the various states and non-US tax jurisdictions in which the Company file tax returns.

11. Accrued expenses and other payables

Accrued expenses and other payables consisted of the following:

	As of September 30, 2017	December 31, 2016
	$	$
Compensation related	9,342	3,980
External research and development activities related	25,267	14,198
Sales rebates and returns related	1,697	—
Professional fees and other	10,685	4,119
Total accrued expenses and other payables	46,991	22,297

12. Warrants and option liabilities

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 was a freestanding instrument and was recorded as liability in accordance with ASC 480, Distinguishing Liabilities from Equity. The Option was initially recognized at fair value with subsequent changes in fair value recorded in losses. 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 the Option of $2,540 was determined based on its intrinsic value, which equaled the difference between the share price at the IPO closing date and the exercise price of such purchased ordinary shares. During the three and nine months ended September 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 to 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 2016 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 at the time of the IPO. As the exercise dates were very close to the IPO closing date, the respective exercise date fair value of the warrants of $1,148 was determined based on the intrinsic value, which equaled the difference between the share price at the IPO closing date and the exercise price of the issued warrants.

For the three and nine months ended September 30, 2016, the Company recognized a loss from the increase in fair value of the warrants of nil and $363, respectively.

Table of Contents

13. Short-term loan

On March 28, 2017, BeiGene Biologics borrowed a RMB denominated short-term loan with a principal amount of $2,470 from GET. The loan was interest-free and was a temporary borrowing for the payment of a land auction deposit. The land was expected to be acquired for building the biologics manufacturing facility in Guangzhou. On April 14, 2017, the short-term loan was fully settled.

14. Long-term bank loan

On September 2, 2015, BeiGene (Suzhou) entered into a loan agreement with Suzhou Industrial Park Biotech Development Co., Ltd. and China Construction Bank to borrow $18,036 at a 7% fixed annual interest rate. As of September 30, 2017, the Company has drawn down the entire $18,036, which is secured by BeiGene (Suzhou)'s equipment with a carrying amount of $23,263 and the Company's rights to a PRC patent on a drug candidate. The loan principal amounts of $9,018 and $9,018 are repayable on September 30, 2018 and 2019, respectively. Interest expense recognized for the three and nine months ended September 30, 2017 amounted to $321 and $936, respectively.

15. Shareholder Loan

On March 7, 2017, BeiGene Biologics entered into the Shareholder Loan Contract with GET, pursuant to which GET agreed to provide a shareholder loan of RMB900,000 to BeiGene Biologics. The Shareholder Loan has a conversion feature, settled in a variable number of shares of common stock upon conversion (the "debt-to-equity conversion"). On April 14, 2017, BeiGene Biologics drew down the entire Shareholder Loan of RMB900,000 from GET.

Key features of the Shareholder Loan

The Shareholder Loan bears interest at a fixed rate of 8% per annum and compounding interest shall not apply. No accrued interest is due and payable prior to the repayment of the principal or the debt-to-equity conversion. The term of the Shareholder Loan is 72 months, commencing from the actual drawdown date of April 14, 2017 and ending on April 13, 2023, unless converted earlier.

The Shareholder Loan can only be used for BeiGene Biologics, including the construction and operation of the biologics manufacturing facility and research and development and clinical trials to be carried out by BeiGene Biologics. If BeiGene Biologics does not use the Shareholder Loan proceeds for the specified purposes, GET may be entitled to certain liquidated damages. In the event of an early termination of the JV Agreement, the Shareholder Loan will become due and payable at the time of termination of the JV Agreement.

The Shareholder Loan may be repaid or converted, either partially or in full, to an additional mid-single digit percentage equity interest in BeiGene Biologics prior to its maturity date, pursuant to the terms of the JV Agreement. BeiGene Biologics has the right to make early repayment at any time; provided, however, that if repayment is to occur before the debt-to-equity conversion it would require written approval of both BeiGene Biologics and GET. Upon conversion of the shareholder loan, GET will receive an additional equity interest in BeiGene Biologics, which will be based on the formula outlined in the JV Agreement.

Accounting for the Shareholder Loan

The Shareholder Loan is classified as a long-term liability and initially measured at the principal of RMB900,000. Interest will be accrued based on the interest rate of 8% per annum. As the Shareholder Loan may be share-settled by a number of shares with a fair value equal to a fixed settlement amount, the settlement is not viewed as a conversion feature, but as a redemption feature because the settlement amount does not vary with the share price. This in-substance redemption feature does not require bifurcation because it is clearly and closely related to the debt host that does not involves a substantial premium or discount. Since there is no conversion feature embedded in the Shareholder Loan, no beneficial conversion feature was recorded. There are no other embedded derivatives that are required to be bifurcated.

Table of Contents

The portion of interest accrued on the Shareholder Loan related to borrowings used to construct the BeiGene factory in Guangzhou is being capitalized in accordance with ASC 835-20, Interest – Capitalization of Interest.

For the three and nine months ended September 30, 2017, total interest expense generated from the Shareholder Loan was $2,690 and $4,929, respectively, among which, $125 and $129 were capitalized, respectively.

16. Related party balances and transactions

During the three and nine months ended September 30, 2017, a shareholder, who is also a director, provided consulting services to the Company at a fee of $25 and $75, respectively. During the three and nine months ended September 30, 2016, a shareholder, who is also a director, provided consulting services to the Company at a fee of $25 and $75, respectively.

17. Product revenue, net

The Company’s product sales are derived from the sale of ABRAXANE® and REVLIMID®, in China under a distribution license from Celgene. The table below presents the Company’s net product sales for the three and nine months ended September 30, 2017 and 2016.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	$	$	$	$
Product revenue - gross	10,521	—	10,521	—
Less: Rebate and sales return	(1,699)	—	(1,699)	—
Product revenue - net	8,822	—	8,822	—

18. Net income/(loss) per share

Net income/(loss) per share was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	$	$	$	$
Basic net income/(loss) per share				

Numerator:				
Net income/(loss) attributable to BeiGene, Ltd. ordinary shareholder	117,386	(35,494)	6,218	(81,619)
Denominator:				
Weighted average shares outstanding	547,546,656	428,137,509	527,329,985	383,472,372
Basic net income/(loss) per share	0.21	(0.08)	0.01	(0.21)
Diluted net income/(loss) per share				
Numerator:				
Net income/(loss) attributable to BeiGene, Ltd. ordinary shareholder	117,386	(35,494)	6,218	(81,619)
Denominator:				
Number of shares used in basic computation	547,546,656	428,137,509	527,329,985	383,472,372
Weighted average effect of dilutive shares:				
Employee stock options and restricted stock units	51,838,863	—	32,802,202	—
Non-employee stock options	1,227,161	—	1,105,631	—
Number of shares used in per share computation	600,612,680	428,137,509	561,237,818	383,472,372
Diluted net income/(loss) per share	0.20	(0.08)	0.01	(0.21)

Table of Contents

For the three and nine months ended September 30, 2017, basic net income per share was computed using the weighted-average number of ordinary shares outstanding during the period. Diluted net income per share was computed using the weighted-average number of ordinary shares and the effect of potentially dilutive shares outstanding during the periods. Potentially dilutive shares consist of stock options and restricted stock units. The dilutive effect of outstanding stock options and restricted stock units is reflected in diluted net income per share by application of the treasury stock method.

For the three and nine months ended September 30, 2016, the computation of basic earnings /(loss) per share using the two-class method was not applicable as the Company was in a net loss position.

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 September 30, 2016. The effects of all convertible preferred shares, share options, restricted shares, warrants and options to purchase ordinary or preferred shares were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive during the nine months ended September 30, 2016.

19. 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 the 2016 Share Option and Incentive Plan (the “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 Option Plan (the “2011 Plan”), and not subject to any outstanding options as of the effective date of the 2016 Plan, along with underlying share awards under the 2011 Plan that are cancelled or forfeited without issuance of ordinary shares. As of September 30, 2017, ordinary shares cancelled or forfeited under the 2011 Plan that were provided back to the 2016 Plan totaled 4,857,136. The 2016 Plan provides for an annual increase in the shares available for issuance, to be added on the first day of each fiscal year, beginning on January 1, 2017 and continuing until the expiration of the 2016 Plan, equal to the lesser of (i) five percent (5%) of the outstanding shares of the Company’s ordinary shares on the last day of the immediately preceding fiscal year or (ii) such number of shares determined by the Company’s board of directors or the compensation committee. On January 1, 2017, 25,791,680 ordinary shares were added to the 2016 Plan under this provision. The number of shares available for issuance under the 2016 Plan is subject to adjustment in the event of a share split, share dividend or other change in the Company’s capitalization.

During the nine months ended September 30, 2017, the Company granted 60,450,462 options, with an exercise price per ordinary share equal to 1/13 of the closing price of the Company’s ADS quoted on the NASDAQ Stock Exchange on the applicable grant date, 1,212,411 restricted stock units and 300,000 restricted ordinary shares under the 2016 Plan. As of September 30, 2017, options and restricted stock units outstanding totaled 130,809,417 and 1,212,411, respectively.

During the nine months ended September 30, 2017 and 2016, no grants to employees and non-employees were made outside of the Company’s 2011 Plan and 2016 Plan.

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. Restricted shares and restricted stock units vest over a four-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 yearly basis thereafter.

Modification

Upon the completion of the Company's IPO on February 8, 2016, a consultant became a member of the Company's board of directors. On April 1, 2017, another consultant became an employee of the Company. Under the terms of the original option agreements, the individuals retain the option grants on a change in status; hence, there is no modification to account for. The fair value of the options granted by the Company to the consultants was re-measured as of

Table of Contents

February 8, 2016 and April 1, 2017, respectively. The compensation charges have been accounted for prospectively over the remaining vesting period. There were no other material modifications to the Company's share option arrangements for all the periods presented.

The following table summarizes total share-based compensation expense recognized for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	$	$	$	$
Research and development	10,382	2,135	19,660	5,178
Selling, general and administrative	2,945	644	6,741	1,500
Total	13,327	2,779	26,401	6,678

20. Accumulated other comprehensive income/(loss)

The movement of accumulated other comprehensive income/(loss) was as follows:

	Foreign Currency Translation Adjustments	Unrealized Losses on Available-for-Sale Securities	Total
	$	$	$
Balance as of December 31, 2016	(847)	(99)	(946)
Other comprehensive income before reclassifications	926	68	994
Amounts reclassified from accumulated other comprehensive income	—	(10)	(10)
Net-current period other comprehensive income	926	58	984
Balance as of September 30, 2017	79	(41)	38

21. Noncontrolling interest

As of September 30, 2017, a noncontrolling interest of $14,349 was recognized in the Company's condensed consolidated balance sheet, representing the capital cash contribution by GET in BeiGene Biologics in the nine months ended September 30, 2017, offset by comprehensive losses attributable to GET's noncontrolling interest in BeiGene Biologics.

For the three and nine months ended September 30, 2017, net losses of $102 and $237, respectively, attributable to the noncontrolling interest of BeiGene Biologics were recognized in the Company's condensed consolidated statements of operations, based on GET's 5% equity interest in BeiGene Biologics.

Table of Contents

Reconciliation for the equity attributable to noncontrolling interests for the nine months ended September 30, 2017 is as follows:

	BeiGene, Ltd. Shareholders' Equity	Non-controlling Interest	Total Equity
	$	$	$
Balance as of January 1, 2017	352,907	—	352,907
Net income/(loss)	6,218	(237)	5,981
Issuance of ordinary shares in secondary follow-on offering, net of transaction costs	188,517	—	188,517
Equity purchase by Celgene, net of transaction costs	149,928	—	149,928
Discount on the sale of ordinary shares to Celgene	23,606	—	23,606
Contributions from shareholders	—	14,527	14,527
Share-based compensation	26,401	—	26,401
Exercise of options	1,579	—	1,579
Other comprehensive income, net of tax of nil:			
Foreign currency translation adjustments	926	59	985
Unrealized holding gain, net	58	—	58
Other comprehensive income, net of tax of nil	984	59	1,043
Balance as of September 30, 2017	750,140	14,349	764,489

22. Shareholders' equity

Initial public offering

On February 8, 2016, the Company completed its 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 ordinary share (the "IPO Price"). Additionally, the underwriters exercised their options to purchase an additional 990,000 ADSs representing 12,870,000 ordinary shares from the Company. Net proceeds from the IPO including underwriter option after deducting underwriting discounts and offering expenses were $166,197.

Follow-on public offerings

On November 23, 2016, the Company completed a follow-on public offering at a price of $32.00 per ADS, or $2.46 per ordinary share. In this offering, the Company sold 5,781,250 ADSs representing 75,156,250 ordinary shares. Additionally, the underwriters exercised their option to purchase an additional 850,000 ADSs representing 11,050,000 ordinary shares from the Company. The selling shareholders sold 468,750 ADSs representing 6,093,750 ordinary shares. Net proceeds from this offering including underwriter option after deducting the underwriting discounts and offering expenses were $198,625. The Company did not receive any proceeds from the sale of the shares by the selling shareholders.

On August 16, 2017, the Company completed a follow-on public offering at a price of $71.00 per ADS, or $5.46 per ordinary share. In this offering, the Company sold 2,465,000 ADS representing 32,045,000 ordinary shares. Additionally, the underwriters exercised their option to purchase an additional 369,750 ADSs representing 4,806,750 ordinary shares from the Company. Net proceeds from this offering including underwriter option after deducting the

underwriting discounts and offering expenses were $188,517.

Table of Contents

Share Subscription Agreement

On August 31, 2017, the Company sold 32,746,416 of its ordinary shares to Celgene Switzerland for an aggregate cash price of $150,000, or $4.58 per ordinary share, or $59.55 per ADS, pursuant to the Share Subscription Agreement in connection with the entry into the A&R PD-1 License Agreement. Proceeds from the issuance are recorded net of $72 of fees related to the share issuance. The offer and sale of the shares issued pursuant to the Share Subscription Agreement was made in a private placement in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act, for transactions by an issuer not involving a public offering, and/or Regulation D under the Securities Act. All certificates evidencing the shares will bear a standard restrictive legend under the Securities Act.

Conversion of Preferred Shares and Senior Promissory Note

Upon completion of the IPO in 2016, 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 in 2016.

Exercise of warrants and option

In January 2016 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 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 in 2016.

23. 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 September 30, 2017 and December 31, 2016, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to $25,037 and $9,955, respectively.

24. Commitments and contingencies

Operating lease commitments

The Company leases office and manufacturing facilities under non-cancelable operating leases expiring on different dates in the United States and China. Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases. There are no restrictions placed upon the Company by entering into these leases. Total expenses under these operating leases were $1,065 and $2,486 for the three and nine months ended September 30, 2017, respectively. Total expenses under these operating leases were $748 and $1,373 for the three and nine

months ended September 30, 2016, respectively.

Table of Contents

Future minimum payments under non-cancelable operating leases consist of the following as of September 30, 2017:

	$
Three months ending December 31, 2017	1,676
Year ending December 31, 2018	5,691
Year ending December 31, 2019	5,338
Year ending December 31, 2020	4,118
Year ending December 31, 2021	2,565
Year ending December 31, 2022 and thereafter	3,693
Total	23,081

Capital commitments

The Company had capital commitments amounting to $36,149 for the acquisition of property, plant and equipment as of September 30, 2017, which were mainly for BeiGene Guangzhou Factory’s manufacturing facility in Guangzhou, China.

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," "ongoi "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other similar expressions, althoug 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 with our internally discovered drug candidates and third-party agents; the timing or likelihood of regulatory filings and approvals; the commercialization of our approved cancer therapies licensed from Celgene in China; our ability to develop and effectively maintain sales and marketing capabilities; the pricing and reimbursement of our drug candidates, if approved, and drugs; the implementation of our business model, strategic plans for our business, drug candidates and technology; the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology; our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; cost associated with defending against intellectual property infringement, product liability and other claims; regulatory developments in the United States, China, the United Kingdom, the European Union and other jurisdictions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and our need for additional financing; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our ability to maintain and establish collaborations or obtain additional funding; the rate and degree of market acceptance of our drug candidates and drugs; developments relating to our competitors and our industry, including competing therapies; the size of the potential markets for our drug candidates and drugs 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; statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance; the future trading price of our 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" of this Quarterly Report. 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, commercial-stage biopharmaceutical company dedicated to becoming a leader in the discovery, development and commercialization of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. We believe the next generation of cancer treatment will utilize therapeutics both as

monotherapies and in combination to attack multiple underlying mechanisms of cancer cell growth and survival. We further believe that discovery of next-generation cancer therapies requires new research tools. To that end, we have developed a proprietary cancer biology platform that addresses the importance of tumor-immune system interactions and the value of primary biopsies in developing new models to support our drug discovery effort.

Table of Contents

Our strategy is to develop a pipeline of drug candidates that will have the potential to be best-in-class monotherapies and also be important components of multiple-agent combination regimens. Over the last seven years, using our cancer biology platform, we have developed clinical-stage drug candidates that inhibit the important oncology targets Bruton's tyrosine kinase, or BTK, RAF dimer protein complex and PARP family of proteins, and an immuno-oncology agent that inhibits the immune checkpoint protein receptor PD-1. For each of our molecularly targeted drug candidates, we have established proof-of-concept by observing objective responses in defined patient populations. Globally outside of China, our BTK inhibitor is currently in three registrational trials in the United States, Europe, Australia and other countries. Our PD-1, PARP and RAF dimer inhibitors are currently in the dose-expansion phases of their respective clinical trials. In China, our BTK inhibitor is in three registrational trials and our PD-1 inhibitor is in two registrational trials. Recently, we completed enrollment to the pivotal trial of BGB-3111 in Chinese patients with relapsed/refractory mantle cell lymphoma and the pivotal trial of BGB-A317 in Chinese patients with relapsed/refractory classical Hodgkin's lymphoma. As of August 23, 2017, trials of our four clinical-stage drug candidates, as monotherapies and in combination, have enrolled a total of over 1,500 patients and healthy adults. We have Investigational New Drug, or IND, applications in effect for our BTK, PD 1 and PARP inhibitors with the U.S. Food and Drug Administration, or FDA, and all four of our drug candidates are in clinical testing in China. We believe that each of our clinical-stage drug candidates is the first in its respective class being developed in China under the Category 1.1 domestic regulatory pathway to enter into human testing and to present clinical data. 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 clinical testing in the next 12 months.

Since our inception on October 28, 2010, our operations have focused on organizing and staffing our company, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials, building manufacturing capabilities, business planning and raising capital. Since September 2017, we market ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and are preparing to market VIDAZA® (azaciditine) in China excluding Hong Kong, Macau and Taiwan under a license from Celgene. We have primarily financed operations through a combination of public and private equity and debt financings and public and private grants and contracts, including the net proceeds from our initial public offering and follow-on public offerings, the net proceeds from the issuance of a senior note and convertible promissory note to Merck Sharp & Dohme Research GmbH, or MSD, an affiliate of Merck Sharp & Dohme Corp.; the private placements of our Series A preferred shares and Series A-2 preferred shares; our collaborations with Merck KGaA, Darmstadt Germany; and our collaboration and share subscription agreements with Celgene. On February 8, 2016, we completed our initial public offering and received net proceeds of $166.2 million after deducting underwriter discounts and offering expenses. On November 23, 2016 and August 16, 2017, we completed follow-on public offerings and raised net proceeds of $198.6 million and $188.5 million, respectively, after deducting underwriting discounts and offering expenses. On April 14, 2017, BeiGene Biologics received a cash capital contribution of RMB100 million from GET, and also drew down the Shareholder Loan of RMB900 million from GET for the construction and operation of a biologics manufacturing facility in Guangzhou, China and research and development and clinical trials to be carried out by BeiGene Biologics. On August 31, 2017, we entered into a license agreement with Celgene for our PD-1 inhibitor drug candidate, BGB-A317, under which Celgene agreed to pay us $263 million in up-front license fees, and a share subscription agreement under which Celgene purchased $150 million of our ordinary shares. Although it is difficult to predict our liquidity requirements, based upon our current operating plans, we believe we have sufficient cash to meet our projected operating requirements for at least the next 12 months after the date that the financial statements in this report are issued. See "—Liquidity and Capital Resources."

Since inception we have incurred significant net operating losses. However, for the three months ended September 30, 2017, we earned a profit as a result of the upfront fees allocable to the licensing of rights to BGB-A317 to Celgene. Our net income was $117.3 million and $6.0 million for the three and nine months ended September 30, 2017, respectively. Our net losses were $35.5 million and $81.6 million for the three and nine months ended September 30, 2016, respectively. As of September 30, 2017, we had an accumulated deficit of $231.2 million. During the three

months ended September 30, 2017, we generated revenue from product sales and under our collaboration agreement with Celgene, and 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, selling costs, licensing and acquisitions and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the

Table of Contents

foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue preclinical and clinical development of our programs, including our ongoing and planned registrational trials for BGB-3111, BGB-A317 and BGB-290;
- support potential regulatory filings and registration of our late-stage drug candidates;
- continue investment in our cancer biology platform;
- continue investment in our manufacturing facilities;
- establish and expand our commercial operations;
- hire additional research, development and business personnel;
- support strategic investments and business development activities, including the potential acquisition or licensing of additional technologies, assets or businesses;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional costs associated with supporting our growing organization.

We expect that the revenue we generate from product sales and collaboration agreements will fluctuate from quarter to quarter and year to year, primarily as a result of the timing and amount of license fees, milestones, reimbursement of costs incurred and other payments, and sales of third-party products and sales of internally developed products, 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 $81.0 million and $63.4 million, respectively, for the nine months ended September 30, 2017 and 2016. As of September 30, 2017, we had cash, cash equivalents and short-term investments of $757.4 million, compared with $368.2 million as of December 31, 2016. As of September 30, 2017, our cash and cash equivalents included approximately $91.6 million of cash held by BeiGene Biologics to build a commercial biologics facility in Guangzhou, China and to fund research and development of biologics drug candidates in China.

Recent Developments

On August 31, 2017, we announced the closing of our strategic collaboration with Celgene that the parties previously announced on July 5, 2017, as further described below.

Exclusive License and Collaboration Agreement

On July 5, 2017, we entered into an Exclusive License and Collaboration Agreement (the “PD-1 License Agreement”) with Celgene and its wholly-owned subsidiary, Celgene Switzerland LLC (“Celgene Switzerland”), pursuant to which we granted to the Celgene parties an exclusive right to develop and commercialize our investigational anti-programmed cell death protein 1 (“PD-1”) inhibitor, BGB-A317, in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia. On August 31, 2017, we, Celgene and Celgene Switzerland amended and restated the PD-1 License Agreement (such agreement, the “A&R PD-1 License Agreement”) to, among other things, clarify the parties’ responsibilities relating to the conducting and funding of certain global registration clinical trials and clarify the scope of the regulatory materials transferred by us to Celgene.

Table of Contents

Concurrent with the closing of the other transactions with Celgene and its affiliates, and following the expiration or termination of applicable waiting periods under all applicable antitrust laws, the A&R PD-1 License Agreement became effective as of August 31, 2017 (the "Effective Date"). Celgene is required to pay us $263.0 million in upfront license fees after the effectiveness of the A&R PD-1 License Agreement, $92.0 million of which has been paid to us as of September 30, 2017. The remaining $171.0 million is due on December 1, 2017.

Celgene China Agreements

On the Effective Date, a wholly-owned subsidiary of ours, BeiGene HK, acquired 100% of the equity interests of Celgene Pharmaceutical (Shanghai) Co., Ltd. ("Celgene Shanghai"), a wholly-owned subsidiary of Celgene Holdings East Corporation established under the laws of China. Celgene Shanghai is in the business of, among other things, providing marketing and promotional services in connection with certain pharmaceutical products manufactured by its affiliates. Prior to the Effective Date, Celgene Shanghai separated certain business functions, including regulatory and drug safety, that will continue to support the business acquired by us. In addition, the name of Celgene Shanghai has been changed to BeiGene Pharmaceutical (Shanghai).

On July 5, 2017, we and a wholly-owned subsidiary of Celgene, Celgene Logistics Sàrl ("Celgene Logistics"), entered into a License and Supply Agreement (the "China License Agreement"), pursuant to which we have been granted the right to exclusively distribute and promote Celgene's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®, and Celgene's investigational agent CC-122 in clinical development, in China excluding Hong Kong, Macau and Taiwan. The China License Agreement became effective as of the Effective Date concurrent with the closing of our acquisition of Celgene Shanghai.

Share Subscription Agreement

On the Effective Date, we closed the sale of 32,746,416 of our ordinary shares to Celgene Switzerland for an aggregate cash price of $150.0 million, or $4.58 per ordinary share, or $59.55 per American Depositary Share, pursuant to the Share Subscription Agreement. The offer and sale of the shares issued pursuant to the Share Subscription Agreement was made in a private placement in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act, for transactions by an issuer not involving a public offering, and/or Regulation D under the Securities Act. All certificates evidencing the shares bear a standard restrictive legend under the Securities Act.

The transactions described above were previously disclosed by us in our Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on August 31, 2017.

Components of Operating Results

Revenue

To date, our revenue has consisted of in-licensed product sales revenue, upfront license fees, reimbursed research and development expenses and milestone payments from our strategic collaboration with Celgene and collaboration agreements with Merck KGaA, Darmstadt Germany on BGB-283 and BGB-290. We do not expect to generate significant revenue from internally developed product candidates unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty.

Table of Contents

Strategic Collaboration with Celgene

As described in "—Recent Developments" above, we entered into the A&R PD-1 License Agreement with Celgene and Celgene Switzerland, and the China License Agreement with Celgene Logistics. We recognized revenues for the three and nine months ended September 30, 2017 as follows:

	Three and Nine Months Ended
	September 30, 2017
	(in thousands)
Product revenue, net	$ 8,822
License revenue	211,391
Total	$ 220,213

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has transferred to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured, all performance obligations have been met, and returns and allowances can be reasonably estimated. Product sales are recorded net of estimated rebates, estimated product returns and other deductions. Provisions for estimated reductions to revenue are provided for in the same period the related sales are recorded and are based on the sales terms, historical experience and trend analysis.

Product revenue was $8.8 million for the three months ended September 30, 2017, which related to our distribution and promotion of ABRAXANE® and REVLIMID® in China. We began recognizing product revenue with sales to our distributors in China, beginning in September 2017 following the closing of our strategic collaboration with Celgene. Product revenue is net of accrual for rebates and returns, which totaled $1.7 million as of September 30, 2017. We had no product revenue for the three months ended September 30, 2016.

We are accounting for the A&R PD-1 License Agreement with Celgene under ASC 605, Revenue Recognition ("ASC 605"), and identified the following deliverables of the collaboration agreement with stand-alone value, which are accounted for as separate units of accounting: (a) the license provided to Celgene for the exclusive right to develop and commercialize BGB-A317, in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia ("the license"); and (b) the research and development services provided to Celgene to develop BGB-A317 within specified indications ("R&D services"). For each deliverable, we determined the best estimated selling price ("BESP") and allocated the non-contingent consideration allocated to the A&R PD-1 License Agreement of $250.0 million to the units of accounting using the relative selling price method. The consideration allocated to the license, $211.4 million was recognized upon transfer of the license to Celgene at contract inception and the consideration allocated to the R&D services will be recognized over the term of the respective clinical studies for the specified indications.

For the potential future payments associated with the defined developmental, regulatory, and commercialization goals, we determined that upon achievement of the developmental, regulatory, and commercialization goals, such payments will be allocated to the separate deliverables using the initial allocation based on the relative selling price method. Further, sales-based milestones and royalty payments will be recognized when reported sales are reliably measurable and collectability is reasonably assured.

For the three and nine months ended September 30, 2017, the Company recognized $211.4 million as license revenue within collaboration revenue in the Company's condensed consolidated statements of operations. The consideration

allocated to the R&D services, $38.6 million, is recorded as deferred revenue in the September 30, 2017 balance sheet and will be recognized over the term of the respective clinical studies for the specified indications.

Collaboration with Merck KGaA, Darmstadt Germany

On May 24, 2013, we entered into license agreements with Merck KGaA, Darmstadt Germany on BGB 283, which we amended and restated on December 10, 2013, and further amended on October 1, 2015 and December 3, 2015. In the latest amendment, Merck KGaA, Darmstadt Germany granted us an exclusive license under certain of its intellectual

Table of Contents

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. In March 2017, Merck KGaA, Darmstadt Germany informed us that it would not exercise a continuation option in the ex-PRC Territory, and thus, the ex-PRC BRAF Agreement has terminated in its entirety, except for certain provisions that survive termination. Under these agreements, we received $13.0 million in non-refundable payments in 2013 following their execution, $5.0 million in milestone payments in 2014 and $4.0 million in milestone payments in 2015. We are eligible to receive $14.0 million in payments upon the successful achievement of pre-specified clinical milestones in the PRC Territory. In consideration for the licenses Merck KGaA, Darmstadt Germany granted to us, we are required to pay Merck KGaA, Darmstadt Germany a high single-digit royalty on aggregate net sales of licensed BRAF inhibitors in the PRC Territory.

On October 28, 2013, we entered into license agreements with Merck KGaA, Darmstadt Germany on BGB-290, pursuant to which (1) we granted to Merck KGaA, Darmstadt Germany an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA, Darmstadt Germany 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, Darmstadt Germany granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the licensed PARP inhibitors in the PRC Territory. Under these license agreements, we received $6 million in non-refundable payments in November 2013 following their execution and $9.0 million in milestone payments in 2014. We were eligible to receive up to $7.0 million and $2.5 million, in payments upon the successful achievement of pre-specified clinical and regulatory milestones in the PRC Territory, respectively. On October 1, 2015, pursuant to a purchase of rights agreement, we repurchased all of Merck KGaA, Darmstadt Germany's worldwide rights under the ex-PRC license agreement, in consideration for, among other things, a one-time payment of $10.0 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 $3.0 million of deferred revenue related to PARP as of October 1, 2015 was netted against the $10.0 million repurchase consideration. In consideration for the licenses granted to us, we are required to pay Merck KGaA, Darmstadt Germany a high single-digit royalty percentage on aggregate net sales of licensed products in the PRC Territory. In addition, if Merck KGaA, Darmstadt Germany exercises its PRC commercialization option under certain specified conditions, Merck KGaA, Darmstadt Germany is required to pay us a $50.0 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 as well as royalties on any product sales.

We recognized no collaboration revenue from the Merck KGaA, Darmstadt Germany collaboration for the three and nine months ended September 30, 2017, and $1.4 million and $4.1 million of collaboration revenue from this collaboration for the three and nine months ended September 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, Darmstadt Germany, 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 $3.0 million in deferred revenue that was netted against the $10.0 million repurchase consideration relating to the PARP inhibitors under the ex-PRC license agreement. In accordance with our revenue recognition policy, we have recognized 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 nine months ended September 30, 2017, our revenue was generated from sales of our in-licensed drugs in China and from our collaboration agreement with Celgene. For the three and nine months ended September 30, 2016, substantially all of our revenue was generated solely from our collaboration agreements with Merck KGaA,

Table of Contents

Darmstadt Germany. For the next several years, we expect our revenue will be generated from product revenue from sales of in-licensed drugs in China, potential future milestones under our collaboration agreements with Celgene and Celgene Switzerland, and with Merck KGaA, Darmstadt Germany, if any, and any other strategic relationships we may enter into. If our development efforts are successful and we receive regulatory approval, we may also generate revenue from product sales of our internally developed drug candidates.

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;
- costs of comparator drugs in certain of our clinical trials;
- 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 highly selective small molecule inhibitor of BTK;
- BGB-A317, a humanized monoclonal antibody against PD 1;
- BGB 290, a potent and highly selective 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, it is difficult to estimate or know, for certain, 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;

Table of Contents

- 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 our drug candidates, if and when approved, whether as monotherapies or in combination with our internally discovered drug candidates or third-party products;
- 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 personnel.

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

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, including as we continue to support the clinical trials of BGB 3111, BGB-A317, BGB 290 and BGB 283 as a treatment for various cancers and move these drug candidates into additional clinical trials, including registrational 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of product promotion costs, distribution costs, salaries and related benefit costs, including share-based compensation for selling, general and administrative personnel. Other selling, 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, travel costs, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support increases in commercialization activities, with respect to ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azaciditine) in China and the preparation for launch and potential commercialization of our internally developed drug candidates, if approved. We also expect selling, general and administrative expenses to increase in future periods to support our research and development efforts, 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 clinical trials for other drug candidates. These cost increases will likely be due to increased promotional costs, increased headcount, increased share-based compensation expenses, expanded infrastructure and increased costs for insurance. We also anticipate increased legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company.

Interest Income (Expense), Net

Interest Income

Interest income consists primarily of interest generated from our cash and short-term investments in money markets, time deposits and U.S. Treasury securities.

Table of Contents

Interest Expense

Interest expense consists primarily of interest on our senior promissory note, convertible promissory note, long-term bank loan and Shareholder Loan.

Other Income (Expense), Net

Other income consists primarily of government grants and subsidies received that involve no conditions or continuing performance obligations by us. Other expense consists primarily of loss from property and equipment disposals and donations made to sponsor certain events. Other income (expense) also consists of unrealized gains and losses related to changes in foreign currency exchange rates and realized gains and losses on the sale of investments.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
	(in thousands)					
Product revenue, net	$ 8,822	$ —	$ 8,822	$ 8,822	$ —	$ 8,822
Collaboration revenue	211,391	—	211,391	211,391	1,070	210,321
Total revenue	220,213	—	220,213	220,213	1,070	219,143
Expenses						
Cost of sales - product	(1,944)	—	(1,944)	(1,944)	—	(1,944)
Research and development	(87,660)	(30,106)	(57,554)	(177,678)	(69,100)	(108,578)
Selling, general and administrative	(15,641)	(4,722)	(10,919)	(35,187)	(11,760)	(23,427)
Amortization of intangible assets	(63)	—	(63)	(63)	—	(63)
Total expenses	(105,308)	(34,828)	(70,480)	(214,872)	(80,860)	(134,012)
Income/(loss) from operations	114,905	(34,828)	149,733	5,341	(79,790)	85,131
Interest (expense)/income, net	(1,785)	(75)	(1,710)	(3,581)	336	(3,917)
Changes in fair value of financial instruments	—	—	—	—	(1,514)	1,514
(Loss)/gain on sale of available-for-sale securities	—	(137)	137	10	(1,077)	1,087
Other income/(expense), net	1,103	(327)	1,430	1,531	732	799
Income/(loss) before income tax expense	114,223	(35,367)	149,590	3,301	(81,313)	84,614
Income tax benefit /(expense)	3,061	(127)	3,188	2,680	(306)	2,986

Net income/(loss)	117,284	(35,494)	152,778	5,981	(81,619)	87,600
Less: Net loss attributable to noncontrolling interest	(102)	—	(102)	(237)	—	(237)
Net income/(loss) attributable to BeiGene, Ltd.	$ 117,386	$ (35,494)	$ 152,880	$ 6,218	$ (81,619)	$ 87,837

Table of Contents

Comparison of the Three Months Ended September 30, 2017 and 2016

Revenue

Net product revenue was $8.8 million for the three months ended September 30, 2017, which related to our distribution and promotion of ABRAXANE® and REVLIMID® in China. We had no product revenue for the three months ended September 30, 2016.

Collaboration revenue was $211.4 million for the three months ended September 30, 2017, which was due to revenue recognition related to the license fee under our collaboration agreement with Celgene and Celgene Switzerland with respect to BGB-A317. The portion of the upfront license fee allocated to R&D services, $38.6 million, is recorded as deferred revenue in the September 30, 2017 balance sheet and will be recognized over the term of the respective clinical studies for the specified indications. There was no collaboration revenue for the three months ended September 30, 2016.

Research and Development Expense

Research and development expense increased by $57.6 million, or 191.2%, to $87.7 million for the three months ended September 30, 2017 from $30.1 million for the three months ended September 30, 2016. The following table summarizes external clinical, external preclinical and internal research and development expense for the three months ended September 30, 2017 and 2016, respectively:

	Three Months Ended September 30,		
	2017	2016	Changes
	(in thousands)		
External cost of clinical-stage programs	$ 45,341	$ 15,151	$ 30,190
External cost of preclinical-stage programs	3,602	3,264	338
Internal research and development expenses	38,717	11,691	27,026
Total research and development expenses	$ 87,660	$ 30,106	$ 57,554

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 $17.3 million, $8.1 million and $6.0 million, respectively, for BGB-3111, BGB-A317 and BGB-290, partially offset by a decrease of approximately $1.2 million for BGB-283. The expense increases were primarily due to the expansion of our ongoing clinical development plan, including the initiation of two global Phase 1 and Phase 1b/2 combination trials of BGB-290, the continued enrollment of our three global registrational BGB-3111 trials, the initiation of a pivotal Phase 2 BGB-3111 trial and a Phase 2 BGB-3111 combination trial in China, and the initiation of a registational trial and two Phase 2 combination trials of BGB-A317 in China.

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:

· $8.9 million increase of employee salary and benefits, which was primarily attributable to hiring more research and development personnel to support our expanding research and clinical activities;
· $8.3 million increase of share-based compensation expense ($10.4 million in the three months ended September 30, 2017 compared to $2.1 million in the three months ended September 30, 2016), primarily attributable to our increased

headcount, as well as the increased valuation of non-employee grants;
· $2.6 million increase of materials and reagent expenses, mainly in connection with the in-house manufacture of drug candidates used for clinical purposes, that were previously outsourced and recorded as external cost; and

Table of Contents

· $7.2 million increase of consulting fees, facility and travel expenses, rental fees and other expenses, primarily attributable to the global expansion of our company.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $10.9 million, or 231.2%, to $15.6 million for the three months ended September 30, 2017 from $4.7 million for the three months ended September 30, 2016. The increase was primarily attributable to the following:

· $3.8 million increase of professional fees for legal, consulting, recruiting and audit services, mainly in connection with our patent prosecution activities, consulting services, business development activities, including the Celgene transactions, recruiting services and the preparation of periodic reports;
· $3.0 million increase of employee salary and benefits, which was primarily attributable to the hiring of more personnel to support our growing organization, including the acquired workforce in the acquisition of Celgene's China operations;
· $2.3 million increase of share-based compensation expense, primarily attributable to our increased headcount; and
· $1.8 million increase of facility and travel expenses, rental fees and other selling, administrative expenses, primarily attributable to the global expansion of our business, including the post-combination operating costs of BeiGene Pharmaceutical (Shanghai).

Interest Income (Expense), Net

Interest expense (net) increased by $1.7 million for the three months ended September 30, 2017 as compared to the three months ended September 30, 2016. The increase in interest expense was primarily attributable to interest accrued for the long-term bank loan and Shareholder Loan.

Gain on Sale of Available-for-sale Securities

The gain on sale of available-for-sale securities was nil for the three months ended September 30, 2017, compared to a nominal loss for the three months ended September 30, 2016.

Other Income (Expense), Net

Other income (expense), net, increased by $1.4 million for the three months ended September 30, 2017, compared with the three months ended September 30, 2016. Other income (expense), net primarily consisted of government grants received and foreign currency exchange gains/losses recognized.

Income Tax Benefit (Expense)

Income tax benefit was $3.1 million for the three months ended September 30, 2017 compared with income tax expense of $0.1 million for the three months ended September 30, 2016. The income tax benefit in the three months ended September 30, 2017 was primarily attributable to the effect of estimated realized research and development tax credits and the U.S. Orphan Drug Credit related to BeiGene USA.

Table of Contents

Comparison of the Nine Months Ended September 30, 2017 and 2016

Revenue

Product revenue was $8.8 million for the nine months ended September 30, 2017 and relates to the exclusive distribution and promotion of ABRAXANE® and REVLIMID® in China.

Collaboration revenue increased by $210.3 million to $211.4 million for the nine months ended September 30, 2017 from $1.1 million for the nine months ended September 30, 2016. The increase in revenue was primarily due to revenue recognition related to the license fee under our collaboration agreement with Celgene and Celgene Switzerland with respect to BGB-A317.

Research and Development Expense

Research and development expense increased by $108.6 million, or 157.1%, to $177.7 million for the nine months ended September 30, 2017 from $69.1 million for the nine months ended September 30, 2016. The following table summarizes external clinical, external preclinical and internal research and development expense for the nine months ended September 30, 2017 and 2016, respectively:

	Nine Months Ended September 30,		
	2017	2016	Changes
	(in thousands)		
External cost of clinical-stage programs	$ 92,099	$ 37,221	$ 54,878
External cost of preclinical-stage programs	8,943	5,150	3,793
Internal research and development expenses	76,636	26,729	49,907
Total research and development expenses	$ 177,678	$ 69,100	$ 108,578

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

· increases of approximately $33.4 million, $12.2 million and $11.4 million, respectively, for BGB-3111, BGB-A317 and BGB-290, offset by a decrease of approximately $2.1 million for BGB-283. The expense increases were primarily due to the expansion of our ongoing clinical development plan, including the initiation of two global Phase 1 and Phase 1b/2 combination trials of BGB-290, the continued enrollment of our three global registrational BGB-3111 trials, the initiation of a pivotal Phase 2 BGB-3111 trial and a Phase 2 BGB-3111 combination trial in China, and the initiation of a registrational trial and two Phase 2 combination trials of BGB-A317 in China; and
· increase of approximately $3.8 million in external spending for our preclinical-stage programs, primarily related to costs associated with advancing our next preclinical candidate toward clinical trials.

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:

· $20.7 million increase of employee salaries and benefits, which was primarily attributable to hiring more research and development personnel to support our expanding research and clinical activities;
· $14.5 million increase of share-based compensation expense ($19.7 million in the nine months ended September 30, 2017 compared to $5.2 million in the nine months ended September 30, 2016), primarily attributable to our increased headcount, as well as the increased valuation of non-employee grants;

· $3.6 million increase of materials and reagent expenses, mainly in connection with the in-house manufacture of drug candidates used for clinical purposes, that were previously outsourced and recorded as external cost; and

Table of Contents

· $11.1 million increase of consulting fees, facilities, travel, rental fee and other expenses, primarily attributable to the global expansion of our company.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $23.4 million, or 199.2%, to $35.2 million for the nine months ended September 30, 2017 from $11.8 million for the nine months ended September 30, 2016. The increase was primarily attributable to the following:

· $7.7 million increase of professional fees for legal, consulting, recruiting and audit services, mainly in connection with our patent prosecution activities, consulting services, business development activities, including the Guangzhou joint venture and Celgene transactions, recruiting services and the preparation of periodic reports;
· $6.1 million increase of employee salaries and benefits, which was primarily attributable to hiring of more personnel to support our growing organization, including the acquired workforce in the acquisition of Celgen's China operations;
· $5.2 million increase of share-based compensation expense, primarily attributable to our increased headcount; and
· $4.4 million increase of office, travel, rental fee and other administrative expenses, primarily attributable to the global expansion of our company, including the post-combination operating costs of BeiGene Pharmaceutical (Shanghai).

Interest Income (Expense), Net

Net interest (expense) income decreased by $3.9 million for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016. The decrease was primarily attributable to increase of interest expense from the long-term bank loan and Shareholder Loan.

Changes in Fair Value of Financial Instruments

Loss from changes in fair value of financial instruments was nil for the nine months ended September 30, 2017, compared with $1.5 million for the nine months ended September 30, 2016. The decrease in loss from changes in fair value of financial instruments was primarily attributable to change in the fair value of warrants and option liabilities, both of which were exercised in January 2016 and February 2016 in connection with the IPO.

Gain on Sale of Available-for-sale Securities

The gain on sale of available-for-sale securities was nominal for the nine months ended September 30, 2017, compared to a loss of $1.1 million for the nine months ended September 30, 2016.

Other Income, Net

Net other income increased by $0.8 million to $1.5 million for the nine months ended September 30, 2017 from $0.7 million for the nine months ended September 30, 2016. Net other income primarily consisted of government grants received and foreign currency exchange gains/losses recognized.

Income Tax Expense

Income tax benefit was $2.7 million for the nine months ended September 30, 2017, compared with income tax expense of $0.3 million for the nine months ended September 30, 2016. The income tax benefit in the nine months ended

Table of Contents

September 30, 2017 was primarily attributable to the effect of estimated realized research and development tax credits and the U.S. Orphan Drug Credit related to BeiGene USA.

Liquidity and Capital Resources

Since inception, we have incurred net losses and negative cash flows from our operations except for net income in the current reporting period due to recognition of an up-front license fee under our exclusive license agreement with Celgene. Substantially all of our losses have resulted from funding our research and development programs, selling costs and general and administrative costs associated with our operations. We incurred net income of $117.3 million and $6.0 million, respectively, for the three and nine months ended September 30, 2017, and net loss of $35.5 million and $81.6 million, respectively, for the three and nine months ended September 30, 2016. As of September 30, 2017, we had an accumulated deficit of $231.2 million. Our primary use of cash is to fund research and development costs. Our operating activities used $81.0 million and $63.4 million of cash flows during the nine months ended September 30, 2017 and 2016, respectively. Historically, we have financed our operations principally through proceeds from public and private offerings of our securities and proceeds from our collaboration agreements, such as those with Merck KGaA, Darmstadt Germany and Celgene. During the three months ended September 30, 2017, we raised an aggregate of $601.4 million, consisting of $188.5 million in net proceeds from a public offering of our ordinary shares, $149.9 million in net proceeds from the sale of ordinary shares to Celgene in connection with our collaboration agreement, and $263.0 million in up-front license fees under our collaboration agreement with Celgene, of which $171.0 million is due in December 2017.

As of September 30, 2017, we had cash, cash equivalents and short-term investments of $757.4 million, including approximately $91.6 million of cash held by BeiGene Biologics to build a commercial biologics facility in Guangzhou, China and to fund research and development of biologics drug candidates in China. In addition, we had $10.5 million of accounts receivable related to product sales and $171.0 million of unbilled receivables related to the balance of the upfront fees from Celgene, payable to us in December 2017.

The following table provides information regarding our cash flows for the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Net cash used in operating activities	$ (80,997)	$ (63,373)
Net cash used in investing activities	(288,077)	(51,129)
Net cash provided by financing activities	487,308	182,210
Net effect of foreign exchange rate changes	2,762	(45)
Net increase in cash and cash equivalents	$ 120,996	$ 67,663

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 research and development, regulatory and other clinical trial costs, selling costs and related supporting administrative expenses. Our prepaid expenses and other current assets, accounts payable and accrued expense balances in all periods presented were affected by the timing of vendor invoicing and payments.

During the nine months ended September 30, 2017, operating activities used $81.0 million of cash, which resulted principally from our net income of $6.0 million, adjusted for non-cash charges of $28.1 million and by cash used in operations due to increased operating assets and liabilities of $115.1 million. Our operating assets increased $10.5 million for accounts receivable related to product sales and $171.0 million for unbilled receivables related to the balance of the upfront fees from Celgene due in December 2017. Operating liabilities increased $38.6 million related to deferred revenue under the Celgene collaboration and $45.1 million due to increased payables and accrued expenses from increased payroll-related costs, R&D external costs and selling, general and administrative expenses to support our growing business. Our net non-cash charges during the nine months ended September 30, 2017 primarily consisted of

Table of Contents

$26.4 million of share-based compensation expense, $4.8 million of non-cash interest expense and $2.7 million of depreciation expense, offset by $5.9 million related to deferred tax benefits.

During the nine months ended September 30, 2016, operating activities used $63.4 million of cash, which resulted principally from our net loss of $81.6 million, adjusting for non-cash charges of $10.7 million and interest expense of $0.1 million, and by cash provided by operations due to decreased operating assets and liabilities of $7.4 million. Our net non-cash charges during the nine months ended September 30, 2016 primarily consisted of a $1.4 million depreciation charge, a $6.7 million share-based compensation expense, a $1.1 million disposal loss on available-for-sale securities and a $1.5 million loss from changes in the fair value of financial instruments.

Net Cash Used in Investing Activities

Net cash used in investing activities was $288.1 million for the nine months ended September 30, 2017, compared to $51.1 million for the nine months ended September 30, 2016. The increase in cash used in investing activities was primarily due to $218.1 million of net purchases of available-for-sale securities, $50.1 million of investment in time deposits, $27.4 million paid to purchase property and equipment, primarily related to our Guangzhou and Suzhou manufacturing facilities, and $12.4 million paid to acquire land use rights in Guangzhou, China, partially offset by $19.9 million of cash acquired in the acquisition of BeiGene Pharmaceutical (Shanghai), net of cash paid.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $487.3 million for the nine months ended September 30, 2017, compared to $182.2 million for the nine months ended September 30, 2016. During the nine months ended September 30, 2017, we received $132.8 million of proceeds from the Shareholder Loan, $14.5 million from the capital contribution in BeiGene Biologics by GET, $188.5 million of net proceeds from our follow-on offering, net of underwriter discount and offering costs, $149.9 million from equity contribution by Celgene Switzerland, net of offering costs and $1.6 million from the exercise of employee options. During the nine months ended September 30, 2016, we received net proceeds of $167.9 million from our initial public offering, net of underwriter discount and offering costs, $12.2 million from a long-term bank loan and $2.1 million from the exercise of warrants and options.

Operating Capital Requirements

We do not expect to generate significant revenue from product sales of our internally developed drug candidates unless and until we obtain regulatory approval of and commercialize one of our current or future drug candidates. We have exclusive rights to distribute and promote Celgene’s approved cancer therapies in China, for which we began recognizing revenue in the third quarter of 2017. We anticipate that we will continue to generate losses for the foreseeable future, and we expect our losses to increase as we continue the development of, and seek regulatory approvals for, our drug candidates, and prepare for commercialization and begin to commercialize any approved products. As a growing public company, we will continue to incur additional costs associated with our operations. In addition, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing of our in-licensed drug products in China and, subject to obtaining regulatory approval, our drug candidates. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of September 30, 2017, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in this report are issued. We expect that our expenses will continue to 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.

Table of Contents

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, timing, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- the number and characteristics of the drug candidates 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 costs of establishing and expanding our commercial operations;
- 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. Under SEC rules, we currently qualify as a “well-known seasoned issuer,” which allows us to file shelf registration statements to register an unspecified amount of securities that are effective upon filing. On May 26, 2017, we filed such a shelf registration statement with the SEC for the issuance of an unspecified amount of ordinary shares (including in the form of ADSs), preferred shares, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement was effective upon filing and will remain in effect for up to three years from filing. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder 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 your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings, collaborations or other sources 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.

Table of Contents

Contractual Obligations and Commitments

The following table summarizes our significant contractual obligations as of the payment due date by period at September 30, 2017:

	Payments Due by Period				
	Total (in thousands)	Less Than 1 Year	1–3 Years	3–5 Years	More Than 5 Years
Contractual obligations					
Operating lease commitments	$ 23,081	$ 5,960	$ 9,884	$ 5,290	$ 1,947
Debt obligations	158,347	9,018	9,018	—	140,311
Capital commitments	36,149	36,149	—	—	—
Total	$ 217,577	$ 51,127	$ 18,902	$ 5,290	$ 142,258

Operating Lease Commitments

We lease office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou, PRC and office facilities in the United States in California, Massachusetts and New Jersey 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. The future minimum payments under these non-cancelable operating leases are summarized in the table above.

Long-term Debt Obligations

Long-term Bank Loan

On September 2, 2015, BeiGene (Suzhou) entered into a loan agreement with Suzhou Industrial Park Biotech Development Co., Ltd. and China Construction Bank, to borrow $18.0 million at a 7% fixed annual interest rate. As of September 30, 2017, we have drawn down the entire $18.0 million, which is secured by BeiGene (Suzhou)’s equipment with a carrying amount of $23.3 million and our rights to a PRC patent on a drug candidate. $9.0 million is repayable on each of September 30, 2018 and 2019.

Shareholder Loan

On March 7, 2017, BeiGene Biologics entered into a Shareholder Loan Contract with GET, pursuant to which, GET provided a Shareholder Loan to BeiGene Biologics with the principal of RMB900 million at an 8% fixed annual interest rate. The term of the Shareholder Loan is 72 months, commencing from the actual drawdown date of April 14, 2017 and ending on April 13, 2023, unless converted earlier. On April 14, 2017, we drew down the entire RMB900 million from GET.

Capital Commitments

We had capital commitments amounting to $36.1 million for the acquisition of property, plant and equipment as of September 30, 2017, which was primarily for BeiGene Guangzhou Factory’s manufacturing facility in Guangzhou, China.

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.

Table of Contents

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. For financial statement items relating to the three months ended September 30, 2017, see the accounting policies described in "Notes to the Condensed Consolidated Financial Statements—2. Summary of significant accounting policies" of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding recent 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. 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 discussion and analysis.

We have determined that, as of June 30, 2017, we have at least $700 million of equity securities held by non-affiliates, and as such we will no longer qualify as an emerging growth company as of December 31, 2017. As a result,

Table of Contents

we will no longer be able to take advantage of specified reduced disclosure and other requirements that are available to emerging growth companies after such date.

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 $208.5 million and $87.5 million and short-term investments of $548.9 million and $280.7 million at September 30, 2017 and December 31, 2016, respectively. At September 30, 2017, 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 September 30, 2017, our short-term investments consisted primarily of U.S. Treasury securities and time deposits. We believe that the U.S. Treasury securities are of high credit quality and 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 estimate that a hypothetical 100-basis point change in market interest rates would impact the fair value of our investment portfolio as of September 30, 2017 by $2.3 million.

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 the U.S. dollar, but a portion of our operating transactions and assets and liabilities are in other currencies, such as RMB, Australian dollar and Euro. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge exposure to such risk.

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange prices. From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For the RMB against U.S. dollars, there was appreciation of approximately 4.4% in the nine months ended September 30, 2017 and depreciation of approximately 6.3% in the year ended December 31, 2016, respectively. 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 the U.S. dollar would have an adverse effect on the RMB amount we

would receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of the U.S. dollar 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.

Table of Contents

Currency Convertibility Risk

A majority of our expenses and a significant portion of our assets and liabilities are denominated in RMB. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China, or PBOC. However, the unification of exchange rates does not imply that the RMB may be readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2017.

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 September 30, 2017. 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 September 30, 2017, our management, including 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2017, that have materially affected, or are 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 legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Table of Contents

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.

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 an ability to successfully complete large-scale, registrational 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 internally developed drug candidates. We have no internally developed products approved for commercial sale and have not generated any revenue from internally developed product sales. Since September 2017, we have generated revenues from the sale of ABRAXANE®, REVLIMID®, and VIDAZA® under a license from Celgene Corporation as described in this Quarterly Report. 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 an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

We are focused on the discovery, development and commercialization 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 a history of incurring net losses 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 nonclinical development activities and clinical trials. 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, except in the third quarter of 2017, where we were profitable due to revenue recognized from up-front license

fees in connection with our strategic collaboration with Celgene. As of September 30, 2017, we had a deficit accumulated of $231.2 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations.

Table of Contents

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 the approved drugs we have licensed from Celgene in China and any other drugs that we may successfully develop or license. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, our ability to generate revenues and the timing and amount of milestones and other required payments to third parties in connection with our potential future arrangements with third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our cancer biology platform and our ongoing and planned clinical trials for our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283. Furthermore, we expect to incur increased sales and marketing expenses for the approved drugs we have licensed from Celgene in China and any other drugs that we may successfully develop or license. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a global biotechnology 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 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 and successfully market our in-licensed drugs in China and any other drugs that we may successfully develop or license. We expect to continue to incur substantial and increasing losses through the commercialization of our in-licensed drugs and internally developed drug candidates, if approved. None of our internally developed 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 in part 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 nonclinical and clinical development of, our drug candidates;
- obtaining regulatory approvals 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 drugs and drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing our drugs and any drug candidates for which we obtain regulatory approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of our drugs and drug candidates as viable treatment options;

50

Table of Contents

- identifying, assessing, acquiring and/or developing new drugs and 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 Celgene and Merck KGaA, Darmstadt Germany;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

In addition, because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA, the CFDA, the 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 in-licensed drugs and any other drugs that we may successfully develop or license, 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, collaboration and license agreements, and private and public grants. Since our inception through September 30, 2017, we have raised approximately $1.0 billion, consisting of an aggregate of $180.0 million in private financings prior to our IPO; an aggregate of $553.3 million in our IPO and follow-on public offerings, including most recently $188.5 million in net proceeds in August 2017; $150.0 million from an equity investment from Celgene in connection with our collaboration agreement; and an aggregate of $300.0 million from upfront and milestone payments through our collaboration arrangements with Merck KGaA, Darmstadt Germany and Celgene, including $171 million in upfront license fees expected to be received under our Celgene agreement in December 2017. In addition, under our collaboration with Celgene, we are eligible to receive up to $980 million in development, regulatory and sales milestone payments and royalties in the low-double digit to mid-twenty percentages on any future sales of BGB-A317, based on specified terms. While we have generated product revenue in China since September 2017 from sales of our approved drugs licensed from Celgene, our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with additional product sales revenue.

Our operations have consumed substantial amounts of cash since inception. Our operating activities used $81.0 million and $63.4 million of net cash during the nine months ended September 30, 2017 and 2016, respectively. We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, commercializing our approved drugs and launching and commercializing any drug candidates for which we receive regulatory approval, including building our own commercial organization to address China and other markets.

We will need to obtain additional financing to fund our future operations, including completing the development and potential commercialization of our primary drug candidates: BGB-3111, BGB-A317, BGB-290 and BGB-283. We

Table of Contents

will need to obtain additional financing to conduct additional clinical trials for the approval of our drug candidates if requested by regulatory bodies, and completing the development of any additional drug candidates we might discover. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA, CFDA, EMA and comparable regulatory authorities, including the potential that the FDA, CFDA, EMA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the number and characteristics of drug candidates that we may in-license and develop;
- our ability to successfully commercialize our drugs and drug candidates;
- the amount of sales and other revenues from the drugs and drug candidates that we may commercialize, if any, including the selling prices for such 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 collaborations with Merck KGaA, Darmstadt Germany and Celgene;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our current drug products in China and any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- 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 development and completion of commercial-scale internal or 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

Table of Contents

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

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

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

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

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

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy adopted by the PRC, Australia and other non-U.S. governments. For instance, in August 2015, the People's Bank of China, or PBOC, changed the way it calculates the mid-point price of Renminbi against the U.S. dollar, requiring the market-makers who submit for reference rates to consider the previous day's closing spot rate, foreign-exchange demand and supply as well as changes in major currency rates. It is difficult to predict how market forces or PRC, Australia, other non-U.S. governments and U.S.

Table of Contents

government policies may impact the exchange rate of RMB and the U.S. dollar or any other currencies in the future. There remains significant international pressure on the PRC government to adopt a more flexible currency policy, including from the U.S. government, which has threatened to label China as a "currency manipulator," which could result in greater fluctuation of the RMB against the U.S. dollar.

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

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

We had cash, cash equivalents and short-term investments of $757.4 million and $368.2 million at September 30, 2017 and December 31, 2016, respectively. In addition, we expect to receive $171 million in upfront license fees under our Celgene collaboration in December 2017. At September 30, 2017, our short-term investments mainly consisted of U.S. Treasury securities and time deposits. 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 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, clinical trials, as well as completion of preclinical studies;
- receipt of regulatory approvals from the FDA, CFDA, EMA and other comparable regulatory authorities for our drug candidates, including our companion diagnostics;

Table of Contents

- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- relying on third parties to conduct our clinical trials safely and efficiently;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- protecting our rights in our intellectual property;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- launching commercial sales of our drug candidates, if and when approved;
    - obtaining reimbursement from third-party payors for drug candidates, if and when approved;
- competition with other drug candidates and drugs;
- continued acceptable safety profile for our drug candidates following regulatory approval, if and when received; and
- obtaining sufficient supplies of any competitor drug products that may be necessary for use in clinical trials for evaluation of our drug candidates.

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

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;

Table of Contents

- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

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

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

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

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

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

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

Table of Contents

competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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

Some of our drug candidates represent a departure from more commonly used methods for cancer treatment, and therefore represent a novel approach that carries inherent development risks. The need to further develop or modify in any way the protocols related to our drug candidates to demonstrate safety or efficacy may delay the clinical program, regulatory approval or commercialization, if approved. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than enroll patients in any current or 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 protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

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, 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;

Table of Contents

- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or 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 affects, 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.

Table of Contents

Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

The regulatory approval processes of the FDA, CFDA, EMA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

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

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

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective or that a biologic drug candidate is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our drug candidates to support the submission and filing of a New Drug Application, or NDA; Biologics License Application, or BLA; or other submission or to obtain regulatory approval;
- the FDA, CFDA, EMA or comparable regulatory authority's finding of deficiencies related to the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

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

Table of Contents

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

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

- our inability to obtain sufficient funds required for a clinical trial;
- regulatory requests for additional analyses, reports, data, nonclinical 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 contract research organizations, or CROs, to satisfy their contractual duties or regulatory requirements 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 nonclinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;

Table of Contents

- feedback from the FDA, CFDA, EMA, an IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- decision by the FDA, CFDA, EMA, an IRB, comparable entities, or us, or recommendation by a data safety monitoring board or comparable regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to demonstrate a benefit from using a drug or biologic;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to reach agreements on acceptable terms with prospective 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 internally developed product sales and generate related 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

Table of Contents

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

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

Undesirable adverse events, or AEs, caused by our 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 AEs. 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.

Treatment-related serious adverse events, or SAEs, that have been reported in our monotherapy clinical trials include the following: (i) for BGB-3111, petechiae (spots that appear on the skin as a result of bleeding), purpura (subcutaneous bleeding), bruising, other serious hemorrhage (grade 3 hemorrhage or central nervous system, or CNS, hemorrhage of any grade), atrial fibrillation, diarrhea, haemothorax, colitis, febrile neutropenia, neutropenia, anemia, thrombocytopenia, pneumonia, renal hematoma, urinary tract infection, pneumonitis, leukocytosis, lymphocytosis, toxic epidermal necrolysis and headache; (ii) for BGB-A317, colitis, hypotension, diarrhea, diabetes mellitus, diabetic ketoacidosis, dyspnea, hypoxia, pneumonitis, fatigue, alanine aminotransferase, or ALT, increase, aspartate aminotransferase, or AST, increase, gamma-glutamyl transferase, or GGT, increase, autoimmune pancreatitis, back pain, dermatitis, hyperglycaemia, hyperthyroidism, nausea, proteinuria, stomatitis, bilirubin increase, leukopenia, neutropenia, pyrexia, mucosal inflammation and hepatitis; (iii) for BGB-290, anemia, neutropenia, nausea, vomiting, thrombocytopenia, diarrhea, fatigue, neutropenia and acute myeloid leukemia / myelodysplastic syndrome; and (iv) for BGB-283, thrombocytopenia, fatigue, nausea, anemia, neutropenia, vomiting, hepatitis, ALT increase, AST increase, GGT increase, pyrexia, decreased appetite, hypophosphataemia, hand-foot syndrome, hypertension, weight decrease, lymphopenia, leukopenia, and constipation.

In addition, treatment-related SAEs that have been reported in our combination clinical trials include the following: (i) for the BGB-3111 and obinutuzumab combination, neutropenia, thrombocytopenia, pneumonia,

infusion-related reaction, and serious hemorrhage, including one report of a grade 3 intracranial hemorrhage SAE, which is possibly drug related, in one Diffuse Large B-Cell Lymphoma patient that caused the patient's treatment with BGB-3111 to be interrupted; (ii) for the BGB-3111 and BGB-A317 combination, haemolytic anaemia, pneumonia, pneumonitis, anemia, autoimmune encephalitis, dyspnea, ALT increase, GGT increase, infusion-related reaction, peripheral edema, pyrexia, thrombocytopenia, limb abscess, ulcerative keratitis, catheter site hemorrhage, hemolytic transfusion reaction, nausea,

Table of Contents

lymph gland infection and eczema; and (iii) for the BGB-290 and BGB-A317 combination, nausea, vomiting, hepatitis, ALT increase, AST increase, GGT increase, fatigue, anemia, liver injury, hypophysitis, and neutropenia.

Drug-related AEs or SAEs could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly.

Additionally, if we or others identify undesirable side effects caused by our drugs or any future approved drug candidates, 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, as is the case with REVLIMID®, or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- 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 or drug candidate, and could significantly harm our business, results of operations and prospects.

Further, combination therapy, such as using our wholly-owned drug candidates as well as third-party products, involves unique AEs that could be exacerbated compared to AEs from monotherapies. These types of AEs could be caused by our drug candidates and could also cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CFDA, EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of AEs.

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 need 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.

Table of Contents

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 designation and 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 CLL, MCL and WM in 2016.

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

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

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

Our in-licensed drugs in China and any additional drug candidates that are approved 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,

Table of Contents

including both federal and state requirements in the United States and requirements of comparable regulatory authorities in China and other countries.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, CFDA, EMA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers 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 any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The regulatory approvals for our in-licensed drugs and any 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 or comparable regulatory authorities may also require a REMS program as a condition of approval of our drug candidates or following approval, as is the case with REVLIMID®, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, CFDA, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

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

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

The FDA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, 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.

65

Table of Contents

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 that we are currently developing or may develop in the future. 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/or 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, or the biologic product candidate is safe, pure, and potent, 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 candidate. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA or BLA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

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

Specifically, in China, the CFDA categorizes domestically-manufactured innovative drug applications as Category 1 and imported innovative drug applications as Category 5. 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 5 applicable to imported drugs, formerly known as Category 3 prior to the reclassification implemented by CFDA in 2016. 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 5. 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

Table of Contents

priority list. The imported drug registration pathway, Category 5, is more complex and is evolving. China Category 5 registration applications for certain drugs may only be submitted after a drug has obtained an NDA approval and received the Certificate of Pharmaceutical Product, or CPP, granted by a major drug regulatory authority, such as the FDA or EMA.

Further, in August 2015, the Chinese State Council issued a statement, Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices that contained several potential policy changes that could benefit the pharmaceutical industry:

- A plan to accelerate innovative drug approval with a special review and approval process, with a focus on areas of high unmet medical needs, including drugs for HIV, cancer, serious infectious diseases and orphan diseases, drugs on national priority lists.
- A plan to adopt a policy which would allow companies to act as the marketing authorization holder and to hire contract manufacturing organizations to produce drug products.
- A plan to improve the review and approval of clinical trials, and to allow companies to conduct clinical trials at the same time as they are being conducted in other countries and encourage local clinical trial organizations to participate in international multi-center clinical trials.

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

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

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

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

Table of Contents

the same production line in China; (6) traditional Chinese medicines (including ethnic medicines) with clear clinical position in prevention and treatment of serious diseases; and (7) registration application of new drugs sponsored by national key technology projects or national key development projects.

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

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

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

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the United States and China, and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the FDA, 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.

n April 2017, the NHFPC, Ministry of Finance, the National Development and Reform Commission and four other four government agencies jointly issued the Notice on Overall Implementation of Public Hospital Comprehensive Reform, or the Public Hospital Reform Notice. The Public Hospital Reform Notice requires all prefecture-level cities to formulate plans for full implementation of the urban public hospital reforms by July 31, 2017. According to the Public Hospital Reform Notice, the public hospital reform plans were to be implemented by September 30, 2017. Under the public hospital reform plan, public hospitals will no longer be able to sell all drugs, except for traditional Chinese medicines, at prices higher than they paid for purchasing the drugs, also known as a zero-markup policy. The Public Hospital Notice also provides that the first four batches of public hospital reform cities should reduce the proportion of their drug sales-related income to around 30%. Because the zero-markup policy proposed by the Public Hospital Reform Notice has not taken effect nationwide, there is still substantial uncertainty with respect to the interpretation and implementation in different cities. However, the implementation of a zero-markup policy may disincentivize public hospitals to purchase and sell new drugs with high prices, which may negatively affect our business operations and financial performance.

In May 2017, the CFDA issued four draft policies for public comment, proposing further reforms in the current drug regulatory regime, including 2017 CFDA Circular 52, 2017 CFDA Circular 53, 2017 CFDA Circular 54 and 2017 CFDA Circular 55. These draft policies propose significant reforms in the areas of the new drug approval process, clinical trial regulation, life-cycle management and post-marketing, and regulatory data protection and patent linkage.

These draft policies, if adopted as currently proposed, will further streamline and accelerate the market access of novel drugs, including domestic and foreign drug candidates. For example, 2017 CFDA Circular 52 proposes an accelerated approval regime for drugs meeting urgent clinical needs, under which drugs that meet urgent clinical needs may receive conditional approval, if the early and middle stage clinical trials show positive results and there is anticipated clinical

Table of Contents

value. Also, the National Health and Family Planning Commission, or NHFPC, will publish a list of orphan diseases. Applicants with drugs treating such orphan diseases may apply for a clinical trial waiver. If a new drug for orphan diseases has been approved outside China, the CFDA may grant a conditional approval, and the applicant must complete a trial in China within a prescribed timeframe after such approval. 2017 CFDA Circular 53 proposes to streamline the clinical trial approval process by adoption of a notification system for clinical trial applications, under which the applicants only need to wait for 60 business days before proceeding with the protocol, unless the Center for Drug Evaluation rejects the application or issues a deficiency notice during the 60-day period. 2017 CFDA Circular 53 also proposes that foreign clinical data be admitted to support registration of drugs in China, as long as (1) the clinical trial data satisfy the requirements under PRC regulations, (2) the trials pass the CFDA's on-site inspection, and (3) applicants can provide clinical data to prove that no ethnicity difference affects the drug candidates' safety and efficacy.

Based on the draft policies, in October 2017, the General Office of the State Council of China announced The Opinions on Deepening Review and Approval System Reform and Encouraging the Innovation of Drugs and Medical Devices, or the Opinions on Reform. The Opinions on Reform upholds the draft policies' proposal to improve clinical trial approval procedures by adopting a notification system for clinical trial applications under which applicants may proceed with the protocol unless the drug evaluation authority issues a negative opinion or queries within a prescribed period. In addition, the Opinions on Reform upholds the draft policies' proposal of conditional approval for drugs treating life-threatening diseases or meeting urgent public health needs. According to the Opinions on Reform, the marketing authorization holder system will roll out nationwide in China and marketing authorization holders will be held ultimately responsible for pre-approval and post-approval compliance obligations, as well as for the activities of their contracted research organizations, manufacturers and distributors. The Opinions on Reform are recently announced high-level opinions to be further supplemented and implemented with the adoption of the detailed draft policies proposed by the CFDA.

In October 2017, the CFDA issued the Decisions Concerning the Adjustment of Imported Drug Registration, or the Imported Drug Registration Adjustment Decisions. The Imported Drug Registration Adjustment Decisions (1) allow drugs to launch synchronized Phase 1 international multi-center clinical trials within and outside China, (2) allow applicants to apply for drug marketing approval upon completion of international multi-center clinical trials, and (3) remove the requirement of marketing authorization in the country or region of the foreign pharmaceutical manufacturers for new chemical drugs and therapeutic biological innovative drugs applying for imported drug clinical trials and imported drug marketing. Although the Imported Drug Registration Adjustment Decisions are newly issued and uncertainty remains with respect to their implementation, we expect the advantage of our conduct clinical trials as domestic drugs in China over imported drugs could be reduced with the implementation of Imported Drug Registration Adjustment Decisions.

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 5. 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 5 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 research and development, clinical trial capacities, and 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.

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

Our drugs and any future approved drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on

Table of Contents

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

- the clinical indications for which our drugs and drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drugs and drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drugs and drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of 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 drugs and 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 drugs and drug candidates;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our drugs and any approved drug candidates 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.

* If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates and third-party drugs, we may not be able to generate product sales revenue.

Prior to the closing of our transaction with Celgene, we had no sales, marketing or commercial product distribution capabilities and had no experience in marketing drugs. On August 31, 2017, we closed a strategic collaboration with Celgene in which we were granted an exclusive license in China, excluding Hong Kong, Macau and Taiwan, to commercialize Celgene's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®, and Celgene's investigational agent CC-122 in clinical development, and acquired Celgene's commercial operations in China, excluding certain functions. We plan to further build our salesforce in China to market these in-licensed drugs and our

Table of Contents

internally developed drug candidates, in the event they receive commercial approval, and any additional drugs or drug candidates that we may in-license, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all drugs we develop or in-license, 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 further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

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

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drugs and drug candidates and any future drugs that we may develop or in-license from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of cancer for which we are commercializing our in-licensed drugs or 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 titled “Item 1—Business—Competition” of our 2016 Annual Report.

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties

compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Table of Contents

*Our drugs and 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 ACA, 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, and it 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. We do expect competition from generic drugs with our in-licensed drugs in China but currently do not know the actual impact. In the United States, the enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012 established a user fee program that will generate hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, could significantly decrease the timeframe for FDA review and approval of generic drug applications.

*The market opportunities for our drugs and 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 molecule drugs 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.

Table of Contents

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 drugs and drug candidates may be limited or may not be amenable to treatment with our drugs and drug candidates. Even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy.

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 our drugs and any approved 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 drugs or any drug candidates, even if our drug candidates obtain regulatory approval.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug which we commercialize. Obtaining or maintaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we in-license or successfully develop.

There may be significant delays in obtaining reimbursement for approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or other comparable regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments

allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. 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 our drugs and any new drugs that we

Table of Contents

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 drugs and drug candidates and drugs, which could make it difficult for us to sell our drugs and drug candidates profitably.

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

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

· a covered benefit under its health plan;
· safe, effective and medically necessary;
· appropriate for the specific patient;
· cost-effective; and
· neither experimental nor investigational.

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

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy.

In February 2017, the Ministry of Human Resources and Social Security of China released a new edition of the NRDL, or the 2017 NRDL, which expands its scope by including an additional 339 drugs. The 2017 NRDL reflects an emphasis on innovative drugs and drugs that treat cancer and other serious diseases. For instance, most of the innovative chemical drugs and biological products approved in China between 2008 and the first half of 2016 have been included in the 2017 NRDL or its candidate list. In July 2017, our in-licensed drug, REVLIMID® was included in the NRDL at a negotiated price lower than we have previously charged. There can be no assurance that our other

drugs and any

Table of Contents

approved drug candidates will be included in the NRDL. Products included in the NRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance. As a result, revenue from sales of drugs not listed in the NRDL is largely self-paid by patients. On the other hand, inclusion of a drug in the NRDL or provincial or local medical insurance catalogues may increase demand but result in decreased revenue as a result of lower prices that are included in the NRDL or provincial or local medical insurance catalogues.

The Chinese State Council asked central and provincial authorities across the PRC to promote a medical insurance program for major illnesses.

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. 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. 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 drugs and drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs and any approved 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, China, 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 our drugs and any drug candidates for which we obtain regulatory approval.

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

More recently, in March 2010, then-President Obama signed into law the ACA, 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 ACA 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;

Table of Contents

- 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 ACA 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, then-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 laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

With the new Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In May 2017, the House of Representatives passed legislation to repeal and replace parts of the ACA. The Senate considered but did not pass that legislation, and there are other legislative proposals relating to healthcare reform. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In addition, while the Trump Administration has threatened to allow the ACA to implode, a bipartisan group of legislators is working to address certain problems with the ACA. Accordingly, it remains to be seen whether new legislation modifying the ACA is enacted and, if so, precisely what the new legislation will

Table of Contents

provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. The implications of a potential repeal and/or replacement of the ACA for our business and financial condition, if any, are not yet clear.

*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 and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- 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;
- 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 ACA, 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

77

Table of Contents

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

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

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

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, 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 ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

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

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

78

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. For example, in connection with the Celgene transactions, we retained exclusive rights for the development and commercialization of BGB-A317 for hematological cancers globally and for solid tumors in China and the rest of Asia, other than Japan. We intend to focus on additional opportunities in China, in particular. 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.

Table of Contents

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

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

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

Risks Related to Our 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 October 31, 2017, we own eleven issued U.S. patents, nine pending U.S. patent applications and one U.S. provisional patent application as well as corresponding patents and patent applications internationally. In addition, we own eight pending international patent applications under the PCT and seven priority international patent applications under the PCT, which we plan to file nationally in the United States and other jurisdictions. With respect to any issued patents in the United States and Europe, we may be entitled to obtain a patent term extension to extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. We have sought to protect our proprietary position by filing patent applications in the United States, the PRC and other countries related to novel technologies and drug candidates that we consider are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the Leahy-Smith America Invents Act enacted in 2011, the United States moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in interference inter partes review, post grant

review, ex parte reexamination, derivation, opposition or other similar 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.

Table of Contents

There can be no assurance that our pending patent applications will result in issued patents in the United States or non-U.S. jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

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

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

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

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

Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

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

Table of Contents

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

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

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

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

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

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

Table of Contents

*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 United States Patent and Trademark Office or oppositions and other comparable proceedings in non-U.S. jurisdictions. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

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

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

Specifically, we are aware of three U.S. patents owned by Ono Pharmaceutical Co., or Ono, and licensed to Bristol-Myers Squibb Co., or BMS, that are relevant to our BGB-A317 drug candidate. These patents are expected to expire in 2023, 2023 and 2024, respectively. In addition, we are aware of two other U.S. patents that cover antibodies containing certain stabilizing mutations that are relevant to our BGB-A317 drug candidate. These patents are expected to expire in 2026 and 2029 in the United States. Although we believe that the claims of these various patents 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 of these various patents is upheld upon a validity challenge, and BGB-A317 is approved for sale in the United States before the expiration of these various patents, then we will need licenses to commercialize BGB-A317 in the United States before the expiration of these patents. In addition, depending upon the circumstances, we may need licenses for jurisdictions outside the United States where we wish to commercialize BGB-

Table of Contents

A317 before the expiration of corresponding patents covering BGB-A317. Although Merck & Co. was able to obtain a non-exclusive license for its KEYTRUDA product from BMS and Ono in January 2017 as part of a settlement of a patent dispute between the parties, we can provide no assurance that we will be able to obtain such a license or other licenses on commercially reasonable terms or at all, 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 the 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 trials 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 the circumstances, we may need a license for jurisdictions outside the United States where we wish to commercialize BGB 290 before the expiration of a corresponding patent covering BGB 290. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

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

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

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

Table of Contents

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 drugs and 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. For example, the approved cancer therapies we have licensed from Celgene in China, ABRAXANE®, REVLIMID®, and VIDAZA®, face or are expected to face competition from generic medications, and we may face similar competition for any approved drug candidates even if we successfully obtain patent protection once the patent life has expired for the drug. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our owned or licensed patents in court, and we or our licensors may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. If patents are issued on our currently pending patent applications, the resulting patents will be expected to expire on dates ranging from 2031 to 2035, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patent or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened

the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in a recent case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable.

Table of Contents

Although we do not believe that our currently-issued patent and any patents that may issue from our pending patent applications directed to our drug candidates if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

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

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

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

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

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

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or

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

Table of Contents

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 and we must work effectively with collaborators to develop our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, 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 or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, CFDA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

Table of Contents

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

Switching or adding additional CROs involves additional cost and 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.

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

*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 some or all of our drugs and any approved drug candidates. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

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

Although we intend to further develop our own manufacturing facilities, we also intend to use third parties as part of our manufacturing process. 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 evaluate and/or

approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by FDA, 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 and drug candidates;

Table of Contents

- our manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drugs and drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may not perform as agreed, may not devote sufficient resources to our drugs and drug candidates, 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 and drug candidates;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with cGMPs and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates and drugs;
- 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; and
- 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 drugs and drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and 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

Table of Contents

discovered in our supply of our drugs and drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drugs for commercial sale andour drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

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

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

Table of Contents

For example, in October 2013, we entered into license agreements with Merck KGaA, Darmstadt Germany, which we refer to respectively as the Ex-PRC PARP Agreement and the PRC PARP Agreement, pursuant to which (a) we granted to Merck KGaA, Darmstadt Germany an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA, Darmstadt Germany exercised a continuation option, to commercialize and manufacture our compound BGB-290 and any other compound covered by the same existing patent rights with primary activity to inhibit PARP 1, 2 or 3 enzymes, or the Licensed PARP Inhibitors, in all countries of the world excluding The People's Republic of China, and (b) Merck KGaA, Darmstadt Germany granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the Licensed PARP Inhibitors in The People's Republic of China, or the PRC Territory. Under the terms of the PRC PARP Agreement, Merck KGaA, Darmstadt Germany has an option to acquire exclusive commercialization rights under the BGB-290 PARP program in the PRC Territory if BGB-290 does not receive national priority project status in China under its 12th or 13th five-year plan by July 28, 2017. We applied for national priority project status for BGB-290 to be effective from the beginning of 2017. Our application is in process and we believe it will be approved. However, there have been unanticipated governmental delays that have impacted the 2017 applicant pool for national project priority status and we expect that we will now receive formal notification in 2018. As such, we intend to discuss with Merck KGaA, Darmstadt Germany the impact of this delay on the PRC PARP Agreement.

In addition, on August 31, 2017, we closed a strategic collaboration with Celgene pursuant to which we granted Celgene exclusive rights to develop and commercialize BGB-A317 in patients with solid tumor cancers in the United States, Europe, Japan and the rest of world outside Asia. We and Celgene also agreed to collaborate on up to eight registrational trials for BGB-A317 in solid tumors, including trials currently being planned by us. We retain exclusive rights for the development and commercialization of BGB-A317 for hematological cancers globally and for solid tumors in China and the rest of Asia, other than Japan. In connection with this collaboration, we also acquired Celgene's commercial operations and salesforce in China as disclosed elsewhere in this report.

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

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

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

91

Table of Contents

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

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

Risks Related to Our Industry, Business and Operations

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

We are highly dependent on Xiaodong Wang, Ph.D., our Founder, Chairman of our scientific advisory board and director; John V. Oyler, our Founder, Chief Executive Officer and Chairman of the Board; and the other principal members of our management and scientific teams and scientific advisory board. Although we have formal employment agreements with each of our executive officers, 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 and restricted share grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the ADS 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

92

Table of Contents

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.

In the beginning of 2016, we had 192 full-time employees, and we ended the year with 321 full-time employees. As of September 30, 2017, we had 727 employees, including 129 employees added in connection with our acquisition of Celgene's China operations on August 31, 2017. Most of our employees are full-time. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- 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 drugs and drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. 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 manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the

tasks necessary to further develop and commercialize our drugs and drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

Table of Contents

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

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

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

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

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

*In order to continue 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 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, particularly in the area of financial planning and analysis, 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.

Table of Contents

*If we engage in acquisitions or strategic partnerships, such as our global collaboration with Celgene and acquisition of Celgene's commercial operations in China, 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 completed, in-process or potential acquisition or strategic partnership, including our acquisition of Celgene's commercial operations in China, the exclusive license from Celgene to us of the right to commercialize certain of Celgene's cancer therapies in China (excluding Hong Kong, Macau and Taiwan) and our global collaboration with Celgene for BGB-A317, which we refer to collectively as the Celgene Transaction, may entail numerous risks, including:

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

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For example, in connection with the Celgene Transaction, we issued to an affiliate of Celgene 32,746,416 ordinary shares, or approximately 4.3% of our outstanding shares as of September 30, 2017. Moreover, we may not be able to locate suitable acquisition or license 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.

Table of Contents

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

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

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

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

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

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

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

Table of Contents

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 drugs and 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 drugs and 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 drugs and drug candidates. Our ability to obtain supplies of our drugs and drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. A large portion of our operations is located in a single facility in Changping, Beijing, PRC. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our drug candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

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

We face an inherent risk of product liability as a result of the commercialization of our drugs in China and the clinical testing of our drug candidates globally. For example, we may be sued if our drugs or drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates and drugs. 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;

Table of Contents

- 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 or in-license. Although we currently hold $10 million in product liability coverage in the aggregate, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. We may seek to expand our insurance coverage for products to include the sale of commercial products, 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 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 director and officer 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 are subject to the risks of doing business outside of the United States.

Because we operate in China and other countries outside of the United States, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country’s or region’s political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain countries;
- enforcement of anti-corruption and anti-bribery laws, such as the Foreign Corrupt Practices Act;

Table of Contents

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

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

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

*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"). In June 2017, the U.K. government began negotiations to leave the European Union. These negotiations are expected to determine the terms of the United Kingdom's withdrawal from the European Union as well as its relationship with the European Union going forward, including the terms of trade between the United Kingdom and the European Union. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Brexit could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and the European Union; however, the full effects of Brexit are uncertain and will depend on any agreements the United Kingdom may make to retain access to European Union markets.

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

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

Table of Contents

*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. In addition, to increase our manufacturing capabilities, we lease an approximately 11,000 square meter space and have built a manufacturing facility in Suzhou, China, where we intend to produce drug candidates for clinical or, in the future, commercial use. This facility consists of one oral-solid-dosage production line for small molecule drug products and one pilot plant for monoclonal antibody drug substances. This new manufacturing facility was completed in 2017. In addition, BeiGene Biologics is building a biologics manufacturing facility in Guangzhou through a wholly-owned subsidiary, BeiGene Guangzhou Factory. These projects may encounter unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. If construction or regulatory evaluation and/or 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. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources.

In addition to the similar manufacturing risks described in "—Risks Related to Our Reliance on Third Parties," our manufacturing facilities will be subject to ongoing, periodic inspection by the FDA, 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 or drugs, 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.

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

Table of Contents

facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA, CFDA, EMA or and other comparable regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates.

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

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages;
- damage to or destruction of either facility due to natural disasters;
- regional power shortages;
- product tampering; or
- terrorist activities.

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

Currently, we maintain insurance coverage against damage to our property and equipment in the amount of up to RMB 100 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.

*The Celgene Transaction could disrupt our business and harm our financial condition if we are not able to successfully integrate Celgene’s commercial business in China into ours, and the expected benefits of the acquisition may not materialize.

On August 31, 2017, we closed the Celgene Transaction pursuant to which we were granted the right to exclusively distribute and promote three of Celgene’s drugs and one of Celgene’s drug candidates in China, excluding Hong Kong, Macau and Taiwan, and acquired Celgene’s commercial operations in China. We also have specified rights to future oncology drugs that Celgene may seek to commercialize in China.

The Celgene Transaction involves numerous risks, including problems combining the purchased operations of Celgene’s commercial operations in China with our own operations and unanticipated costs and diversion of our management’s attention from our drug discovery and development business. There can be no assurance that we will be able to successfully manage and integrate Celgene’s commercial operations in China and its personnel into our business, which could disrupt our business and harm our financial results.

Moreover, we may not achieve the revenue and cost synergies expected from the Celgene Transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from the Celgene Transaction may be offset by costs incurred in integrating Celgene’s commercial operations in China, increases in other expenses, operating

Table of Contents

losses or problems in the business unrelated to the Celgene Transaction. As a result, there can be no assurance that such synergies will be achieved.

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. 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 2016 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 or drugs in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the Chinese government's policies, but we cannot ensure that our strategy and approach will continue to be aligned.

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

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

The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

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

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

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

Table of Contents

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the nonbinding nature of such decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

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

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

The Ministry of Commerce published a discussion draft of the proposed Foreign Investment Law in January 2015 aiming to, upon its enactment, replace the trio of existing laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. The draft Foreign Investment Law embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Ministry of Commerce has solicited comments on this draft and substantial uncertainties exist with respect to its enactment timetable, the final version, interpretation and implementation. The draft Foreign Investment Law, if enacted as proposed, may materially impact the viability of our current corporate governance if we, in the future, have PRC shareholders.

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

Table of Contents

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 establish complex procedures for some acquisitions of Chinese companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

PRC regulations and rules concerning mergers and acquisitions including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of PRC promulgated on August 30, 2007 and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the Prior Notification Rules issued by the State Council in August 2008, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Lenders, or the Security Review Rules issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

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

Table of Contents

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

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

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

We and our directors, executive officers and other employees who are PRC residents have participated in our employee equity incentive plans. Upon completion of our initial public offering, we became an overseas listed company. Pursuant to SAFE Circular 37, PRC residents who participate in share incentive plans in overseas non-publicly-listed companies may submit applications to SAFE or its local branches for the foreign exchange registration with respect to offshore special purpose companies. Our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted shares or options may follow SAFE Circular 37 to apply for the foreign exchange registration before our company became an overseas listed company. However, in practice, different local SAFE branches may have different views and procedures on the application and implementation of SAFE regulations, and there remains uncertainty with respect to its implementation. If we or our directors, executive officers or other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted shares or options, including but not limited to the four shareholders referred to above, fail to register the employee equity incentive plans or their exercise of options, we and such employees may be subject to (i) legal or administrative sanctions imposed by the SAFE or other PRC authorities, including fines; (ii) to restrictions on our cross-border investment activities; (iii) to limits on the ability of our wholly owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us; and (iv) to prohibitions on our ability to inject additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected. Upon completion of our initial public offering, we became an overseas

listed company, and therefore, we and our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted shares or options are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, issued by SAFE in February 2012, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than

Table of Contents

one year, subject to limited exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. Failure to complete the SAFE registrations may subject them to fines and legal sanctions and may also limit our ability to make payments under our equity incentive plans or receive dividends or sales proceeds related thereto, or our ability to contribute additional capital into our wholly-foreign owned enterprises in China and limit our wholly-foreign owned enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law.

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

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

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

Under PRC laws, rules and regulations, each of our subsidiaries incorporated in China is required to set aside a portion of its net income each year to fund certain statutory reserves. These reserves, together with the registered equity, are not distributable as cash dividends. As a result of these laws, rules and regulations, our subsidiaries incorporated in China are restricted in their ability to transfer a portion of their respective net assets to their shareholders as dividends. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each operating subsidiary. As of September 30, 2017, these restricted assets totaled RMB166.6 million.

The Enterprise Income Tax Law, or the EIT Law and its implementation rules, both of which became effective on January 1, 2008, provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor's jurisdiction of 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 HK, 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 HK currently does not hold a Hong Kong tax resident certificate from the Inland Revenue

Department of Hong Kong and there is no assurance that the reduced withholding tax rate will be available.

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

Table of Contents

to make investments or acquisitions that could be beneficial to our businesses, pay dividends, or otherwise fund and conduct our business.

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

Under the EIT Law an enterprise established outside China with "de facto management bodies" within China is considered a "resident enterprise," meaning that it is treated in a manner similar to a Chinese enterprise for PRC enterprise income tax, or EIT, purposes. The implementing rules of the EIT Law define "de facto management bodies" as "management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties" of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders' meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011, the SAT issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial), or Bulletin 45, which became effective on September 1, 2011 and was most recently amended on October 1, 2016, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration. In 2014, the SAT, released the Announcement of the SAT on Issues Concerning the Recognition of Chinese-Controlled Enterprises Incorporated Overseas as Resident Enterprises on the Basis of Their Actual Management Bodies and supplemented some provisions on the administrative procedures for the recognition of resident enterprise, while the standards used to classify resident enterprises in Circular 82 remain unchanged.

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

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

Table of Contents

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

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

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

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

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax

authorities make adjustments to the taxable income of the transactions under Circular 698/Bulletin 7, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

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

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue may in the future be denominated in RMB. Shortages

Table of Contents

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.

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

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

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

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

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

not require these firms to admit to any violation of law and preserves these firms' legal defenses in the event the administrative proceeding is restarted. In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings

Table of Contents

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

*The trading prices of the ADSs are 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 since that 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, clinical development and commercialization programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- fluctuations in product revenue, sales and marketing expenses and profitability;
- manufacture, supply or distribution shortages;

Table of Contents

- variations in our results of operations;
- announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- media reports, whether or not true, about our business;
- additions to or departures of our management;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs;
- sales or perceived potential sales of additional ordinary shares or ADSs;
- sales of the ADSs by us, our executive officers and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- changes in accounting principles;
- changes or developments in the PRC or global regulatory environment; and
- the outcome of proceedings recently instituted by the SEC against five PRC-based accounting firms, including the affiliate of our independent registered public accounting firm.

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

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

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

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

Table of Contents

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

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

As of November 8, 2017, we had 591,072,330 ordinary shares outstanding, of which 377,568,555 ordinary shares were held in the form of 29,043,735 ADSs. Of this amount, 32,746,416 ordinary shares issued to Celgene at the closing of the Celgene Transaction are subject to a one-year lock-up.

Furthermore, we have registered or plan to register the offer and sale of all ordinary shares that we have issued and may issue in the future under our equity compensation plans, including upon the exercise of share options and vesting of restricted share units. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

On May 26, 2017, we filed a registration statement on behalf of certain shareholders, registering 299,279,370 ordinary shares in the form of 23,021,490 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. As of September 30, 2017, the holder of approximately 224,372 of our then-outstanding ordinary shares, had rights, subject to some conditions, to include its ordinary shares in registration statements we may file for ourselves or other shareholders. We have also agreed to grant certain registration rights with respect to the shares to be issued to Celgene in the event that they are not eligible for sale under Rule 144.

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

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

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

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

We have determined that, as of June 30, 2017, we have at least $700 million of equity securities held by non-affiliates, and as such we will no longer qualify as an emerging growth company as of December 31, 2017. As a result, we will no longer be able to take advantage of specified reduced disclosure and other requirements that are available to emerging growth companies after such date.

112

Table of Contents

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 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.

Table of Contents

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 a substantial amount 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, as amended.

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

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

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

For example, our board of directors has the authority, without further action by our shareholders, to issue 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.

Table of Contents

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 any of our public offerings, would be preempted by federal law. Similarly, it is unclear how courts might apply the standard that a claiming party must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of our fee-shifting article in connection with such claims, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting article in any particular dispute, including any claims related to our public offerings. Consistent with our directors' fiduciary duties to act in the best interests of the company, the directors may in their sole discretion from time to time decide whether or not to enforce this article. In addition, given the unsettled state of the law related to fee-shifting articles, such as ours, we may incur significant additional costs associated with resolving disputes with respect to such articles, which could adversely affect our business and financial condition.

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

Table of Contents

The depositary for the ADSs will give us a discretionary proxy to vote our ordinary shares underlying your ADSs if you do not vote at shareholders' meetings, except in limited circumstances, which could adversely affect your interests.

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

- we have failed to timely provide the depositary with our notice of meeting and related voting materials;
- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- 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, as amended, or for any other reason, subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares.

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

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

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

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

Table of Contents

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 66.7% of our outstanding ordinary shares as of November 1, 2017. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and reducing the price of the ADSs. These actions may be taken even if they are opposed by our other shareholders, including the holders of the ADSs. In addition, these persons could divert business opportunities away from us to themselves or others.

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

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

time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

Table of Contents

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 were first required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2016. Because we remain an emerging growth company, we are not currently required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, we will no longer qualify as an emerging growth company as of December 31, 2017, and will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm after such date.

To achieve compliance with Section 404 within the prescribed period, we will continue to 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 determined that we were a “passive foreign investment company” in 2016 and we may be a passive foreign investment company in future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders.

U.S. investors should be aware that we determined that we were a passive foreign investment company, within the meaning of Section 1297 of the Internal Revenue Code of 1986, as amended, or PFIC, for 2016. Given that the transactions with Celgene closed during the third quarter of 2017, we do not expect to be a PFIC for 2017. However, as our PFIC status must be determined annually with respect to each taxable year and will depend on the composition and character of our assets and income and the value of our assets (which may be determined, in part, by reference to the market value of our ADSs, which may be volatile) over the course of such taxable year, we may be a PFIC in any taxable year. If we are a PFIC for any taxable year during a U.S. shareholder’s holding period of the ADSs or ordinary shares, then, regardless of whether we cease to meet the threshold requirements for PFIC status, 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. In addition, the U.S. shareholder would be subject to the same adverse U.S. federal income tax consequences on (i) certain distributions by any of our subsidiaries treated as PFICs (“lower-tier PFICs”), and (ii) a disposition of sharers of a lower-tier PFIC, in each case as if the U.S. shareholder owned the shares of the relevant lower-tier PFIC directly, even though the U.S. shareholder has not received the proceeds of those distributions or dispositions. A U.S. shareholder who makes an effective QEF election generally must report on a current basis its share of our net capital gain and ordinary earnings for any taxable year in which we are a PFIC, whether or not we distribute any amounts to our shareholders. If a QEF election is not in effect for the first taxable

year in your holding period in which we are a PFIC, a QEF election can only be made if you elect to recognize gain as if you had sold the ADSs or ordinary shares for their fair market value on the first day of your taxable year in which the PFIC becomes a QEF pursuant to the QEF election. The gain recognized on this deemed sale would be subject to the general tax treatment of PFICs discussed above. We have posted on our website the information necessary for U.S. investors to make a QEF election for 2016. We intend to determine our PFIC status at the end of each taxable year and to satisfy any

Table of Contents

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 and advisability 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.

We may be subject to adverse legislative or regulatory tax changes that could negatively affect our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many changes have been made and changes are likely to continue to be made in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided that could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

*Failure to comply with NASDAQ Marketplace Rules could materially and adversely affect our business.

We currently have two members on our Audit Committee and one vacancy. In accordance with NASDAQ Marketplace Rule 505(c)(2)(A), we are required to maintain an audit committee composed of at least three members who meet certain eligibility criteria in order to remain listed on the NASDAQ Global Select Market. Under NASDAQ rules, we have a cure period which extends until the earlier of (1) our next annual general meeting of shareholders or (2) June 1, 2018 to regain compliance, or, if the next annual general meeting of shareholders is held no later than November 28, 2017, then we must regain compliance no later than November 28, 2017. We intend to appoint an additional independent director to the Audit Committee prior to the end of the cure period. In the event that we were delisted from the NASDAQ Global Select Market, our ADSs would become significantly less liquid, which would adversely affect their value. Although our ADSs would likely be traded over-the-counter or on pink sheets, these types of listings involve more risk and trade less frequently and in smaller volumes than securities traded on the NASDAQ

Global Select Market.

Table of Contents

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

Recent Sales of Unregistered Securities

We did not sell any of our ordinary shares or ADSs, or grant any share options or other equity awards, during the three months ended September 30, 2017 that were not registered under the Securities Act of 1933, as amended, or the Securities Act, except as follows:

On August 31, 2017, we sold 32,746,416 ordinary shares to Celgene Switzerland LLC, or Celgene Switzerland, for an aggregate cash price of $150 million, or $4.58 per ordinary share, or $59.55 per ADS, pursuant to Share Subscription Agreement dated July 5, 2017 by and between BeiGene and Celgene Switzerland, or the Share Subscription Agreement. The offer and sale of the shares issued pursuant to the Share Subscription Agreement was made in a private placement in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act, for transactions by an issuer not involving a public offering, and/or Regulation D under the Securities Act. All certificates evidencing the shares will bear a standard restrictive legend under the Securities Act.

Use of Proceeds from Sales of Registered Securities

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

We raised $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 ten percent or more of any class of our equity securities or to any other affiliates.

As of September 30, 2017, we have used all of 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. Prior to their use, we invested a significant portion of the balance of the net proceeds from our initial public offering in short-term, interest-bearing investment-grade securities and government securities in accordance with our investment policy. Our use of the net offering proceeds was consistent with the use of proceeds described in our final prospectus filed with the SEC on February 3, 2016 pursuant to Rule 424(b) under the Securities Act, and there has been no material change in our planned use of the balance of the net proceeds from the offerings described in such prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Table of Contents

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

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.	10-Q	08/10/2016	4.7	
4.8	Registration Rights Agreement, dated as of November 16, 2016, by and among the Registrant and the investors name therein	8-K	08/10/2016	4.1	
4.9	Form of Letter Agreement, between the Registrant and Citibank, N.A.	10-Q	05/10/2017	4.9	
10.1	Share Subscription Agreement, dated July 5, 2017, by and between Celgene Switzerland LLC and the Registrant	8 K	07/06/2017	10.1	
10.2#	Amended and Restated Exclusive License and Collaboration Agreement, dated August 31, 2017, by and among the Registrant, Celgene Corporation and Celgene Switzerland LLC				X
10.3#	License and Supply Agreement, dated July 5, 2017, by and between the Registrant and Celgene Logistics Sàrl				X
10.4†	Amendment No. 1 to BeiGene, Ltd. 2016 Share Option and Incentive Plan				X
10.5†	Forms of Restricted Share Unit Award Agreement and Share Option Agreement under BeiGene, Ltd. 2016 Share Option and Incentive Plan				X

Table of Contents

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
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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 Income (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.

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

*Furnished herewith.

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: November 13, 2017 By: /s/ John V. Oyler
John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: November 13, 2017 By: /s/ Howard Liang
Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)