BeiGene, Ltd.
Form 10-Q
November 13, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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FORM 10-Q

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(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from to

Commission File Number: 001-37686

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BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

| Cayman Islands | 98-1209416 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

| c/o Mourant Ozannes Corporate Services (Cayman) Limited<br>94 Solaris Avenue, Camana Bay<br>Grand Cayman<br>Cayman Islands | KY1-1108 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

+1 (345) 949 4123

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

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

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

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BeiGene, Ltd.

Quarterly Report on Form 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BEIGENE, LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

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

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

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

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BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

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

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

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

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BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)

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

(Unaudited)

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

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

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BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

(Unaudited)

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

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

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

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BEIGENE, LTD.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

1. Organization

BeiGene, Ltd. (the “Company”) is a globally focused, commercial-stage biopharmaceutical company dedicated to becoming a leader in the discovery, development and commercialization of innovative, molecularly targeted and immuno-oncology drugs for the treatment of cancer. The Company’s development strategy is based on a novel translational platform that combines its unique access to internal patient-derived biopsies with strong oncology biology. The Company was incorporated under the laws of the Cayman Islands as an exempted company with limited liability on October 28, 2010. The Company completed its initial public offering (“IPO”) on the NASDAQ Global Select Market on February 8, 2016 and has completed subsequent follow-on public offerings and a sale of ordinary shares to Celgene Switzerland LLC (“Celgene Switzerland”) in a business development transaction, as described in Note 22, Shareholders’ Equity.

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

| Name of Company | Place of Incorporation | Date of Incorporation | Percentage of Ownership by the Company | Principal Activities |
|---|---|---|---|---|
| BeiGene (Hong Kong) Co., Limited.("BeiGene HK") | Hong Kong | November 22, 2010 | 100 % | Investment holding |
| BeiGene (Beijing) Co., Ltd. ("BeiGene (Beijing)") | The People’s Republic of China (“PRC” or “China”) | January 24, 2011 | 100 % | Medical and pharmaceutical research |
| BeiGene AUS Pty Ltd. | Australia | July 15, 2013 | 100 % | Clinical trial activities |
| BeiGene 101 | Cayman Islands | August 30, 2012 | 100 % | Medical and pharmaceutical research |
| BeiGene (Suzhou) Co., Ltd. (“BeiGene (Suzhou)”) | PRC | April 9, 2015 | 100 % | Medical and pharmaceutical research |
| BeiGene USA, Inc.("BeiGene (USA)") | United States | July 8, 2015 | 100 % | Clinical trial activities |
| BeiGene (Shanghai) Co., Ltd. (“BeiGene (Shanghai)”) | PRC | September 11, 2015 | 100 % | Medical and pharmaceutical research |

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

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

Manufacturing facility in Guangzhou

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

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

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

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

2. Summary of significant accounting policies

Basis of presentation and principles of consolidation

The accompanying condensed consolidated balance sheet as of September 30, 2017, the condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2017 and 2016, the condensed consolidated statements of cash flows for the nine months ended September 30, 2017 and 2016, and the related footnote disclosures are unaudited. The accompanying unaudited interim financial statements were prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), including guidance with respect to interim financial information and in conformity with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for annual financial statements. These financial statements should be read in conjunction with the consolidated financial statements and related footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 ("Annual Report").

The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all normal recurring adjustments, necessary to present a fair statement of the results for the interim periods presented. Results of the operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results expected for the full fiscal year or for any future annual or interim period.

The condensed consolidated financial statements include the financial statements of the Company and its subsidiaries. All significant intercompany transactions and balances between the Company and its subsidiaries are eliminated upon consolidation.

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

Use of estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during

the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating sales rebates and returns allowance to arrive at net product revenues, identifying separate accounting units and estimating the best estimate of selling price of each deliverable in the Company's revenue arrangements, estimating the fair value of net assets acquired in business combinations, assessing the impairment of long-lived assets, share-based compensation expenses, inventory, realizability of deferred tax assets and the fair value of financial instruments. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

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Cash and cash equivalents

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

Accounts receivable

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

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

Inventory

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

Land use right, net

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

Business combination

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

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

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

Goodwill and other intangible assets

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

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

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

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

Revenue recognition

Product revenue

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

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

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

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

Collaboration revenue

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

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

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

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

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

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

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

Fair value measurements

Fair value of financial instruments

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

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

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

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

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

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

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Financial instruments measured at fair value on a recurring basis

The following tables set forth assets and liabilities measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016:

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

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

Recent accounting pronouncements

In August 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (“ASU”) No. 2015-14, Revenue from Contracts with Customers-Deferral of the Effective Date (“ASU 2015-14”). The amendments in ASU 2015-14 defer the effective date of ASU No. 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”), issued in May 2014. According to the amendments in ASU 2015-14, the new revenue guidance in ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers - Principal versus Agent Considerations (“ASU 2016-08”), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU

No. 2016-10, Revenue from Contracts with Customers - Identifying Performance Obligations and Licensing ("ASU 2016-10"), which clarify guidance related to identifying performance obligations and licensing implementation guidance contained in ASU No. 2014-09. In May 2016, the FASB issued ASU No. 2016-12 , Revenue from Contracts with Customers - Narrow-Scope Improvements and Practical Expedients ("ASU 2016-12"), which addresses narrow-scope improvements to the guidance on collectability, non-cash consideration, and completed contracts at transition and provides practical expedients for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers. The effective date for the amendment in ASU 2016-08, ASU 2016-10 and ASU 2016-12 are the same as the effective date of ASU No. 2014-09. The Company anticipates adopting the new standard under the modified retrospective approach, effective January 1, 2018. The Company is continuing to assess the potential impact that ASC 606 may have on its financial position and results of operations as it relates to its collaboration agreements with Celgene and Merck KGaA, Darmstadt Germany. The Company expects that certain of its accounting conclusions will require further judgment. Further, the Company is continuing to analyze the potential impacts of the adoption of the new standard on its condensed consolidated financial

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

In February 2016, the FASB issued ASU No. 2016-02, Leases, which requires lessees to recognize assets and liabilities related to lease arrangements longer than 12 months on the balance sheet. This standard also requires additional disclosures by lessees and contains targeted changes to accounting by lessors. The updated guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. The Company is currently evaluating the financial statement impact of adoption.

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

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

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

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

3. Research and development collaborative arrangements

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

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

Celgene and Celgene Switzerland

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

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

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

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

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

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

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

Merck KGaA, Darmstadt Germany

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

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

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

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

4. Business Combination

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

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

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

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Share Subscription Agreement

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

Determination of Purchase Price

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

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

Purchase Price Allocation

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

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

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

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

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

5. Short-term investments

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

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

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

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

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

6. Inventories

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

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7. Property and equipment

Property and equipment consisted of the following:

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

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

8. Land use right, net

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

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

| | | |
|---|---|---|
| Land use right, net | 12,251 | — |

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

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

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9. Intangible assets and Goodwill

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

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

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

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

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

Goodwill

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

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

10. Income taxes

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

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

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

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

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

11. Accrued expenses and other payables

Accrued expenses and other payables consisted of the following:

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

12. Warrants and option liabilities

Option to purchase shares by rental deferral

On September 1, 2012, in conjunction with a lease agreement of one of its premises, the Company granted the landlord an option to purchase the Company's ordinary shares (the "Option") in exchange for the deferral of the payment of one year's rental expense. The Option was a freestanding instrument and was recorded as liability in accordance with ASC 480, Distinguishing Liabilities from Equity. The Option was initially recognized at fair value with subsequent changes in fair value recorded in losses. Prior to the Company's IPO, the Company determined the fair value of the Option with the assistance of an independent third party valuation firm. On February 8, 2016, immediately prior to the Company's IPO, the landlord exercised the Option to purchase 1,451,586 ordinary shares of the Company. As the exercise date was the IPO closing date, the exercise date fair value of the Option of $2,540 was determined based on its intrinsic value, which equaled the difference between the share price at the IPO closing date and the exercise price of such purchased ordinary shares. During the three and nine months ended September 30, 2016, the Company recognized a loss from the increase in fair value of the Option of nil and $1,151, respectively.

Warrants in connection with the promissory notes

During the years ended December 31, 2012 to 2014, the Company entered into agreements with several investors to issue convertible promissory notes, and related warrants to purchase the Company's preferred shares up to 10% of the convertible promissory notes' principal amount concurrently, for an aggregate principal amount of $2,410. The warrants were freestanding instruments and were recorded as liabilities in accordance with ASC480. The warrants were initially recognized at fair value with subsequent changes in fair value recorded in losses. In January 2016 and February 2016, the warrants issued in connection with the promissory notes were exercised for 621,637 Preferred

Shares, which shares were converted into 621,637 ordinary shares at the time of the IPO. As the exercise dates were very close to the IPO closing date, the respective exercise date fair value of the warrants of $1,148 was determined based on the intrinsic value, which equaled the difference between the share price at the IPO closing date and the exercise price of the issued warrants.

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

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13. Short-term loan

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

14. Long-term bank loan

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

15. Shareholder Loan

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

Key features of the Shareholder Loan

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

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

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

Accounting for the Shareholder Loan

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

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

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

16. Related party balances and transactions

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

17. Product revenue, net

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

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

18. Net income/(loss) per share

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

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

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

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

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

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

19. Share-based compensation

2016 Share Option and Incentive Plan

On January 14, 2016, in connection with the IPO, the board of directors and shareholders of the Company approved the 2016 Share Option and Incentive Plan (the “2016 Plan”), which became effective on February 2, 2016. The Company initially reserved 65,029,595 ordinary shares for the issuance of awards under the 2016 Plan, plus any shares available under the 2011 Option Plan (the “2011 Plan”), and not subject to any outstanding options as of the effective date of the 2016 Plan, along with underlying share awards under the 2011 Plan that are cancelled or forfeited without issuance of ordinary shares. As of September 30, 2017, ordinary shares cancelled or forfeited under the 2011 Plan that were provided back to the 2016 Plan totaled 4,857,136. The 2016 Plan provides for an annual increase in the shares available for issuance, to be added on the first day of each fiscal year, beginning on January 1, 2017 and continuing until the expiration of the 2016 Plan, equal to the lesser of (i) five percent (5%) of the outstanding shares of the Company’s ordinary shares on the last day of the immediately preceding fiscal year or (ii) such number of shares determined by the Company’s board of directors or the compensation committee. On January 1, 2017, 25,791,680 ordinary shares were added to the 2016 Plan under this provision. The number of shares available for issuance under the 2016 Plan is subject to adjustment in the event of a share split, share dividend or other change in the Company’s capitalization.

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

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

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

first tranche vesting one calendar year after the grant date or the service relationship start date and the remainder of the awards vesting on a yearly basis thereafter.

Modification

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

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

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

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

20. Accumulated other comprehensive income/(loss)

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

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

21. Noncontrolling interest

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

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

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

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

22. Shareholders' equity

Initial public offering

On February 8, 2016, the Company completed its IPO on the NASDAQ Global Select Market. 6,600,000 ADSs representing 85,800,000 ordinary shares were sold at $24.00 per ADS, or $1.85 per ordinary share (the "IPO Price"). Additionally, the underwriters exercised their options to purchase an additional 990,000 ADSs representing 12,870,000 ordinary shares from the Company. Net proceeds from the IPO including underwriter option after deducting underwriting discounts and offering expenses were $166,197.

Follow-on public offerings

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

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

underwriting discounts and offering expenses were $188,517.

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Share Subscription Agreement

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

Conversion of Preferred Shares and Senior Promissory Note

Upon completion of the IPO in 2016, all outstanding Preferred Shares were converted into 199,990,641 ordinary shares and the related carrying value of $176,084 was reclassified from mezzanine equity to shareholders' equity. The outstanding unpaid principal and interest of the Senior Promissory Note were converted into 7,942,314 ordinary shares, computed at the initial public offering price of $1.85 per ordinary share and the related carrying value of $14,693 was reclassified from current liability to shareholders' equity in 2016.

Exercise of warrants and option

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

23. Restricted net assets

As a result of PRC laws and regulations, the Company's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company. As of September 30, 2017 and December 31, 2016, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to $25,037 and $9,955, respectively.

24. Commitments and contingencies

Operating lease commitments

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

months ended September 30, 2016, respectively.

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

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

Capital commitments

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

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

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

Overview

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

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

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

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

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

months ended September 30, 2017, we generated revenue from product sales and under our collaboration agreement with Celgene, and in the future, we may generate revenue from product sales, collaboration agreements, strategic alliances and licensing arrangements, or a combination of these. Substantially all of our losses have resulted from funding our research and development programs, selling costs, licensing and acquisitions and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the

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

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

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

Cash used in operations were $81.0 million and $63.4 million, respectively, for the nine months ended September 30, 2017 and 2016. As of September 30, 2017, we had cash, cash equivalents and short-term investments of $757.4 million, compared with $368.2 million as of December 31, 2016. As of September 30, 2017, our cash and cash equivalents included approximately $91.6 million of cash held by BeiGene Biologics to build a commercial biologics facility in Guangzhou, China and to fund research and development of biologics drug candidates in China.

Recent Developments

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

Exclusive License and Collaboration Agreement

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

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

Celgene China Agreements

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

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

Share Subscription Agreement

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

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

Components of Operating Results

Revenue

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

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Strategic Collaboration with Celgene

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

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

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

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

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

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

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

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

Collaboration with Merck KGaA, Darmstadt Germany

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

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

On October 28, 2013, we entered into license agreements with Merck KGaA, Darmstadt Germany on BGB-290, pursuant to which (1) we granted to Merck KGaA, Darmstadt Germany an exclusive license under certain of our intellectual property rights to develop and manufacture, and, if Merck KGaA, Darmstadt Germany exercises a certain continuation option, to commercialize and manufacture our compound BGB-290 and any other compound covered by the same existing patent rights with primary activity to inhibit PARP 1, 2 or 3 enzymes in the Ex-PRC Territory, and (2) Merck KGaA, Darmstadt Germany granted us an exclusive license under certain of its intellectual property rights to develop, manufacture and commercialize the licensed PARP inhibitors in the PRC Territory. Under these license agreements, we received $6 million in non-refundable payments in November 2013 following their execution and $9.0 million in milestone payments in 2014. We were eligible to receive up to $7.0 million and $2.5 million, in payments upon the successful achievement of pre-specified clinical and regulatory milestones in the PRC Territory, respectively. On October 1, 2015, pursuant to a purchase of rights agreement, we repurchased all of Merck KGaA, Darmstadt Germany's worldwide rights under the ex-PRC license agreement, in consideration for, among other things, a one-time payment of $10.0 million and reduction of future milestone payments that we are eligible to receive under the PRC license agreement. In connection with such repurchase, the ex-PRC license agreement terminated except for certain provisions therein. The remaining $3.0 million of deferred revenue related to PARP as of October 1, 2015 was netted against the $10.0 million repurchase consideration. In consideration for the licenses granted to us, we are required to pay Merck KGaA, Darmstadt Germany a high single-digit royalty percentage on aggregate net sales of licensed products in the PRC Territory. In addition, if Merck KGaA, Darmstadt Germany exercises its PRC commercialization option under certain specified conditions, Merck KGaA, Darmstadt Germany is required to pay us a $50.0 million non-refundable payment upon such exercise, and we are eligible for a $12.5 million milestone payment upon the successful achievement of a certain additional regulatory event in the PRC Territory as well as royalties on any product sales.

We recognized no collaboration revenue from the Merck KGaA, Darmstadt Germany collaboration for the three and nine months ended September 30, 2017, and $1.4 million and $4.1 million of collaboration revenue from this collaboration for the three and nine months ended September 30, 2016, respectively. The following table summarizes the revenue recognition schedule of an aggregate of $34.0 million in revenue from our collaboration agreements with Merck KGaA, Darmstadt Germany, comprised of an aggregate of $22.0 million related to BGB-283 and $12.0 million related to BGB-290. The revenue consists of an upfront non-refundable license fee, Phase 1 research and development fees, and a development based target payment related to the collaborative arrangements for BRAF, excluding the $3.0 million in deferred revenue that was netted against the $10.0 million repurchase consideration relating to the PARP inhibitors under the ex-PRC license agreement. In accordance with our revenue recognition policy, we have recognized these amounts as shown in the table below:

| | BGB-283 | BGB-290 | Total |
|---|---|---|---|
| | (in thousands) | | |
| 2013 | $ 8,317 | $ 2,823 | $ 11,140 |

| | | | |
|---|---|---|---|
| 2014 | 5,906 | 7,048 | 12,954 |
| 2015 | 6,707 | 2,109 | 8,816 |
| 2016 | 1,070 | — | 1,070 |
| Total | $ 22,000 | $ 11,980 | $ 33,980 |

For the three and nine months ended September 30, 2017, our revenue was generated from sales of our in-licensed drugs in China and from our collaboration agreement with Celgene. For the three and nine months ended September 30, 2016, substantially all of our revenue was generated solely from our collaboration agreements with Merck KGaA,

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

Operating Expenses

Research and Development Expenses

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

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

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

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

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

At this time, it is difficult to estimate or know, for certain, the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our drug candidates. This is due to the numerous risks and uncertainties associated with developing such drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;

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- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing our drug candidates, if and when approved, whether as monotherapies or in combination with our internally discovered drug candidates or third-party products;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- continued acceptable safety profiles of the products following approval; and
- retention of key personnel.

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of product promotion costs, distribution costs, salaries and related benefit costs, including share-based compensation for selling, general and administrative personnel. Other selling, general and administrative expenses include professional fees for legal, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, travel costs, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support increases in commercialization activities, with respect to ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azaciditine) in China and the preparation for launch and potential commercialization of our internally developed drug candidates, if approved. We also expect selling, general and administrative expenses to increase in future periods to support our research and development efforts, including the continuation of the clinical trials of BGB-3111, BGB-A317, BGB-290 and BGB-283 as a treatment for various cancers and the initiation of clinical trials for other drug candidates. These cost increases will likely be due to increased promotional costs, increased headcount, increased share-based compensation expenses, expanded infrastructure and increased costs for insurance. We also anticipate increased legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company.

Interest Income (Expense), Net

Interest Income

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

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Interest Expense

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

Other Income (Expense), Net

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

Results of Operations

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

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

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

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

Revenue

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

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

Research and Development Expense

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

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

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

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

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

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

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

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

Selling, General and Administrative Expense

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

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

Interest Income (Expense), Net

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

Gain on Sale of Available-for-sale Securities

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

Other Income (Expense), Net

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

Income Tax Benefit (Expense)

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

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

Revenue

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

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

Research and Development Expense

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

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

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

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

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

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

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

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

Selling, General and Administrative Expense

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

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

Interest Income (Expense), Net

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

Changes in Fair Value of Financial Instruments

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

Gain on Sale of Available-for-sale Securities

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

Other Income, Net

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

Income Tax Expense

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

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

Liquidity and Capital Resources

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

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

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

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

Net Cash Used in Operating Activities

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

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

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

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

Net Cash Used in Investing Activities

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

Net Cash Provided by Financing Activities

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

Operating Capital Requirements

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

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of September 30, 2017, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in this report are issued. We expect that our expenses will continue to increase substantially as we fund clinical development of BGB-3111, BGB-A317, BGB-290 and BGB-283 as monotherapies and in combination, fund new and ongoing research and development

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

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and government grants. Under SEC rules, we currently qualify as a “well-known seasoned issuer,” which allows us to file shelf registration statements to register an unspecified amount of securities that are effective upon filing. On May 26, 2017, we filed such a shelf registration statement with the SEC for the issuance of an unspecified amount of ordinary shares (including in the form of ADSs), preferred shares, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement was effective upon filing and will remain in effect for up to three years from filing. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs or ordinary shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings, collaborations or other sources when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

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Contractual Obligations and Commitments

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

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

Operating Lease Commitments

We lease office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou, PRC and office facilities in the United States in California, Massachusetts and New Jersey under non-cancelable operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of the respective leases. The future minimum payments under these non-cancelable operating leases are summarized in the table above.

Long-term Debt Obligations

Long-term Bank Loan

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

Shareholder Loan

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

Capital Commitments

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

Other Business Agreements

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

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Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies from those described in the section titled "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report. For financial statement items relating to the three months ended September 30, 2017, see the accounting policies described in "Notes to the Condensed Consolidated Financial Statements—2. Summary of significant accounting policies" of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

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

JOBS Act

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards at the same time as other public companies that are not emerging growth companies. For example, as an emerging growth company, we are exempt from Sections 14A(a) and (b) of the Exchange Act which would otherwise require us to (1) submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency" and "golden parachutes;" and (2) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our chief executive officer's compensation to our median employee compensation. We also rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and the rule requiring us to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial

statements, known as the auditor discussion and analysis.

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest and Credit Risk

Financial instruments that are potentially subject to credit risk consist of cash and cash equivalents and short-term investments. The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $208.5 million and $87.5 million and short-term investments of $548.9 million and $280.7 million at September 30, 2017 and December 31, 2016, respectively. At September 30, 2017, our cash and cash equivalents were deposited with various major reputable financial institutions located in the PRC and international financial institutions outside of the PRC. The deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. We believe that these financial institutions are of high credit quality, and we continually monitor the credit worthiness of these financial institutions. At September 30, 2017, our short-term investments consisted primarily of U.S. Treasury securities and time deposits. We believe that the U.S. Treasury securities are of high credit quality and continually monitor the credit worthiness of these institutions.

The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significant increasing risk. Our primary exposure to market risk relates to fluctuations in the interest rates which are affected by changes in the general level of PRC and U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We estimate that a hypothetical 100-basis point change in market interest rates would impact the fair value of our investment portfolio as of September 30, 2017 by $2.3 million.

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

Foreign Currency Exchange Rate Risk

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

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange prices. From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For the RMB against U.S. dollars, there was appreciation of approximately 4.4% in the nine months ended September 30, 2017 and depreciation of approximately 6.3% in the year ended December 31, 2016, respectively. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for capital expenditures and working capital and other business purpose, appreciation of RMB against the U.S. dollar would have an adverse effect on the RMB amount we

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

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

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Currency Convertibility Risk

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

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

Effects of Inflation

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017. The term "disclosure controls and procedures," as defined in Rule 13a 15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2017, our management, including our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

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Item 1A. Risk Factors.

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Quarterly Report, including our financial statements and the related notes and "Part I—Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in the ADSs. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of the ADSs could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a globally focused biopharmaceutical company formed in October 2010. Our operations to date have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our current drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283. We have not yet demonstrated an ability to successfully complete large-scale, registrational clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. We have not yet obtained regulatory approval for, or demonstrated an ability to commercialize, any of our internally developed drug candidates. We have no internally developed products approved for commercial sale and have not generated any revenue from internally developed product sales. Since September 2017, we have generated revenues from the sale of ABRAXANE®, REVLIMID®, and VIDAZA® under a license from Celgene Corporation as described in this Quarterly Report. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

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

*We have a history of incurring net losses and anticipate that we will continue to incur net losses for the foreseeable future.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have devoted most of our financial resources to research and development, including our nonclinical development activities and clinical trials. We continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2010, except in the third quarter of 2017, where we were profitable due to revenue recognized from up-front license

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

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

We expect our research and development expenses to continue to be significant in connection with our continued investment in our cancer biology platform and our ongoing and planned clinical trials for our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283. Furthermore, we expect to incur increased sales and marketing expenses for the approved drugs we have licensed from Celgene in China and any other drugs that we may successfully develop or license. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a global biotechnology company. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our shareholders' deficit, financial position, cash flows and working capital.

*We may never become profitable.

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our drug candidates, such as BGB-3111, BGB-A317, BGB-290 and BGB-283 and successfully market our in-licensed drugs in China and any other drugs that we may successfully develop or license. We expect to continue to incur substantial and increasing losses through the commercialization of our in-licensed drugs and internally developed drug candidates, if approved. None of our internally developed drug candidates have been approved for marketing in the United States, the European Union, the People's Republic of China, or PRC, or any other jurisdiction and may never receive such approval. Our ability to achieve revenue and profitability is in part dependent on our ability to complete the development of our drug candidates, obtain necessary regulatory approvals, and have our drugs manufactured and successfully marketed.

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

- completing research regarding, and nonclinical and clinical development of, our drug candidates;
- obtaining regulatory approvals for drug candidates for which we complete clinical trials;
- obtaining adequate reimbursement from third-party payors, including government payors;
- developing a sustainable and scalable manufacturing process for our drugs and drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing our drugs and any drug candidates for which we obtain regulatory approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of our drugs and drug candidates as viable treatment options;

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- identifying, assessing, acquiring and/or developing new drugs and drug candidates;
- addressing any competing technological and market developments;
- negotiating and maintaining favorable terms in any collaboration, licensing or other arrangements into which we may enter, such as our collaboration arrangements with Celgene and Merck KGaA, Darmstadt Germany;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

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

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

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

We have financed our operations with a combination of equity and debt offerings, collaboration and license agreements, and private and public grants. Since our inception through September 30, 2017, we have raised approximately $1.0 billion, consisting of an aggregate of $180.0 million in private financings prior to our IPO; an aggregate of $553.3 million in our IPO and follow-on public offerings, including most recently $188.5 million in net proceeds in August 2017; $150.0 million from an equity investment from Celgene in connection with our collaboration agreement; and an aggregate of $300.0 million from upfront and milestone payments through our collaboration arrangements with Merck KGaA, Darmstadt Germany and Celgene, including $171 million in upfront license fees expected to be received under our Celgene agreement in December 2017. In addition, under our collaboration with Celgene, we are eligible to receive up to $980 million in development, regulatory and sales milestone payments and royalties in the low-double digit to mid-twenty percentages on any future sales of BGB-A317, based on specified terms. While we have generated product revenue in China since September 2017 from sales of our approved drugs licensed from Celgene, our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with additional product sales revenue.

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

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

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

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

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA, CFDA, EMA and comparable regulatory authorities, including the potential that the FDA, CFDA, EMA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the number and characteristics of drug candidates that we may in-license and develop;
- our ability to successfully commercialize our drugs and drug candidates;
- the amount of sales and other revenues from the drugs and drug candidates that we may commercialize, if any, including the selling prices for such products and the availability of adequate third-party reimbursement;
- the amount and timing of the milestone and royalty payments we receive from our collaborators under our licensing arrangements, such as our collaborations with Merck KGaA, Darmstadt Germany and Celgene;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our current drug products in China and any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other drug candidates;
- the costs of operating as a public company;
- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of the ADSs may not support capital raising transactions such as an additional public or private offering of the ADSs or other securities. In addition, our ability to raise additional capital may be dependent upon the ADSs being quoted on the NASDAQ or upon obtaining shareholder approval. There can be

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no assurance that we will be able to satisfy the criteria for continued listing on the NASDAQ or that we will be able to obtain shareholder approval if it is necessary. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or drug candidates or to grant licenses on terms that may not be favorable to us.

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

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

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

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

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

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

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

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

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

We had cash, cash equivalents and short-term investments of $757.4 million and $368.2 million at September 30, 2017 and December 31, 2016, respectively. In addition, we expect to receive $171 million in upfront license fees under our Celgene collaboration in December 2017. At September 30, 2017, our short-term investments mainly consisted of U.S. Treasury securities and time deposits. We may invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper and money market instruments, which may not yield a favorable return to our shareholders. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. Our primary exposure to market risk relates to fluctuations in the interest rates of the PRC and the United States. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

Risks Related to Clinical Development of Our Drug Candidates

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

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

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- receipt of regulatory approvals from the FDA, CFDA, EMA and other comparable regulatory authorities for our drug candidates, including our companion diagnostics;

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

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

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

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

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;

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

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

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

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

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

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

Our clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, such as BGB 3111, BGB-A317, BGB 290 and BGB 283, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our

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

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

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

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

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

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

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

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

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- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;
- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may cause adverse affects, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

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

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

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

Significant clinical trial delays also could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may harm our business and results of operations.

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Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

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

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

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

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

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

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

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

- our inability to obtain sufficient funds required for a clinical trial;
- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials;
- regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- failure to reach agreement with the FDA, CFDA, EMA or other regulators regarding the scope or design of our clinical trials;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- our inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in a clinical trial;
- our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- clinical sites and investigators deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party contract research organizations, or CROs, to satisfy their contractual duties or regulatory requirements or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- unfavorable or inconclusive results of clinical trials and supportive nonclinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;

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- feedback from the FDA, CFDA, EMA, an IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- decision by the FDA, CFDA, EMA, an IRB, comparable entities, or us, or recommendation by a data safety monitoring board or comparable regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to demonstrate a benefit from using a drug or biologic;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;
- manufacturing issues, including problems with manufacturing or timely obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; and
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data.

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

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

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

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

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

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

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

Undesirable adverse events, or AEs, caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CFDA, EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of AEs. In such an event, our trials could be suspended or terminated and the FDA, CFDA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

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

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

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

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

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

Additionally, if we or others identify undesirable side effects caused by our drugs or any future approved drug candidates, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a REMS for the drug, as is the case with REVLIMID®, or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug or drug candidate, and could significantly harm our business, results of operations and prospects.

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

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

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

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

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

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

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

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the product for the indication can be recovered by sales of the product in the United States. BGB 3111 received orphan drug designation from the FDA for CLL, MCL and WM in 2016.

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

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

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

Our in-licensed drugs in China and any additional drug candidates that are approved will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information,

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

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, CFDA, EMA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or BLA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The regulatory approvals for our in-licensed drugs and any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the drug candidate. The FDA or comparable regulatory authorities may also require a REMS program as a condition of approval of our drug candidates or following approval, as is the case with REVLIMID®, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, CFDA, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

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

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

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

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

Risks Related to Commercialization of Our Drug Candidates

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

We currently do not have any drug candidates that have gained regulatory approval for sale in the United States, European Union, China or any other country, and we cannot guarantee that we will ever have marketable drugs that we are currently developing or may develop in the future. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without first obtaining regulatory approval to market each drug from the FDA, CFDA, EMA and/or comparable regulatory authorities. BGB 3111, BGB-A317, BGB 290 and BGB 283 are each currently undergoing clinical trials. We cannot predict whether these trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

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

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

Specifically, in China, the CFDA categorizes domestically-manufactured innovative drug applications as Category 1 and imported innovative drug applications as Category 5. To date, most of local companies' domestically-manufactured drug applications are filed in Category 1 if the drug has not already been approved by the

FDA or EMA. Most multinational pharmaceutical companies' drug registration applications are filed in Category 5 applicable to imported drugs, formerly known as Category 3 prior to the reclassification implemented by CFDA in 2016. These two categories have distinct approval pathways, as described in the section of our Annual Report titled "Item 1—Business—Regulatory Framework and Structural Advantages of Being a China-Based Research and Development Organization." We believe the local drug registration pathway, Category 1, is a faster and more efficient path to approval in the Chinese market than Category 5. Companies are required to obtain Clinical Trial Application approval before conducting clinical trials in China. This registration pathway has a fast track review and approval mechanism if the drug candidate is on a national

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

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

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

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

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

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

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

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

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

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

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

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the United States and China, and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the FDA, CFDA and EMA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

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

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

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

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

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

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

A Category 1 designation by the CFDA may be revoked or may not be granted for any of our drug candidates or may not lead to faster development or regulatory review or approval process and does not increase the likelihood that our drug candidates will receive regulatory approval.

We believe the local drug registration pathway, Category 1, is a faster and more efficient path to approval in the Chinese market than the drug registration pathway for imported drugs under Category 5. Companies are required to obtain Clinical Trial Application approval before conducting clinical trials in China. This registration pathway has a fast track review and approval mechanism if the drug candidate is on a national priority list. Imported drug candidates under Category 5 cannot qualify for the national priority list to benefit from fast track reviews. Our drug candidates are all new therapeutic agents and we have built research and development, clinical trial capacities, and manufacturing facilities in China. As a result, we expect all of our current drug candidates to fall within the Category 1 application process, but cannot be sure we will be granted or be able to maintain Category 1 designation.

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

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

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

- the clinical indications for which our drugs and drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drugs and drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drugs and drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, CFDA, EMA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, CFDA, EMA or other comparable regulatory authorities;
- the timing of market introduction of our drugs and drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drugs and drug candidates;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

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

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

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. See the section titled “Item 1—Business—Competition” of our 2016 Annual Report.

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

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

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

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

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

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

- a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version; and
- the FDA could consider a combination therapy which contains both drug and biological product components, to be a drug subject to review pursuant to an NDA, and therefore eligible for a significantly shorter marketing exclusivity period as provided under the Drug Price Competition and Patent Term Restoration Act of 1984.

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

In addition, a drug product approved under an NDA, such as BGB 3111, BGB 290 or BGB 283, if they were to be approved, could face generic competition earlier than expected. We do expect competition from generic drugs with our in-licensed drugs in China but currently do not know the actual impact. In the United States, the enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012 established a user fee program that will generate hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, could significantly decrease the timeframe for FDA review and approval of generic drug applications.

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

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

may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

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

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

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

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drugs or any drug candidates, even if our drug candidates obtain regulatory approval.

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

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

allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for our drugs and any new drugs that we

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develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

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

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

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

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

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

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

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

drugs and any

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

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

According to the PRC Central Government's guidance issued in March 2015, each province will decide which drugs to include in its provincial major illness reimbursement lists and the percentage of reimbursement, based on local funding. Although it will take three years to establish a comprehensive national coverage, the affordability of the expensive, novel cancer agents to Chinese patients will improve significantly and the targeted therapy market is expected to enter a fast growing period.

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

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

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

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

More recently, in March 2010, then-President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologics;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

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- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, then-President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding.

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program

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

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

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

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

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

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

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

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

Non-U.S. markets are an important component of our growth strategy. For example, in connection with the Celgene transactions, we retained exclusive rights for the development and commercialization of BGB-A317 for hematological cancers globally and for solid tumors in China and the rest of Asia, other than Japan. We intend to focus on additional opportunities in China, in particular. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- changes in a specific country's or region's political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability, particularly in non-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty and labor unrest, particularly in non-U.S. countries where labor unrest is more common than in the United States;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a non-U.S. market with low or lower prices rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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