

BeiGene, Ltd.
Form 10-Q
November 10, 2016
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, 2016**

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
(State or other jurisdiction of
incorporation or organization)

98-1209416
(I.R.S. Employer
Identification No.)

c/o Maurant 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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

Edgar Filing: BeiGene, Ltd. - Form 10-Q

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 7, 2016, 429,494,031 ordinary shares, par value \$0.0001 per share, were outstanding, of which 151,076,341 ordinary shares were held in the form of 11,621,257 American Depositary Shares, each representing 13 ordinary shares.

Table of Contents

**BeiGene, Ltd.
Quarterly Report on Form 10-Q**

TABLE OF CONTENTS

		Page
<u>PART I.</u>	<u>FINANCIAL INFORMATION</u>	2
<u>Item 1.</u>	<u>Financial Statements</u>	2
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	33
<u>Item 4.</u>	<u>Controls and Procedures</u>	34
<u>PART II.</u>	<u>OTHER INFORMATION</u>	35
<u>Item 1.</u>	<u>Legal Proceedings</u>	35
<u>Item 1A.</u>	<u>Risk Factors</u>	36
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	105
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	105
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	105
<u>Item 5.</u>	<u>Other Information</u>	105
<u>Item 6.</u>	<u>Exhibits</u>	105
<u>SIGNATURES</u>		106

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****BEIGENE, LTD.****CONDENSED CONSOLIDATED BALANCE SHEETS**

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

	Note	December 31, 2015 \$ (audited)	As of September 30, 2016 \$ (unaudited)
Assets			
Current assets:			
Cash and cash equivalents		17,869	85,532
Short-term investments	3	82,617	118,086
Prepaid expenses and other current assets		5,783	6,335
Total current assets		106,269	209,953
Property and equipment, net	4	6,612	16,554
Other non-current assets		3,883	8,918
Total non-current assets		10,495	25,472
Total assets		116,764	235,425
Liabilities and shareholders deficit			
Current liabilities:			
Accounts payable		8,980	7,307
Advances from customers		1,070	
Accrued expenses and other payables	6	8,351	21,715
Senior Promissory Note	9	14,598	
Warrant and option liabilities	7	2,173	
Tax payable			294
Total current liabilities		35,172	29,316
Non-current liabilities:			
Long-term bank loan	8	6,188	18,030
Deferred rental		980	
Other long-term liabilities		105	247
Total non-current liabilities		7,273	18,277
Total liabilities		42,445	47,593
Commitments and contingencies	18		
Convertible preferred shares	10	176,084	

Series A (par value US\$0.0001 per share; 120,000,000 shares authorized; 116,785,517 shares issued and outstanding as of December 31, 2015) and Series A-2 (par value US\$0.0001 per share; 100,000,000 shares

Edgar Filing: BeiGene, Ltd. - Form 10-Q

authorized; 83,205,124 shares issued and outstanding as of December 31, 2015)

Total mezzanine equity		176,084	
Shareholders' deficit:			
Ordinary shares (par value of US\$0.0001 per share; 9,500,000,000 shares authorized; 428,519,031 shares issued and outstanding as of September 30, 2016 (December 31, 2015: 116,174,094 shares))		12	43
Additional paid-in capital		18,227	388,568
Accumulated other comprehensive loss	15	(1,809)	(965)
Accumulated deficit		(118,195)	(199,814)
Total shareholders' (deficit) equity	16	(101,765)	187,832
Total liabilities, mezzanine equity and shareholders' (deficit) equity		116,764	235,425

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

Table of Contents**BEIGENE, LTD.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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

(Unaudited)

	Note	Three Months Ended September 30,		Nine Months Ended September 30,	
		2015 \$	2016 \$	2015 \$	2016 \$
Revenue					
Collaboration revenue		1,380		4,139	1,070
Total revenue		1,380		4,139	1,070
Operating expenses:					
Research and development		(13,351)	(30,106)	(30,147)	(69,100)
General and administrative		(2,021)	(4,722)	(4,361)	(11,760)
Total operating expenses		(15,372)	(34,828)	(34,508)	(80,860)
Loss from operations		(13,992)	(34,828)	(30,369)	(79,790)
Interest income		760	209	1,286	965
Interest expense		(300)	(284)	(840)	(629)
Changes in fair value of financial instruments	7	(300)		(502)	(1,514)
Disposal loss on available-for-sale securities		(241)	(137)	(298)	(1,077)
Other income		187	198	996	1,261
Other expense		(113)	(525)	(125)	(529)
Loss before income tax expense		(13,999)	(35,367)	(29,852)	(81,313)
Income tax expense	5		(127)		(306)
Net loss		(13,999)	(35,494)	(29,852)	(81,619)
Loss per share	13				
Basic and diluted		(0.13)	(0.08)	(0.28)	(0.21)
Weighted-average number of ordinary shares used in net loss per share calculation	13				
Basic and diluted		109,104,674	428,137,509	107,015,707	383,472,372
Loss per ADS					
Basic and diluted		(1.67)	(1.08)	(3.63)	(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 LOSS**

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015 \$	2016 \$	2015 \$	2016 \$
Net loss	(13,999)	(35,494)	(29,852)	(81,619)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	(428)	377	(509)	(13)
Unrealized holding (loss) gain, net	(303)	121	(724)	857
Comprehensive loss	(14,730)	(34,996)	(31,085)	(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. Dollar (\$), except for number of shares and per share data)

(Unaudited)

	Note	Nine Months Ended September 30,	
		2015 \$	2016 \$
Operating activities			
Net loss		(29,852)	(81,619)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation expenses	4	1,127	1,436
Share-based compensation expenses	14	8,043	6,678
Loss on disposal of property and equipment		3	
Changes in fair value of financial instruments		502	1,514
Disposal loss on available-for-sale securities		298	1,077
Interest expense		833	118
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		(4,074)	(2,183)
Other non-current assets		(354)	(1,281)
Accounts payable		1,507	(1,839)
Advances from customers		(4,141)	(1,070)
Accrued expenses and other payables		3,085	13,360
Tax payable			294
Other long-term liabilities		(58)	142
Net cash used in operating activities		(23,081)	(63,373)
Investing activities			
Purchases of property and equipment		(1,892)	(15,440)
Purchase of available-for-sale securities		(103,292)	(193,996)
Proceeds from disposal of available-for-sale securities		38,973	158,307
Proceeds from disposal of property and equipment		3	
Net cash used in investing activities		(66,208)	(51,129)
Financing activities			
Proceeds from issuance of ordinary shares, net of initial public offering costs			167,931
Proceeds from issuance of preferred shares		97,350	
Payment of convertible preferred shares issuance cost		(75)	
Repayment of short-term loan		(322)	
Proceeds from long-term loan		6,294	12,161
Proceeds from exercise of warrants and options		77	2,118
Net cash provided by financing activities		103,324	182,210
Effect of foreign exchange rate changes, net		(483)	(45)
Net increase in cash and cash equivalents		13,552	67,663

Edgar Filing: BeiGene, Ltd. - Form 10-Q

Cash and cash equivalents at beginning of period	13,898	17,869
Cash and cash equivalents at end of period	27,450	85,532
Supplemental cash flow disclosures:		
Income taxes paid		25
Interest expense paid	7	510
Non-cash activities:		
Conversion of Senior Promissory Note		14,693
Conversion of deferred rental		980
Conversion of convertible preferred shares		176,084
Conversion of warrant and option liabilities		3,687
Initial public offering costs accrued in accrued expenses and other payables		166
Acquisitions of equipment included in accounts payable	91	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 (\$), except for number of shares and per share data)

(Unaudited)

1. Organization

BeiGene, Ltd. (the Company) is a globally focused, clinical-stage biopharmaceutical company with the goal of becoming a leader in the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. The Company's development strategy is based on a novel translational platform that combines its unique access to internal patient-derived biopsies with strong oncology biology. The Company was incorporated under the laws of the Cayman Islands as an exempted company with limited liability on October 28, 2010.

On February 8, 2016, the Company completed its initial public offering (IPO) on the NASDAQ Global Select Market. 6,600,000 ADSs representing 85,800,000 ordinary shares were sold at \$24.00 per ADS, or \$1.85 per share (the IPO Price). Additionally, the underwriters exercised their options to purchase an additional 12,870,000 ordinary shares in the form of 990,000 ADSs. Net proceeds from the IPO including underwriter options after deducting underwriting discount and offering expenses were \$166,197. The deferred IPO costs were recorded as a reduction of the proceeds received from the IPO in the shareholders' equity.

As at September 30, 2016, the Company's wholly-owned subsidiaries are as follows:

Name of Company	Place of Incorporation	Date of Incorporation	Percentage of Ownership by the Company	Principal Activities
BeiGene (Hong Kong) Co., Limited.	Hong Kong	November 22, 2010	100%	Investment holding
BeiGene (Beijing) Co., Ltd. (BeiGene Beijing)	The People's Republic of China (PRC or China)	January 24, 2011	100%	Medical and pharmaceutical research
BeiGene AUS Pty Ltd.	Australia	July 15, 2013	100%	Clinical trial activities
BeiGene 101 Ltd.	Cayman Islands	August 30, 2012	100%	

Edgar Filing: BeiGene, Ltd. - Form 10-Q

				Medical and pharmaceutical research
BeiGene (Suzhou) Co., Ltd. (BeiGene (Suzhou))	PRC	April 9, 2015	100%	Medical and pharmaceutical research
BeiGene USA, Inc.	United States	July 8, 2015	100%	Clinical trial activities
BeiGene (Shanghai) Co., Ltd. (BeiGene (Shanghai))	PRC	September 11, 2015	100%	Medical and pharmaceutical research

2. Summary of significant accounting policies

Basis of presentation and principles of consolidation

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

Table of Contents

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

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

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

Use of estimates

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

Cash and cash equivalents

Cash and cash equivalents consist of cash on hand and bank deposits, which are unrestricted as to withdrawal and use. The Company considers all highly liquid investments with an original maturity date of three months or less at the date of purchase to be cash equivalents. Cash equivalents which consist primarily of money market funds are stated at fair value.

Fair value measurements

Fair value of financial instruments

Financial instruments of the Company primarily include cash and cash equivalents, short-term investments, long-term bank loan, accounts payable, Senior Promissory Note, convertible preferred shares, and warrant and option liabilities. As of December 31, 2015 and September 30, 2016, the carrying values of cash and cash equivalents, and accounts payable approximated their fair values due to the short-term maturity of these instruments. The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets. The short-term investments represented the available-for-sale debt securities which are recorded at fair value based on quoted prices in active markets with unrealized gain or loss recorded in other comprehensive income/loss. The long-term bank loan approximates its fair value due to the fact that the related interest rate approximates the rate currently offered by financial institutions for similar debt instruments of comparable maturities. The warrant and option liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. The Senior Promissory Note and

Table of Contents

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

The Company applies ASC topic 820 (ASC 820), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement. ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 - Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments measured at fair value on a recurring basis

The following tables set forth assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and September 30, 2016:

As of December 31, 2015	Quoted Price in Active Market for Identical Assets (Level 1) \$	Significant Other Observable Inputs (Level 2) \$	Significant Unobservable Inputs (Level 3) \$
Available-for-sale securities (note 3):			
Corporate fixed income bonds	69,255		
U.S. Treasury securities	8,000		
Municipal Bonds	5,362		

Edgar Filing: BeiGene, Ltd. - Form 10-Q

Option to purchase shares by rental deferral (note 7)	1,388
Warrants in connection with the convertible promissory notes (note 7)	785

As of September 30, 2016	Quoted Price in Active Market for Identical Assets (Level 1) \$	Significant Other Observable Inputs (Level 2) \$	Significant Unobservable Inputs (Level 3) \$
Available-for-sale securities (note 3):			
Corporate fixed income bonds	6,942		
U.S. Treasury securities	111,144		
Cash equivalents			
Money market funds	43,813		

Table of Contents

The Company has measured the option to purchase shares by rental deferral and the warrants in connection with the convertible promissory notes at fair values on a recurring basis using significant unobservable inputs (Level 3) as of December 31, 2015. The option and warrants have been exercised as of September 30, 2016. The Company determined the exercise date fair value of the warrants and option using significant other observable inputs (Level 2).

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

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

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

Recent accounting pronouncements

In August 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-14, *Revenue from Contracts with Customers-Deferral of the effective date* (ASU 2015-14). The amendments in ASU 2015-14 defer the effective date of ASU No. 2014-09, *Revenue from Contracts with Customers*, (ASU 2014-09), issued in May 2014. According to the amendments in ASU 2015-14, the new revenue guidance ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers Principal versus Agent Considerations* (ASU 2016-08), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers Identifying Performance Obligations and Licensing* (ASU 2016-10), which clarify guidance related to identifying performance obligations and licensing implementation guidance contained in ASU No. 2014-09. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers Narrow-Scope Improvements and Practical Expedients* (ASU 2016-12), which addresses narrow-scope improvements to the guidance on collectability, non-cash consideration, and completed contracts at transition and provides practical expedients for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers. The effective date for the amendment in ASU 2016-08, ASU 2016-10 and ASU 2016-12 are the same as the effective date of ASU No. 2014-09. The Company is currently evaluating the method of adoption to be utilized and it cannot currently estimate the financial statement impact of adoption.

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

Table of Contents

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

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

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

In August 2016, the FASB issued ASU No. 2016-15, *Statement of cash flows - Classification of Certain Cash Receipts* (ASU 2016-15). The amendments in ASU 2016-15 addresses eight specific cash flow issues, including debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (COLIs) (including bank-owned life insurance policies (BOLIs)), distributions received from equity method investees, beneficial interests in securitization transactions and separately identifiable cash flows and application of the predominance principle. For public business entities that are U.S. SEC filers, ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the method of adoption to be utilized and it cannot currently estimate the financial statement impact of adoption.

3. Short-term investments

Short-term investments as of December 31, 2015 consisted of the following available-for-sale exchange-traded debt securities:

Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
-------------------	---------------------------	----------------------------	--

Edgar Filing: BeiGene, Ltd. - Form 10-Q

	\$	\$	\$	\$
Corporate fixed income bonds	70,383		1,128	69,255
U.S. Treasury securities	7,999	1		8,000
Municipal Bonds	5,441		79	5,362
Total	83,823	1	1,207	82,617

Table of Contents

Short-term investments as of September 30, 2016 consisted of the following available-for-sale exchange-traded debt securities:

	Amortized Cost \$	Gross Unrealized Gains \$	Gross Unrealized Losses \$	Fair Value (Net Carrying Amount) \$
Corporate fixed income bonds	7,194		252	6,942
U.S. treasury securities	111,241	12	109	111,144
Total	118,435	12	361	118,086

Contractual maturities of all debt securities as of September 30, 2016 were within one year. The Company does not intend to sell the debt securities and it is not more likely than not that the Company will be required to sell the investment before recovery of its amortized cost basis, which may be maturity. Therefore, the Company does not consider the debt securities to be other-than-temporarily impaired at September 30, 2016.

4. Property and equipment

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

	December 31, 2015 \$	As of September 30, 2016 \$
Office equipment	213	224
Electronic equipment	424	609
Laboratory equipment	5,919	7,275
Computer software	186	330
Leasehold improvements	5,954	6,826
Property and equipment, at cost	12,696	15,264
Less accumulated depreciation and amortization	(6,084)	(7,327)
Construction in progress		8,617
Property and equipment, net	6,612	16,554

Depreciation expenses for the three and nine months ended September 30, 2015 were \$402 and \$1,127, respectively. Depreciation expenses for the three and nine months ended September 30, 2016 were \$505 and \$1,436, respectively.

5. Income taxes

Edgar Filing: BeiGene, Ltd. - Form 10-Q

Income tax expense was \$127 and \$306, respectively, for the three and nine months ended September 30, 2016 compared with nil for both the three and nine months ended September 30, 2015. Current year income tax expense was attributable to BeiGene USA, Inc., a wholly owned subsidiary, which was established in July 2015 and provided general management services and strategic advisory services to the Company. The Company and its other subsidiaries were in a cumulative loss position for the three and nine months ended September 30, 2015 and 2016.

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

6. Accrued expenses and other payables

	December 31, 2015 \$	As of September 30, 2016 \$
Payroll payables	275	205
Accrued operating expenses	5,513	17,392
Other payables	2,563	4,118
Total accrued expenses and other payables	8,351	21,715

Table of Contents**7. Warrant and option liabilities**

	December 31, 2015 \$	As of	September 30, 2016 \$
Option to purchase shares by rental deferral	1,388		
Warrants in connection with the promissory notes	785		
Total	2,173		

Option to purchase shares by rental deferral

On September 1, 2012, in conjunction with a lease agreement of one of its premises, the Company granted the landlord an option to purchase the Company's ordinary shares (the "Option") in exchange for the deferral of the payment of one year's rental expense. The Option is a freestanding instrument and is recorded as liability in accordance with ASC480, *Distinguishing Liabilities from Equity*. The Option was initially recognized at fair value with subsequent changes in fair value recorded in losses. Prior to the Company's IPO, the Company determined the fair value of the Option with the assistance of an independent third party valuation firm. On February 8, 2016, immediately prior to the Company's IPO, the landlord exercised the Option to purchase 1,451,586 ordinary shares of the Company. As the exercise date was the IPO closing date, the exercise date fair value of the Option of \$2,540 was determined based on its intrinsic value, which equals to 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, 2015, the Company recognized a loss from the increase in fair value of the Option of \$240 and \$352, respectively. 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 and 2014, the Company entered into agreements with several investors to issue convertible promissory notes, and related warrants to purchase the Company's preferred shares up to 10% of the convertible promissory notes principal amount concurrently for an aggregate principal amount of \$2,410. The warrants were freestanding instruments and were recorded as liabilities in accordance with ASC480. The warrants were initially recognized at fair value with subsequent changes in fair value recorded in losses. In January and February, 2016, the warrants issued in connection with the promissory notes were exercised for 621,637 Preferred Shares, which shares were converted into 621,637 ordinary shares. As the exercise dates were very close to the IPO closing date, the respective exercise date fair value of the warrants of \$1,148 was determined based on the intrinsic value, which equals to the difference between the share price at the IPO closing date and the exercise price of the issued warrants.

For the three and nine months ended September 30, 2015, the Company recognized loss from the increase in fair value of the warrants of \$60 and \$150, respectively. For the three and nine months ended September 30, 2016, the Company recognized loss from the increase in fair value of the warrants of nil and \$363, respectively.

8. Long-term bank loan

On September 2, 2015, BeiGene Suzhou entered into a loan agreement with Suzhou Industrial Park Biotech Development Co., Ltd. and China Construction Bank, to borrow \$17,995 at a 7% fixed annual interest rate. As of September 30, 2016, the Company has drawn down \$17,995 which is secured by BeiGene Suzhou's future equipment purchases and the Company's rights to a PRC patent on a drug candidate. The loan amounts of \$8,998 and \$8,997 are repayable on September 30, 2018 and 2019,

Table of Contents

respectively. Interest expense recognized for the three and nine months ended September 30, 2016 amounted to \$284 and \$534, respectively.

9. Senior Promissory Note

On January 26, 2016, the Company entered into a note amendment and exchange agreement with Merck Sharp & Dohme Research GmbH (MSD), pursuant to which, the maturity date of the Senior Promissory Note was extended to May 2, 2016 from February 2, 2016. In addition, if the IPO occurred on or prior to May 2, 2016, subject to certain limitations, the outstanding unpaid principal and interest of the Senior Promissory Note as of the effectiveness date of the Company's IPO (the Exchanged Balance) would be automatically exchanged, effective immediately prior to the closing of the IPO, into up to a number of the Company's ordinary shares equal to the quotient of (1) the Exchanged Balance divided by (2) the per ordinary share public offering price in the IPO. The amendments and subsequent extinguishment of the Senior Promissory Note did not result in any gain or loss since the conversion rate was set at the IPO Price.

On February 8, 2016, the outstanding unpaid principal and interest of the Senior Promissory Note of carrying value of \$14,693 were exchanged into 7,942,314 ordinary shares, computed at the IPO Price of \$1.85 per ordinary share.

10. Convertible preferred shares

In October 2014, the Company issued 52,592,590 Series A convertible preferred shares (the Series A Preferred Shares) with a par value of \$0.0001 per share for cash consideration of \$35,500 or \$0.68 per share. At the same time, the previously issued subordinated convertible promissory note, convertible promissory notes, secured guaranteed convertible promissory notes, advances and convertible promissory notes due to a related party were automatically converted into 64,192,927 Series A Preferred Shares in aggregate.

On April 21, 2015, the Company issued 83,205,124 Series A-2 convertible preferred shares (the Series A-2 Preferred Shares) with a par value of \$0.0001 per share for cash consideration of \$97,350 or \$1.17 per share.

The Series A Preferred Shares and the Series A-2 Preferred Shares are collectively referred to as the Preferred Shares.

The significant terms of the Preferred Shares are summarized below.

Dividends

Edgar Filing: BeiGene, Ltd. - Form 10-Q

The holders of the Preferred Shares shall be entitled to receive dividends accruing at the rate of 8% per annum. In addition, holders of the Preferred Shares shall also be entitled to dividends on the Company's ordinary shares on an as if converted basis.

Voting rights

Each holder of Preferred Shares shall have the right to vote the number of votes per ordinary share into which their Preferred Shares could be converted, and shall vote along with the ordinary shares, on all matters in respect to which the holders of ordinary shares are entitled to vote.

Liquidation preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or any deemed liquidation event as defined in the Preferred Shares agreements (Liquidation Transaction), the holders of Preferred Shares then outstanding are entitled to be paid out of the assets of the Company available for distribution to its members before any payment shall be made to the holders of any other class of shares by reason of their ownership thereof, an amount per share equal to the greater of (i) the original issue price, plus accrued but unpaid dividends; or (ii) such amount per share as would have been

Table of Contents

payable had all Preferred Shares been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or deemed liquidation event.

Conversion rights

(i) **Optional conversion:** Each Preferred Share shall be convertible into the Company's ordinary shares at the option of the holder at any time after the issuance date by dividing the original issue price by the conversion price, which is initially equal to the original issue price. Upon conversion of the Preferred Shares, all unpaid, cumulative dividends on the Preferred Shares shall no longer be payable.

(ii) **Automatic conversion:** All outstanding Preferred Shares shall automatically be converted into ordinary shares at the then effective Preferred Shares conversion price upon (i) the closing of a Qualified IPO; or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 80.63% of the then-outstanding Preferred Shares. Upon conversion of the Preferred Shares, all unpaid cumulative dividends on the Preferred Shares shall no longer be payable.

Drag-along right

In the event that each of (i) (A) entities affiliated with Baker Bros. Advisors LP (collectively, Baker Bros.) or (B) Hillhouse BGN Holdings Limited (Hillhouse) and CB Biotech Investment Limited (CITIC PE) jointly; (ii) a majority of the Board of Directors; and (iii) the holders of more than 66.66% of the then-outstanding ordinary shares (other than those issued or issuable upon conversion of the Preferred Shares and any other derivative securities) approve a sale of the Company in writing, then each preferred shareholder agrees to certain joint actions to be taken to ensure such sale of the Company could be completed.

Accounting for preferred shares

The Preferred Shares are classified as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event (i.e., a Liquidation Transaction). The holders of the Preferred Shares have a liquidation preference and will not receive the same form of consideration upon the occurrence of the conditional event as the holders of the ordinary shares would. The initial carrying amount of the Series A Preferred Shares of \$78,809 is the issue price at the date of issuance of \$78,889 net of issuance costs of \$80. The initial carrying amount of the Series A-2 Preferred Shares of \$97,275 is the issue price at the date of issuance of \$97,350 net of issuance costs of \$75. The holders of the Preferred Shares have the ability to convert the instrument into the Company's ordinary shares. The conversion option of the convertible preferred shares do not qualify for bifurcation accounting because the conversion option is clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily

convertible into cash. The contingent redemption options of the convertible preferred shares do not qualify for bifurcation accounting because the underlying ordinary shares are neither publicly traded nor readily convertible into cash. There are no other embedded derivatives that are required to be bifurcated.

Beneficial conversion features exist when the conversion price of the convertible preferred shares is lower than the fair value of the ordinary shares at the commitment date, which is the issuance date in the Company's case. When a beneficial conversion feature exists as of the commitment date, its intrinsic value is bifurcated from the carrying value of the convertible preferred shares as a contribution to additional paid-in capital. On the commitment date of Series A Preferred Shares and Series A-2 Preferred Shares, the most favorable conversion price used to measure the beneficial conversion feature were \$0.68 and \$1.17, respectively. No beneficial conversion feature was recognized for the Series A Preferred Shares and Series A-2 Preferred Shares as the fair value per ordinary share at the commitment date were \$0.28 and \$0.47, respectively, which was less than the most favorable conversion price. The Company determined the fair value of ordinary shares with the assistance of an independent third party valuation firm.

Table of Contents

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

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

11. Related party balances and transactions

During the three and nine months ended September 30, 2015, a shareholder 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.

12. Research and development collaborative arrangements

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015 \$	2016 \$	2015 \$	2016 \$
License revenue				
Research and development revenue	1,380		4,139	1,070
Total	1,380		4,139	1,070

The Company recorded advances from customers related to the research and development collaboration arrangement with Merck KGaA of approximately \$1,070 and nil at December 31, 2015 and September 30, 2016, respectively.

13. Loss per share

Loss per share was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015 \$	2016 \$	2015 \$	2016 \$
Numerator:				
Net loss attributable to ordinary shareholders for computing basic and diluted loss per ordinary share	(13,999)	(35,494)	(29,852)	(81,619)
Denominator:				
Weighted average number of ordinary shares outstanding for computing basic and diluted loss per ordinary share	109,104,674	428,137,509	107,015,707	383,472,372
Basic and diluted loss per share	(0.13)	(0.08)	(0.28)	(0.21)

For the three and nine months ended September 30, 2015 and 2016, the computation of basic loss per share using the two-class method was not applicable as the Company was in a net loss position.

The effects of all convertible preferred shares, share options, restricted shares, warrants and option to purchase ordinary or preferred shares were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive during the three months ended September 30, 2015 and the

Table of Contents

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

14. Share-based compensation

2016 share option and incentive plan

On January 14, 2016, in connection with the IPO, the board of directors and shareholders of the Company approved a new equity compensation plan, the 2016 Share Option and Incentive Plan, or 2016 Plan, which became effective on February 2, 2016. The Company initially reserved 65,029,595 ordinary shares for the issuance of awards under the 2016 Plan plus any shares available under the 2011 Plan and not subject to any outstanding options as of the effective date of the 2016 Plan. The 2016 Plan provides that the number of ordinary shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2017, by 5% of the outstanding number of ordinary shares on the immediately preceding December 31 or such lesser number of ordinary shares as determined by the board of directors or the compensation committee. This number is subject to adjustment in the event of a share split, share dividend or other change in the Company's capitalization. In addition, shares not needed to fulfill any obligations under the 2011 Plan will also be available for issuance under the 2016 Plan.

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

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

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

During the three months ended September 30, 2016, the Company granted an aggregate of 19,935,531 options to employees, 2,872,080 options to consultants, and 600,000 restricted ordinary shares to employees under the 2016 plan. For options granted, exercise price per ordinary share equals to 1/13 of the closing price of the Company's ADS quoted on the NASDAQ Stock Exchange on the applicable grant date.

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.

Edgar Filing: BeiGene, Ltd. - Form 10-Q

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

Modification

Upon the completion of the Company's IPO on February 8, 2016 (Date of the Change in Employment Status), a consultant (the Consultant) became a member of the Company's board of directors and his compensation is now treated as employee compensation. The fair value of the options granted by the Company to the Consultant has been re-measured as of the Date of the Change in Employment Status and compensation charges have been accounted for prospectively over the remaining vesting period. There were no other modifications to the Company's share option arrangements for the periods presented.

The following table summarizes total share-based compensation expense recognized for the three and nine months ended September 30, 2015 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015 \$	2016 \$	2015 \$	2016 \$
Research and development	4,580	2,135	7,765	5,178
General and administrative	239	644	278	1,500
Total	4,819	2,779	8,043	6,678

Table of Contents**15. Accumulated other comprehensive loss**

The movement of accumulated other comprehensive loss was as follows:

	Foreign Currency Translation Adjustments \$	Unrealized Gains (Losses) on available-for-sale securities \$	Total \$
Balance as of December 31, 2015	(602)	(1,207)	(1,809)
Other comprehensive income before reclassifications	(13)	(220)	(233)
Amounts reclassified from accumulated other comprehensive loss		1,077	1,077
Net-current period other comprehensive loss	(13)	857	844
Balance as of September 30, 2016	(615)	(350)	(965)

16. Shareholders' equity*Conversion of Preferred Shares and Senior Promissory Note*

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

Exercise of the option and warrants

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

17. Restricted net assets

As a result of PRC laws and regulations, the Company's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company. As of December 31, 2015 and September 30, 2016, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to \$3,383 and \$2,581, respectively.

Table of Contents**18. Commitments and contingencies***Operating lease commitments*

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

There are no restrictions placed upon the Company by entering into these leases. Total expenses under these operating leases were \$279 and \$830 for the three and nine months ended September 30, 2015, respectively. Total expenses under these operating leases were \$748 and \$1,373 for the three and nine months ended September 30, 2016, respectively.

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

	\$
Three months ending December 31, 2016	656
Year ending December 31, 2017	2,512
Year ending December 31, 2018	2,279
Year ending December 31, 2019	1,832
Year ending December 31, 2020	1,670
Year ending December 31, 2021 and thereafter	481
Total	9,430

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

Capital commitments

The Company had capital commitments amounting to \$9,587 for the acquisition of property, plant and equipment as of September 30, 2016.

Table of Contents**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements (unaudited) and related notes included in the section of this Quarterly Report on Form 10-Q, or this Quarterly Report, titled Item 1 Financial Statements. This Quarterly Report contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: aim, anticipate, believe, continue, could, estimate, expect, goal, intend, may, ongoing, plan, potential, predict, project, negative of these terms or other similar expressions, although not all forward-looking statements contain these words. These forward-looking statements, include, but are not limited to, statements regarding: the initiation, timing, progress and results of our preclinical studies and clinical trials and our research and development programs; our ability to advance our drug candidates into, and successfully complete, clinical trials; the ability of our drug candidates to be granted or to maintain Category 1 designation with the China Food and Drug Administration, or CFDA; our reliance on the success of our clinical-stage drug candidates BGB-3111, BGB-A317, BGB-290 and BGB-283 and certain other drug candidates, as monotherapies and in combination with our internally discovered drug candidates and third-party agents; the timing or likelihood of regulatory filings and approvals; the commercialization of our drug candidates, if approved; our ability to develop sales and marketing capabilities; the pricing and reimbursement of our drug candidates, if approved; the implementation of our business model, strategic plans for our business, drug candidates and technology; the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology; our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; cost associated with defending against intellectual property infringement, product liability and other claims; regulatory developments in the United States, China, the United Kingdom, the European Union and other jurisdictions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and our need for additional financing; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our ability to maintain and establish collaborations or obtain additional grant funding; the rate and degree of market acceptance of our drug candidates; developments relating to our competitors and our industry, including competing therapies; the size of the potential markets for our drug candidates and our ability to serve those markets; our ability to effectively manage our anticipated growth; our ability to attract and retain qualified employees and key personnel; our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance; the future trading price of the American Depositary Shares, or ADSs, and impact of securities analysts' reports on these prices; and other risks and uncertainties, including those listed under Part II Item 1A Risk Factors. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in Part II Item 1A Risk Factors of this Quarterly Report. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Unless the context requires otherwise, in this Quarterly Report, the terms BeiGene, the Company, we, us and our refer to BeiGene, Ltd. and its subsidiaries, on a consolidated basis.

Overview

We are a globally focused, clinical-stage biopharmaceutical company dedicated to becoming a leader in the discovery and development of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. We believe the next generation of cancer treatment will utilize therapeutics both as

Table of Contents

monotherapies and in combination to attack multiple underlying mechanisms of cancer cell growth and survival. We further believe that discovery of next-generation cancer therapies requires new research tools. To that end, we have developed a proprietary cancer biology platform that addresses the importance of tumor-immune system interactions and the value of primary biopsies in developing new models to support our drug discovery effort. Our strategy is to develop a pipeline of drug candidates with the potential to be best-in-class monotherapies and also important components of multiple-agent combination regimens.

We have used our cancer biology platform to develop four clinical-stage drug candidates that we believe have the potential to be best-in-class or first-in-class. In addition, we believe that each has the potential to be an important component of a drug combination addressing major unmet medical needs. Our clinical-stage drug candidates include three molecularly targeted agents, BGB-3111, BGB-290 and BGB-283 and one immuno-oncology agent, BGB-A317. BGB-3111 is a potent and highly selective small molecule inhibitor of BTK. BGB-290 is a molecularly targeted, orally available, potent and highly selective inhibitor of PARP1 and PARP2. BGB-283 is a small molecule inhibitor of both the monomer and dimer forms of the RAF kinase. For each of our molecularly targeted drug candidates, we have achieved proof-of-concept by demonstrating objective responses in the defined patient populations. BGB-3111 received orphan drug designation from the U.S. Food and Drug Administration, or FDA, for chronic lymphocytic leukemia, mantle cell lymphoma and Waldenström's macroglobulinemia. Our clinical-stage immuno-oncology agent, BGB-A317, is an investigational humanized monoclonal antibody against the immune checkpoint receptor, PD-1. We have Investigational New Drug Applications in effect for our BTK, PD-1 and PARP inhibitors with the FDA. We have also received approval of our Clinical Trial Applications for each of our four clinical-stage drug candidates from the China Food and Drug Administration, or CFDA. In addition to our clinical-stage drug candidates, we have a robust pipeline of preclinical programs and are planning to advance one or more of these programs into the clinic in the next 12 months. We have licensed the ex-China rights of BGB-283 to Merck KGaA. We retain full global rights for all of our other clinical and preclinical drug candidates and programs.

Since our inception on October 28, 2010, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any drug candidates approved for sale and have not generated any revenue from product sales. We have financed operations through a combination of debt and equity financings and private and public grants and contracts, including the net proceeds from the issuance of a senior note and a convertible promissory note to Merck Sharp & Dohme Research GmbH, or MSD, an affiliate of Merck Sharp & Dohme Corp., the private placements of our Series A preferred shares and Series A-2 preferred shares, and our collaboration with Merck KGaA, or Merck KGaA Collaboration. Since our inception in 2010, we have raised \$170 million in private equity financing from our dedicated group of investors, including leading healthcare-focused funds, major mutual funds, China-based funds and our founders, and additionally received \$37 million from the Merck KGaA Collaboration to fund our operations. On February 8, 2016, we completed our initial public offering and received net proceeds of \$166.2 million, after deducting underwriting discounts and offering expenses. Although it is difficult to predict our liquidity requirements, based upon our current operating plan and the successful completion of our initial public offering, we believe we have sufficient cash to meet our projected operating requirements for at least the next 12 months. See Liquidity and capital resources.

Since inception, we have incurred significant operating losses. As of September 30, 2016, we had an accumulated deficit of \$199.8 million. In the future, we may generate revenue from product sales, collaboration agreements, strategic alliances and licensing arrangements, or a combination of these. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue investment in our cancer biology platform;

Table of Contents

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

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

Cash used in operations were \$23.1 million and \$63.4 million, respectively, for the nine months ended September 30, 2015 and 2016. As of September 30, 2016, we had cash, cash equivalents and short-term investments of \$203.6 million, compared with \$100.5 million as of December 31, 2015.

Components of operating results

Revenue

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

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

On May 24, 2013, we entered into license agreements with Merck KGaA, which we amended and restated on December 10, 2013, and further amended on October 1, 2015 and December 3, 2015, pursuant to which (1) we granted to Merck KGaA an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA exercises its continuation option, to commercialize and manufacture our compound BGB-283, and any other compound covered by the same existing patent rights with primary activity to inhibit wildtype or certain mutant BRAF, in all countries of the world excluding The People's Republic of China, which we refer to as the Ex-PRC Territory, and (2) Merck KGaA granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the RAF dimer inhibitor in The People's Republic of China, which we refer to as the PRC Territory, subject to certain non-compete restrictions. Under these agreements, we received \$13 million in non-refundable payments in 2013 following their execution, \$5 million in milestone payments in 2014 and \$4 million in milestone payments in 2015. We are eligible to receive up to \$32 million, \$33 million and \$145 million in payments upon the successful achievement of pre-specified clinical, regulatory and commercial milestones in the Ex-PRC Territory, respectively, and another \$14 million in payments upon the successful achievement of pre-specified clinical milestones in the PRC Territory. Merck KGaA also is required to pay us tiered royalties ranging from the mid single-digit to the low-teens, on a country-by-country and licensed product-by-licensed product basis, on aggregate net sales of licensed products in the Ex-PRC Territory. In consideration for the licenses Merck KGaA grants to us, we are required to pay Merck KGaA a high single-digit royalty on aggregate net sales of licensed BRAF gene inhibitors in the PRC Territory.

On October 28, 2013, we entered into license agreements with Merck KGaA, pursuant to which (1) we granted to Merck KGaA an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA exercises a certain continuation option, to commercialize and manufacture our compound BGB-290 and any other compound covered by the same existing patent

Table of Contents

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

For more information on our collaborations with Merck KGaA, see Part I Item 1 Business Collaboration with Merck KGaA of our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC, on March 30, 2016, or our Annual Report.

We recognized \$1.4 million and \$4.1 million of collaboration revenue from the Merck KGaA Collaboration for the three and nine months ended September 30, 2015, respectively. We recognized nil and \$1.1 million of collaboration revenue from the Merck KGaA 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, comprised of an aggregate of \$22.0 million related to BGB-283 and \$12.0 million related to BGB-290. The revenue consists of an upfront non-refundable license fee, Phase 1 research and development fees, and a development based target payment related to the collaborative arrangements for BRAF, excluding the \$3 million in deferred revenue that was netted against the \$10 million repurchase consideration relating to the PARP inhibitors under the ex-PRC license agreement. In accordance with our revenue recognition policy, we recognize these amounts as shown in the table below:

	BGB-283	BGB-290 (in thousands)	Total
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, 2015 and 2016, substantially all of our revenue was generated solely from Merck KGaA. For the foreseeable future, we expect substantially all of our revenue will be generated from the Merck KGaA Collaboration, and any other strategic relationships we may enter into. If our development efforts are successful, we may also generate revenue from product sales.

Operating expenses

Research and development expenses

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

Table of Contents

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

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

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

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

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

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing our drug candidates, if and when approved, whether alone or in collaboration with our internally discovered drug candidates or third-party agents;
- 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

Table of Contents

- retention of key research and development personnel.

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

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

General and administrative expenses

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

Interest income, net

Interest income

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

Interest expense

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

In 2011, we issued \$10 million 8% Senior Promissory Note to MSD. In February 2016, in connection with the closing of our initial public offering, the outstanding unpaid principal and interest of the MSD Senior Promissory Note was automatically exchanged into 7,942,314 of our ordinary shares.

On September 2, 2015, BeiGene Suzhou entered into a loan agreement with Suzhou Industrial Park Biotech Development Co., Ltd. and China Construction Bank, to borrow \$18.0 million at a 7% fixed annual interest rate. As of September 30, 2016, we have drawn down \$18.0 million, which is secured by BeiGene Suzhou's future equipment purchases and our rights to a PRC patent on a drug candidate. The loan amounts of \$9.0 million and \$9.0 million are repayable on September 30, 2018 and 2019, respectively.

Table of Contents**Results of operations**

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2016	Change	2015	2016	Change
	(in thousands)					
Collaboration revenue	\$ 1,380	\$	\$ (1,380)	\$ 4,139	\$ 1,070	\$ (3,069)
Operating expenses:						
Research and development	(13,351)	(30,106)	(16,755)	(30,147)	(69,100)	(38,953)
General and administrative	(2,021)	(4,722)	(2,701)	(4,361)	(11,760)	(7,399)
Total operating expenses	(15,372)	(34,828)	(19,456)	(34,508)	(80,860)	(46,352)
Loss from operations	(13,992)	(34,828)	(20,836)	(30,369)	(79,790)	(49,421)
Net interest income (expense)	460	(75)	(535)	446	336	(110)
Changes in fair value of financial instruments	(300)		300	(502)	(1,514)	(1,012)
Disposal loss on available-for-sale securities	(241)	(137)	104	(298)	(1,077)	(779)
Net other income (expense)	74	(327)	(401)	871	732	(139)
Loss before income tax expense	(13,999)	(35,367)	(21,368)	(29,852)	(81,313)	(51,461)
Income tax expense		(127)	(127)		(306)	(306)
Net loss	\$ (13,999)	\$ (35,494)	\$ (21,495)	\$ (29,852)	\$ (81,619)	\$ (51,767)

Comparison of the three months ended September 30, 2015 and September 30, 2016*Revenue*

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

Research and development expense

Research and development expense increased by \$16.7 million to \$30.1 million for the three months ended September 30, 2016 from \$13.4 million for the three months ended September 30, 2015. The following table summarizes our research and development expense by program and stage of development for the three months ended September 30, 2015 and 2016, respectively:

	Three Months Ended September 30,	
	2015	2016
	(in thousands)	
External cost of clinical-stage programs	\$ 3,599	\$ 15,151
External cost of preclinical-stage programs	1,493	3,264
Internal research and development expenses	8,259	11,691
Total research and development expenses	\$ 13,351	\$ 30,106

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

Table of Contents

Increases of approximately \$7.3 million, \$3.7 million and \$0.9 million, respectively, for BGB-3111, BGB-A317 and BGB-283, offset by decrease of approximately \$0.4 million for BGB-290.

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

- \$2.8 million increase of employee salary and benefits, which was primarily attributable to hiring of more development personnel during the three months ended September 30, 2016;
- \$2.7 million increase of materials and reagent expenses, mainly in connection with in-house manufacture of drugs used for clinical purpose which was previously outsourced and recorded as external cost;
- \$0.2 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our pipeline;
- \$0.2 million increase of facilities, office expense, rental fee and other expenses; and
- Offset by \$2.5 million decrease of stock option expenses (\$2.1 million in the three months ended September 30, 2016 compared to \$4.6 million in the three months ended September 30, 2015).

General and administrative expense

General and administrative expense increased by \$2.7 million to \$4.7 million for the three months ended September 30, 2016 from \$2.0 million for the three months ended September 30, 2015. The increase was primarily attributable to the following:

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

- \$0.8 million increase of professional fees for audit, consulting, recruiting and legal services, mainly in connection with the preparation of our periodic reports, consulting activities, recruiting services and patent prosecution activities;
- \$0.4 million increase of stock option expense (\$0.6 million in the three months ended September 30, 2016 compared to \$0.2 million in the three months ended September 30, 2015); and
- \$0.8 million increase of travel, office, leasing and other administrative expenses, mainly in connection with the global expansion of our company.

Interest income and expense, net

Interest income (net) decreased by \$535,000 to interest expense (net) of \$75,000 for the three months ended September 30, 2016 from interest income (net) of \$460,000 for the three months ended September 30, 2015. The decrease in interest income (net) was primarily attributable to decrease of interest income, mainly generated from short-term investments in treasury securities, municipal bonds and fixed income bonds.

Changes in fair value of financial instruments

Loss from changes in fair value of financial instruments was nil for the three months ended September 30, 2016, compared with \$0.3 million for the three months ended September 30, 2015. The decrease in loss from changes in fair value of financial instruments was primarily attributable to the exercise of warrants and options in January 2016 and February 2016.

Table of Contents

Disposal loss on available-for-sale securities

The \$0.1 million disposal loss on available-for-sale securities was recorded for the three months ended September 30, 2016 following the disposal of the available-for-sale securities.

Other income, net

Other income (net) decreased by \$401,000 to other expense (net) of \$327,000 for the three months ended September 30, 2016 from other income (net) of \$74,000 for the three months ended September 30, 2015. Other income (net) primarily consisted of government grants received and foreign currency exchange gain/loss.

Income tax expense

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

Comparison of the nine months ended September 30, 2015 and September 30, 2016

Revenue

Revenue from the Merck KGaA Collaboration decreased by \$3.0 million to \$1.1 million for the nine months ended September 30, 2016 from \$4.1 million for the nine months ended September 30, 2015. The decrease was primarily attributable to revenue that was no longer being recognized for BGB-290 for the nine months ended September 30, 2016 after we repurchased its ex-PRC right from Merck KGaA in October 2015.

Research and development expense

Edgar Filing: BeiGene, Ltd. - Form 10-Q

Research and development expense increased by \$39.0 million to \$69.1 million for the nine months ended September 30, 2016 from \$30.1 million for the nine months ended September 30, 2015. The following table summarizes our research and development expense by program and stage of development for the nine months ended September 30, 2015 and 2016, respectively:

	Nine Months Ended September 30,	
	2015	2016
	(in thousands)	
External cost of clinical-stage programs	\$ 9,407	\$ 37,221
External cost of preclinical-stage programs	3,264	5,150
Internal research and development expenses	17,476	26,729
Total research and development expenses	\$ 30,147	\$ 69,100

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 \$14.3 million, \$10.0 million, \$2.4 million and \$1.1 million, respectively, for BGB-3111, BGB-A317, BGB-283 and BGB-290.

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

- \$6.6 million increase of employee salary and benefits, which was primarily attributable to hiring of more development personnel during the nine months ended September 30, 2016;

Table of Contents

- \$2.8 million increase of materials and reagent expenses, mainly in connection with in-house manufacture of drugs used for clinical purpose which was previously outsourced and recorded as external cost;
- \$1.0 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our pipeline;
- \$1.4 million increase of facilities, office expense, rental fee and other expenses; and
- Offset by \$2.6 million decrease of stock option expenses (\$5.2 million in the nine months ended September 30, 2016 compared to \$7.8 million in the nine months ended September 30, 2015).

General and administrative expense

General and administrative expense increased by \$7.4 million to \$11.8 million for the nine months ended September 30, 2016 from \$4.4 million for the nine months ended September 30, 2015. The increase was primarily attributable to the following:

- \$2.8 million increase of professional fees for audit, consulting, recruiting and legal services, mainly in connection with the preparation of our periodic reports, consulting activities, recruiting services and patent prosecution activities;
- \$2.2 million increase of employee salary and benefits, which was primarily attributable to hiring of more personnel during the nine months ended September 30, 2016;
- \$1.2 million increase of stock option expense (\$1.5 million in the nine months ended September 30, 2016 compared to \$0.3 million in the nine months ended September 30, 2015); and
- \$1.2 million increase of travel, office, leasing and other administrative expenses, mainly in connection with the global expansion of our company.

Interest income and expense, net

Interest income (net) decreased by \$110,000 to \$336,000 for the nine months ended September 30, 2016 from \$446,000 for the nine months ended September 30, 2015. The decrease in interest income (net) *was* primarily attributable to decrease of interest income, mainly generated from short-term investments in treasury securities, municipal bonds and fixed income bonds.

Changes in fair value of financial instruments

Loss from changes in fair value of financial instruments increased by \$1.0 million to \$1.5 million for the nine months ended September 30, 2016 from \$0.5 million for the nine months ended September 30, 2015. The increase in loss from changes in fair value of financial instruments was primarily attributable to the fair value change of warrants and options.

Disposal loss on available-for-sale securities

The \$1.1 million disposal loss on available-for-sale securities was recorded for the nine months ended September 30, 2016 following the disposal of the available-for-sale securities.

Other income, net

Other income (net) decreased by \$139,000 to \$732,000 for the nine months ended September 30, 2016 from \$871,000 for the nine months ended September 30, 2015. Other income (net) primarily consisted of government grants received and foreign currency exchange gain/loss.

Table of Contents*Income tax expense*

Income tax expense was \$0.3 million for the nine months ended September 30, 2016 compared with nil for the nine months ended September 30, 2015. Current-year income tax expense was attributable to BeiGene USA, Inc., a wholly owned subsidiary, which was established in July 2015 and provided general management services and strategic advisory services to BeiGene, Ltd. BeiGene, Ltd. and its other subsidiaries were in a cumulative loss position for the nine months ended September 30, 2015 and 2016.

Liquidity and capital resources

Since inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We incurred net losses of \$14.0 million and \$29.9 million, respectively, for the three and nine months ended September 30, 2015, and \$35.5 million and \$81.6 million, respectively, for the three and nine months ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of \$199.8 million. Our primary use of cash is to fund research and development costs. Our operating activities used \$23.1 million and \$63.4 million of cash flows during the nine months ended September 30, 2015 and 2016, respectively. Historically, we have financed our operations principally through proceeds from private placements of preferred shares, promissory notes and convertible notes of \$184.4 million and proceeds from the Merck KGaA Collaboration of \$37 million. On February 8, 2016, we completed our initial public offering and received net proceeds of \$166.2 million, after deducting underwriting discounts and offering expenses. At September 30, 2016, we had cash, cash equivalents and short-term investments of \$203.6 million.

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

	Nine Months Ended September 30,	
	2015	2016
	(in thousands)	
Net cash used in operating activities	\$ (23,081)	\$ (63,373)
Net cash used in investing activities	(66,208)	(51,129)
Net cash provided by financing activities	103,324	182,210
Net effect of foreign exchange rate changes	(483)	(45)
Net increase in cash and cash equivalents	\$ 13,552	\$ 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 the development of our research and development, regulatory and other clinical trial costs, and related supporting administration. Our prepaid expenses and other current assets, accounts payable and accrued

expense balances in all periods presented were affected by the timing of vendor invoicing and payments.

During the nine months ended September 30, 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 our 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.

During the nine months ended September 30, 2015, our operating activities used \$23.1 million of cash, which resulted principally from our net loss of \$29.9 million, adjusted for non-cash charges of \$10.0 million and interest expense of \$0.8 million, and by cash used in our operating assets and liabilities of \$4.0 million. Our net non-cash charges during the nine months ended September 30, 2015 primarily consisted of \$1.1 million of depreciation expense, \$8.0 million of share-based compensation expense, a

Table of Contents

\$0.3 million disposal loss on available-for-sale securities and a \$0.5 million loss from changes in fair value of financial instruments.

Net cash used in investing activities

Net cash used in investing activities was \$51.1 million for the nine months ended September 30, 2016 compared to \$66.2 million for the nine months ended September 30, 2015. The increase in cash used in investing activities was primarily due to \$35.7 million net purchase of available-for-sale securities and \$15.4 million paid to purchase property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was \$182.2 million for the nine months ended September 30, 2016 compared to \$103.3 million for the nine months ended September 30, 2015. The increase was primarily due to proceeds of \$167.9 million from our initial public offering, net of offering costs, proceeds of \$12.2 million from long-term loan and proceeds of \$2.1 million from exercise of warrants.

Operating capital requirements

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

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of September 30, 2016, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. In that time, we expect that our expenses will increase substantially as we fund clinical development of BGB-3111, BGB-A317, BGB-290 and BGB-283 as monotherapies and in combination, fund new and ongoing research and development activities and working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and

commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

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

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

Table of Contents

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of holders of ADSs or ordinary shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute the ownership interest of holders of ADSs or ordinary shares. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

The following table summarizes our significant contractual obligations as of payment due date by period at September 30, 2016:

	Total	Payments Due by Period			More Than 5 Years
		Less Than 1 Year	1 3 Years (in thousands)	3 5 Years	
Contractual obligations					
Operating lease commitments	\$ 9,430	\$ 2,540	\$ 4,313	\$ 2,577	
Long-term debt obligation	\$ 18,030		\$ 18,030		
Capital commitments	\$ 9,587	\$ 9,587			
Total	\$ 37,047	\$ 12,127	\$ 22,343	\$ 2,577	

Operating lease commitments

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

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

Long-term debt obligation

On September 2, 2015, BeiGene Suzhou entered into a loan agreement with Suzhou Industrial Park Biotech Development Co., Ltd. and China Construction Bank, to borrow \$18.0 million at a 7% fixed annual interest rate. As of September 30, 2016, we have drawn down \$18.0 million, which is secured by BeiGene Suzhou's future equipment purchases and our rights to a PRC patent on a drug candidate. The

Table of Contents

loan amounts of \$9.0 million and \$9.0 million are repayable on September 30, 2018 and 2019, respectively. As of September 30, 2016, the outstanding unpaid principal and interest of this bank loan was \$18.0 million.

Capital commitments

We had capital commitments amounting to \$9.6 million for the acquisition of property, plant and equipment as of September 30, 2016.

Other business agreements

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

Off-balance sheet arrangements

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

Critical accounting policies and significant judgments and estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the periods. We evaluate our estimates and judgments on an ongoing basis, including but not limited to, estimating the useful lives of long-lived assets, identifying separate accounting units and estimating the best estimate selling price of each deliverable in our revenue arrangements, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets and the fair value of warrant and option liabilities. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Edgar Filing: BeiGene, Ltd. - Form 10-Q

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

Recent accounting pronouncements

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

JOBS Act

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an emerging growth company can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards at the same time as other public companies that are not emerging growth companies. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an

Table of Contents

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 will continue to remain an emerging growth company until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than \$1 billion, (3) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years, or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest and credit risk

Financial instruments that are potentially subject to credit risk consist of cash and cash equivalents and short-term investments. The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of \$17.9 million and \$85.5 million and short-term investments of \$82.6 million and \$118.1 million at December 31, 2015 and September 30, 2016, respectively. At September 30, 2016, our 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, 2016, our short-term investments consisted primarily of high credit quality corporate fixed income bonds and U.S. Treasury securities. We believe that the corporate bonds and the U.S. Treasury securities are of high credit quality and will continually monitor the credit worthiness of these institutions.

The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significant increasing risk. Our primary exposure to market risk relates to fluctuations in the interest rates which are affected by changes in the general level of PRC and U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

We do not believe that our cash, cash equivalents and short-term investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

Foreign currency exchange rate risk

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

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China's

Table of Contents

political and economic conditions and China's foreign exchange prices. From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For the RMB against U.S. dollars, there was depreciation of approximately 4.4% in the year ended December 31, 2015, and depreciation of approximately 2.1% in the nine months ended September 30, 2016. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

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

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

Currency convertibility risk

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

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

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act

is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Material weakness and remediation of material weakness

In connection with the audit of our condensed consolidated financial statements for the years ended December 31, 2013, 2014 and 2015, we identified a material weakness in our internal control over

Table of Contents

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

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

- hiring additional financial professionals with appropriate accounting and SEC reporting experience;
- increasing the number of qualified financial reporting personnel;
- improving the capabilities of existing financial reporting personnel through training and education in the accounting and reporting requirements under GAAP and SEC rules and regulations;
- developing, communicating and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes; and
- establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our condensed consolidated financial statements and related disclosures.

The SEC, as required by Section 404 of the Sarbanes-Oxley Act, adopted rules requiring companies that file reports with the SEC to include a management report on such company's internal control over financial reporting in its annual report. In addition, our independent registered public accounting firm may be required to attest to our internal control over financial reporting. Management will be required to provide an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2016. Our independent registered public accounting firm will first be required to attest to the effectiveness of our internal control over financial reporting for our Annual Report on Form 10-K for the first year we are no longer an emerging growth company under the JOBS Act. We are in the process of improving the internal control over financial reporting required to comply with this obligation. However, there is no guarantee that our efforts will result in management's ability to conclude, or, if required, our independent registered public accounting firm to attest, that our internal control over financial reporting is effective as of December 31, 2016.

Changes in internal control over financial reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

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

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

Edgar Filing: BeiGene, Ltd. - Form 10-Q

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2010. We reported a net loss of \$14.0 million and \$29.9 million, respectively, for the three and nine months ended September 30, 2015, and \$35.5 million and \$81.6 million, respectively, for the three and nine months ended September 30, 2016. As of September 30, 2016, we had a deficit accumulated of \$199.8 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from 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 approved drugs, if any. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, our ability to generate revenues and the timing and amount of milestones and other required payments to third parties in connection with our potential future arrangements with third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

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

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

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

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

- completing research regarding, and non-clinical and clinical development of, our drug candidates;
- obtaining regulatory approvals and marketing authorizations for drug candidates for which we complete clinical trials;
- obtaining adequate reimbursement from third-party payors, including government payors;

- developing a sustainable and scalable manufacturing process for our drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing drug candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our drug candidates as viable treatment options;
- identifying, assessing, acquiring and/or developing new drug candidates;
- addressing any competing technological and market developments;

Table of Contents

- negotiating and maintaining favorable terms in any collaboration, licensing or other arrangements into which we may enter, such as our collaboration arrangements with Merck KGaA;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. Our operating activities used \$23.1 million and \$63.4 million of net cash during the nine months ended September 30, 2015 and 2016, respectively. We expect to continue to spend

substantial amounts on drug discovery advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

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

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

Table of Contents

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

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA, CFDA, EMA and comparable regulatory authorities, including the potential that the FDA, CFDA, EMA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the number and characteristics of drug candidates that we may in-license and develop;
- our ability to successfully commercialize our drug candidates;
- the amount of sales and other revenues from drug candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party reimbursement;
- the amount and timing of the milestone and royalty payments we receive from our collaborators under our licensing arrangements, such as our collaboration with Merck KGaA;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

- cash requirements of any future acquisitions and/or the development of other drug candidates;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

Table of Contents

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

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

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

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

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

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy adopted by the PRC, Australia and other non-U.S. governments. Specifically in the PRC, on July 21, 2005, the PRC government changed its policy of pegging the value of the RMB to the U.S. doll