BeiGene, Ltd.
Form 10-Q
August 09, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from to

Commission File Number: 001-37686

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

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

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

+1 (345) 949 4123

(Registrant's telephone number, including area code)

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

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

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

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

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

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

As of August 8, 2018, 767,163,184 ordinary shares, par value $0.0001 per share, were outstanding, of which 578,529,211 ordinary shares were held in the form of 44,502,247 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 June 30, 2018 $ (unaudited)	December 31, 2017 $ (audited)
Assets			
Current assets:			
Cash and cash equivalents		438,420	239,602
Restricted cash	5	31,591	—
Short-term investments	5	931,208	597,914
Accounts receivable		33,171	29,428
Unbilled receivable		12,702	—
Inventories	6	6,322	10,930
Prepaid expenses and other current assets	12	63,293	35,623
Total current assets		1,516,707	913,497
Property and equipment, net	7	90,510	62,568
Land use right, net	9	12,132	12,465
Intangible assets, net	10	6,875	7,250
Goodwill	4	109	109
Deferred tax assets	11	16,071	7,675
Other non-current assets	12	11,452	42,915
Total non-current assets		137,149	132,982
Total assets		1,653,856	1,046,479
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		85,878	69,779
Accrued expenses and other payables	12	75,037	49,598
Deferred revenue, current portion		15,302	12,233
Tax payable	11	1,151	9,156
Current portion of long-term bank loan	13	9,067	9,222
Total current liabilities		186,435	149,988
Non-current liabilities:			
Long-term bank loan	13	51,467	9,222
Shareholder loan	14	149,217	146,271
Deferred revenue, non-current portion		18,297	24,808
Other long-term liabilities	12	21,772	31,959
Total non-current liabilities		240,753	212,260
Total liabilities		427,188	362,248

Commitments and contingencies	22		
Equity:			
Ordinary shares (par value of US$0.0001 per share; 9,500,000,000 shares authorized; 701,563,184 shares issued and outstanding as of June 30, 2018 (December 31, 2017: 592,072,330 shares))		70	59
Additional paid-in capital		1,804,942	1,000,747
Accumulated other comprehensive income /(loss)	18	3,114	(480)
Accumulated deficit		(594,929)	(330,517)
Total BeiGene, Ltd. shareholders' equity		1,213,197	669,809
Noncontrolling interest	19	13,471	14,422
Total equity	19	1,226,668	684,231
Total liabilities and equity		1,653,856	1,046,479

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 June 30,		Six Months Ended June 30,	
		2018	2017	2018	2017
		$	$	$	$
Revenues					
Product revenue, net	15	31,426	—	54,676	—
Collaboration revenue	3	21,378	—	30,672	—
Total revenues		52,804	—	85,348	—
Expenses					
Cost of sales - product		(6,256)	—	(10,806)	—
Research and development		(164,251)	(47,245)	(273,951)	(90,018)
Selling, general and administrative		(45,160)	(10,777)	(74,075)	(19,546)
Amortization of intangible assets		(187)	—	(375)	—
Total expenses		(215,854)	(58,022)	(359,207)	(109,564)
Loss from operations		(163,050)	(58,022)	(273,859)	(109,564)
Interest income (expense), net		1,892	(1,982)	3,444	(1,796)
Other income (expense), net		75	(475)	804	438
Loss before income tax expense		(161,083)	(60,479)	(269,611)	(110,922)
Income tax benefit (expense)	11	3,368	(201)	6,780	(381)
Net loss		(157,715)	(60,680)	(262,831)	(111,303)
Less: net loss attributable to noncontrolling interests		(828)	(135)	(1,348)	(135)
Net loss attributable to BeiGene, Ltd.		(156,887)	(60,545)	(261,483)	(111,168)
Net loss per share attributable to BeiGene, Ltd.					
Basic and diluted (in dollars)	16	(0.22)	(0.12)	(0.38)	(0.22)
Weighted-average shares used in net loss per share calculation					
Basic and diluted (in shares)	16	698,506,891	517,663,736	684,586,086	517,054,109
Net loss per American Depositary Share ("ADS")					
Basic and diluted (in dollars)		(2.92)	(1.52)	(4.97)	(2.80)
Weighted-average ADSs used in net loss per share calculation					
Basic and diluted (in ADSs)		53,731,299	39,820,287	52,660,468	39,773,393

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

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BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	$	$	$	$
Net loss	(157,715)	(60,680)	(262,831)	(111,303)
Other comprehensive loss, net of tax of nil:				
Foreign currency translation adjustments	2,033	554	2,305	644
Unrealized holding gain, net	719	19	1,048	7
Comprehensive loss	(154,963)	(60,107)	(259,478)	(110,652)
Less: comprehensive loss attributable to noncontrolling interests	(870)	(108)	(1,326)	(108)
Comprehensive loss attributable to BeiGene, Ltd.	(154,093)	(59,999)	(258,152)	(110,544)

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	Six Months Ended June 30, 2018	2017
		$	$
Operating activities:			
Net loss		(262,831)	(111,303)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		4,580	1,404
Share-based compensation expenses	17	36,037	13,074
Acquired in-process research and development	1	10,000	—
Non-cash interest expense		4,115	2,232
Deferred income tax benefits		(8,413)	(4,059)
Other non-cash income		(2,336)	(3)
Changes in operating assets and liabilities:			
Accounts receivable		(3,743)	—
Unbilled receivable		3,605	—
Inventories		4,608	—
Prepaid expenses and other current assets		(27,669)	(5,036)
Other non-current assets		(3,694)	(139)
Accounts payable		10,308	13,242
Accrued expenses and other payables		25,439	130
Tax payable		(8,005)	2,302
Deferred revenue		(3,442)	—
Other long-term liabilities		(197)	559
Net cash used in operating activities		(221,638)	(87,597)
Investing activities:			
Purchases of property and equipment		(20,309)	(8,881)
Payment for the acquisition of land use right		—	(12,124)
Purchases of investments		(1,198,922)	(27,646)
Proceeds from sale or maturity of available-for-sale securities		869,011	161,900
Purchase of in-process research and development	1	(10,000)	—
Net cash used in (provided by) investing activities		(360,220)	113,249
Financing activities:			
Proceeds from public offering, net of underwriter discount		758,001	—
Payment of public offering cost		(414)	—
Proceeds from long-term loan	13	42,315	—
Proceeds from short-term loan		—	2,470
Repayment of short-term loan		—	(2,470)
Capital contribution from noncontrolling interest		—	14,527
Proceeds from shareholder loan	14	—	132,757
Proceeds from option exercises		10,582	316

Net cash provided by financing activities	810,484	147,600
Effect of foreign exchange rate changes, net	1,783	240
Net increase in cash, cash equivalents, and restricted cash	230,409	173,492
Cash, cash equivalents, and restricted cash at beginning of period	239,602	87,514
Cash, cash equivalents, and restricted cash at end of period	470,011	261,006
Supplemental cash flow disclosures:		
Cash and cash equivalents	438,420	261,006
Restricted cash	31,591	—
Income taxes paid	11,842	746
Interest expense paid	667	618
Non-cash activities:		
Acquisitions of equipment included in accounts payable	8,006	1,373
Changes in operating assets and liabilities adjusted through accumulated deficit	2,291	—

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. Description of Business, Basis of Presentation and Consolidation and Significant Accounting Policies

Description of business

BeiGene, Ltd. (the “Company”) is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer. The Company’s internally-developed lead drug candidates are currently in late-stage clinical trials, and it is marketing three in-licensed drugs in China from which it has been generating product revenue since September 2017.

The Company was incorporated under the laws of the Cayman Islands as an exempted company with limited liability in October 2010. The Company completed its initial public offering (“IPO”) on the NASDAQ Global Select Market in February 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 20, Shareholders’ Equity. On August 8, 2018, the Company completed an IPO on the Stock Exchange of Hong Kong Limited (“HKEx”) and a global offering in which it raised approximately $870,107 in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Effective August 8, 2018, the Company was dual-listed in both the U.S. and Hong Kong.

As at June 30, 2018, the Company’s subsidiaries are as follows:

Name of Company	Place of Incorporation	Date of Incorporation	Percentage of Ownership by the Company	Principal Activities
BeiGene (Hong Kong) Co., Limited.	Hong Kong	November 22, 2010	100 %	Investment holding
BeiGene (Beijing) Co., Ltd. ("BeiGene Beijing")	The People’s Republic of China (“PRC” or “China”)	January 24, 2011	100 %	Medical and pharmaceutical research
BeiGene AUS PTY LTD.	Australia	July 15, 2013	100 %	Clinical trial activities
BeiGene 101	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 and manufacturing
	United States	July 8, 2015	100 %	

BeiGene USA, Inc. ("BeiGene (USA)")					Clinical trial activities
BeiGene Biologics Co., Ltd. ("BeiGene Biologics")	PRC	January 25, 2017	95	%	Biologics manufacturing
BeiGene (Shanghai) Co., Ltd. (“BeiGene (Shanghai)”)*	PRC	September 11, 2015	95	%	Medical and pharmaceutical research
BeiGene Guangzhou Biologics Manufacturing Co., Ltd. ("BeiGene Guangzhou Factory")*	PRC	March 3, 2017	95	%	Biologics manufacturing
BeiGene (Guangzhou) Co., Ltd. (“BeiGene Guangzhou”)	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 (“BeiGene Switzerland”)	Switzerland	September 1, 2017	100	%	Research development, manufacturing, and commercial activities
BeiGene Ireland Limited	Republic of Ireland	August 11, 2017	100	%	Clinical trial activities

* Wholly-owned by BeiGene Biologics

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of June 30, 2018, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017, the

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condensed consolidated statements of cash flows for the six months ended June 30, 2018 and 2017, 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, 2017 ("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 six months ended June 30, 2018 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 the minority shareholder's equity interest as a noncontrolling interest in its consolidated financial statements (as described in Note 8).

Use of estimates

The preparation of the 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 the best estimate of selling price of each deliverable in the Company's revenue arrangements, variable consideration in revenue arrangements (including evaluations of the the expected value and the most likely value method to estimate variable payments based on the type of variable consideration), 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.

Recent accounting pronouncements

New accounting standards which have been adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09. Subsequently, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), which adjusted the effective date of ASU 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which amends the principal-versus-agent implementation guidance and illustrations in

ASU 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies identifying performance obligations and licensing implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09; ASU No. 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments

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to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior Securities and Exchange Commission, or SEC, Staff Announcements and Observer Comments (SEC Update), which codifies recent announcements by the SEC staff; and ASU No. 2017-14, Income Statement—Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue from Contracts with Customers (Topic 606) (SEC Update), which adds ASC 606-10-S25-1 as a result of SEC Release 33-10403, or collectively, the Revenue ASUs. The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenue arising from contracts with customers, and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2017, with an option to early adopt for interim and annual periods beginning after December 15, 2016. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method).

On January 1, 2018, the Company adopted the new standard using the modified retrospective method.

The Revenue ASUs apply to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under the Revenue ASUs, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of the Revenue ASUs, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope the Revenue ASUs, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The impact to the Company on adoption of the Revenue ASUs relates to variable consideration related to its collaboration agreement with Celgene and the anticipated opt-in to certain clinical trials that are to be run by the Company, and funded by Celgene. Under Topic 605, even though the Company believed it was probable that the performance obligation related to the variable consideration would be satisfied as of December 31, 2017, the variable consideration was not realizable because formal notice had not been received. Upon its adoption of the Revenue ASUs, the Company determined it was probable that Celgene would opt-in to the clinical trials as of December 31, 2017 such that the variable consideration was not constrained, and therefore, the related revenue would have been recognized. In March 2018, the Company obtained formal notice of opt-in by Celgene.

The Company recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. The cumulative effect of the changes made to the Company’s consolidated January 1, 2018 balance sheet for the adoption of ASU 2014-09 resulted in an increase of $16,307 to both unbilled receivables and the opening balance of accumulated deficit. Please refer to the “Adoption of New Accounting Standards” section below for a tabular presentation of the impact.

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 adopted ASU 2016-16 during the first quarter of

2018 using the modified retrospective adoption method. In 2017, BeiGene (Hong Kong) Co., Limited's contribution of BeiGene Shanghai to BeiGene Biologics (and subsequent receipt of a related government grant) resulted in tax expenses $28,588, which were reflected as other non-current assets in the Company's December 31, 2017 balance sheet. The related government subsidy of $9,990, which was received in 2017, was reflected as other long-term liabilities in the Company's December 31, 2017 balance sheet. The adoption of this accounting standard resulted in an adjustment to

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beginning accumulated deficit for both of these items. In addition, the Company has now established a deferred tax asset resulting from a previous transfer of intellectual property to one of its wholly-owned subsidiaries. This deferred tax asset is entirely offset by a corresponding valuation allowance and therefore did not result in a change to beginning accumulated deficit. Please refer to the “Adoption of New Accounting Standards” section below for a tabular presentation of the impact.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, which requires entities to present the aggregate changes in cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, the statement of cash flows will be required to present restricted cash and restricted cash equivalents as a part of the beginning and ending balances of cash and cash equivalents. The updated guidance became effective on January 1, 2018, and resulted in the presentation of restricted cash of $31,591 within the ending cash, cash equivalents, and restricted cash balance on the Company’s consolidated statement of cash flows.

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 as of January 1, 2017. 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 became effective on January 1, 2018, and there was no material impact to the Company’s consolidated financial statements.

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Impact of adopted accounting standards

The cumulative effect of changes made to the Company's consolidated January 1, 2018 balance sheet for the adoption of the revenue ASUs and ASU 2016-16 were as follows:

	Balance at December 31, 2017 $	Adjustments Due to Revenue ASUs $	Adjustments Due to ASU 2016-16 $	Balance at January 1, 2018 $
Assets:				
Unbilled receivable	—	16,307	—	16,307
Other non-current assets	42,915	—	(28,588)	14,327
Liabilities:				
Other long-term liabilities	31,959	—	(9,990)	21,969
Equity:				
Accumulated other comprehensive loss	(480)	—	263	(217)
Accumulated deficit	(330,517)	16,307	(19,236)	(333,446)
Noncontrolling interest	14,422	—	375	14,797

New accounting standards which have not yet been adopted

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. As of June 30, 2018, the Company had non-cancellable operating lease commitments of $38,275. The Company is in the process of evaluating its leasing arrangements to determine what extent these contractual commitments will affect the recognition of the related right-of-use assets and liabilities for future lease payments in the consolidated balance sheet. Some of the commitments under short term leases may be exempted from the recognition of relevant assets or liabilities under ASU 2016-02. The Company does not expect that the adoption of ASU 2016-02 will result in significant impact on the operating performance, cash flows and net assets of the Group, but does expect that a certain portion of these operating lease commitments will be required to be recognized on the balance sheet as right-of-use assets and lease liabilities under ASU 2016-02.

In February 2018, the FASB issued ASU 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This update allows companies the option to reclassify to retained earnings the tax effects related to items in accumulated other comprehensive income (loss) as a result of the Tax Cuts and Jobs Act that was enacted in the United States on December 22, 2017. This update is effective in fiscal years, including interim periods, beginning after December 15, 2018, and early adoption is permitted. This guidance should be applied either in the period of adoption or retrospectively to each period in which the effects of the change in the U.S. federal income tax rate in the Tax Cuts

and Jobs Act is recognized. The Company does not expect the impact of this guidance to have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. This update expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. This update also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in

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a grantor's own operations by issuing share-based payment awards. This update is effective in fiscal years, including interim periods, beginning after December 15, 2018. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the financial statement impact of adoption.

Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the consolidated financial statements and notes thereto should be read in conjunction with the consolidated financial statements included in the Company's Annual Report for the year ended December 31, 2017.

Acquired in-process research and development expense

The Company has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. Royalties owed on sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

Except for the changes to the Company's significant accounting policies related to the adoption of the Revenue ASUs and ASU 2016-16, and the accounting for the acquisition of in-process research and development expense, there have been no other material changes to the Company's significant accounting policies as of and for the three and six months ended June 30, 2018, as compared to the significant accounting policies described in the Annual Report.

2. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value. Fair value is determined based upon the exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as determined by either the principal market or the most advantageous market. Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy, as follows:

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

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in market with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the asset or liability.

The Company considers an active market to be one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis, and considers an inactive market to be one in which there are infrequent or few transactions for the asset or liability, the prices are not current, or price quotations

vary substantially either over time or among market makers.

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The following tables present the Company's financial assets and liabilities measured and recorded at fair value on a recurring basis using the above input categories as of June 30, 2018 and December 31, 2017:

As of June 30, 2018	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	903,415	—	—
U.S. agency securities	17,621	—	—
Time deposits	10,172	—	—
Cash equivalents			
U.S. treasury securities	9,988	—	—
Money market funds	127,423	—	—
Total	1,068,619	—	—

As of December 31, 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	561,327	—	—
U.S. agency securities	17,663	—	—
Time deposits	18,924	—	—
Cash equivalents			
Money market funds	44,730	—	—
Total	642,644	—	—

The Company had no liabilities measured and recorded at fair value on a recurring basis as of June 30, 2018 or December 31, 2017.

3. Research and Development Collaborative Arrangements

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

investigational PD-1 inhibitor, tislelizumab (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 fees, of which $92,050 was paid in the third quarter of 2017 and the remaining $170,950 was paid 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

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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 $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, which was completed contemporaneously with the A&R PD-1 License Agreement.

In addition to the exclusive right to develop and commercialize tislelizumab, the terms of the A&R PD-1 License Agreement provide Celgene with the right to collaborate with the Company on the development of tislelizumab 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 tislelizumab for clinical studies associated with specified indications. Celgene will reimburse the Company for certain research and development costs based on external cost, plus agreed upon markup for the development of tislelizumab related to the clinical trials that Celgene opts into, as outlined in the development plan.

The following table summarizes total collaboration revenue recognized for the three and six months ended June 30, 2018 and 2017:

The following table summarizes total collaboration revenue recognized for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	$	$	$	$
Reimbursement of research and development costs	18,175	—	25,730	—
Research and development service revenue	3,203	—	4,942	—
Total	21,378	—	30,672	—

For the three and six months ended June 30, 2018, the Company recognized collaboration revenue of $21,378 and $30,672, respectively. The Company recognized $18,175 and $25,730 of research and development reimbursement revenue for the three and six months ended June 30, 2018 for the trials that Celgene has opted into. In addition, $16,307 of reimbursement that was billed to Celgene was included as an adjustment to beginning accumulated deficit. The $1,703 and $3,442 of research and development services revenue, respectively, for the three and six months ended June 30, 2018, reflect the recognition of upfront consideration that was allocated to R&D services at the time of the collaboration and is recognized from deferred revenue over the term of the respective clinical studies for the specified indications.

In May 2018, the Company achieved the milestone related to its collaboration agreement with Merck KGaA for dosing patients in the first Phase 3 clinical trial of pamiparib in the PRC Territory, and the related $1,500 milestone payment was recognized as research and development services revenue for the three months ended June 30, 2018.

The Company did not have any collaboration revenue for the three and six months ended June 30, 2017.

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, for total consideration of

$28,138. BeiGene HK made an initial cash payment of $4,532, and issued non-cash consideration of $23,606, related to the discount on ordinary shares issued to Celgene, pursuant to the Share Subscription Agreement dated July 5, 2017 by and between the Company and Celgene Switzerland (the "Share Subscription Agreement"). See Note 20 for further description of the Share Subscription Agreement.

Assets acquired and liabilities assumed were recorded at their estimated fair values as of the acquisition date. The excess of the purchase price over the assets acquired and liabilities assumed was recorded as goodwill. The preliminary

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fair values of goodwill, intangible assets and other net assets were $109, $7,500 and $20,529, respectively. These preliminary amounts are subject to subsequent adjustment as the Company obtain additional information to finalize certain components of working capital.

5. Restricted Cash and Short-term Investments

The Company's restricted cash balance of $31,591 as of June 30, 2018 consisted of BeiGene Guangzhou Factory's secured deposits held in designated bank accounts for issuance of letter of credit, and restricted cash deposits as security for the long-term bank loan (Note 13).

Short-term investments as of June 30, 2018 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	902,771	644	—	903,415
U.S. agency securities	17,612	9	—	17,621
Time deposits	10,172	—	—	10,172
Total	930,555	653	—	931,208

Short-term investments as of December 31, 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	561,733	—	406	561,327
U.S. agency securities	17,651	12	—	17,663
Time deposits	18,924	—	—	18,924
Total	598,308	12	406	597,914

Contractual maturities of all debt securities as of June 30, 2018 were within one year. The Company does not consider the investment in U.S. treasury securities or U.S. agency securities to be other-than-temporarily impaired at June 30, 2018.

6. Inventories

The Company’s inventory balance of $6,322 and $10,930 as of June 30, 2018 and December 31, 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 June 30, 2018 $	December 31, 2017 $
Laboratory equipment	17,986	15,596
Leasehold improvements	16,272	15,298
Manufacturing equipment	15,534	15,737
Office equipment	1,718	1,597
Electronic equipment	1,260	1,244
Computer software	1,238	598
Construction in progress	53,738	26,125
Property and equipment, at cost	107,746	76,195
Less accumulated depreciation	(17,236)	(13,627)
Property and equipment, net	90,510	62,568

As of June 30, 2018 and December 31, 2017, construction in progress of $53,738 and $26,125 primarily related to the buildout of the Guangzhou manufacturing facility. In the three months ended June 30, 2018, assets totaling $971 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 six months ended June 30, 2018 was $2,099 and $4,083, respectively. Depreciation expense for the three and six months ended June 30, 2017 was $540 and $1,404, respectively.

8. Manufacturing Facility in Guangzhou

On March 7, 2017, BeiGene HK 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. 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 certain rights to 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, 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 Note 14). 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.

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 14).

In the fourth quarter of 2017, BeiGene HK and BeiGene Biologics entered into an Equity Transfer Agreement to transfer 100% of the equity interest of BeiGene Shanghai into BeiGene Biologics. The transfer consideration for the purchased interests under this Equity Transfer Agreement is the fair value of the 100% equity of BeiGene Shanghai appraised by a qualified Chinese valuation firm under the laws of PRC. Upon the transfer of equity in BeiGene Shanghai, BeiGene HK fulfilled its contribution obligation to subscribe for registered capital in BeiGene Biologics and BeiGene HK’s equity interest in BeiGene Shanghai became 95%.

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On April 4, 2018, BeiGene Guangzhou Factory entered into a nine-year loan agreement with China Construction Bank to borrow a RMB denominated loan of $87,652 (RMB580,000) at a floating interest rate benchmarking RMB loans interest rate of financial institutions in PRC. As of June 30, 2018, the Company has drawn down the loan of $42,315, as further described in Note 13.

As of June 30, 2018, the Company and GET held 95% and 5% equity interests in BeiGene Biologics, respectively. As of June 30, 2018, the Company's cash, cash equivalents, restricted cash and short-term investments included $145,279 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.

9. Land Use Right

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 total term of the right, which is 50 years. The land use right asset as of June 30, 2018 and December 31, 2017 is summarized as follows:

	As of June 30, 2018	December 31, 2017
	$	$
Land use right, cost	12,422	12,633
Accumulated amortization	(290)	(168)
Land use right, net	12,132	12,465

Amortization expense of the land use right for the three and six months ended June 30, 2018 was $61 and $122, respectively. Amortization expense of the land use right for the three and six months ended June 30, 2017 was nil and nil, respectively.

As of June 30, 2018, expected amortization expense for the land use right was approximately $124 for the remainder of 2018, $248 in 2019, $248 in 2020, $248 in 2021, $248 in 2022 and $11,016 in 2023 and thereafter.

10. Intangible Assets

Intangible assets outstanding as of June 30, 2018 and December 31, 2017 are summarized as follows:

	As of June 30, 2018	December 31, 2017

	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	(625)	6,875	7,500	(250)	7,250
Total finite-lived intangible assets	7,500	(625)	6,875	7,500	(250)	7,250

Product distribution rights consist of distribution rights in China for the approved cancer therapies licensed from Celgene, ABRAXANE®, REVLIMID®, and VIDAZA®, and its investigational agent CC-122 acquired as part of the Celgene transaction. The Company is amortizing the product distribution rights over a period of 10 years.

Amortization expense for the three and six months ended June 30, 2018 was $187 and $375, respectively. Amortization expense for the three and six months ended June 30, 2017 was nil and nil, respectively.

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As of June 30, 2018, expected amortization expense for the unamortized finite-lived intangible assets is approximately $375 for the remainder of 2018, $750 in 2019, $750 in 2020, $750 in 2021, $750 in 2022, and $3,500 in 2023 and thereafter.

11. Income Taxes

Income tax benefit was $3,368 and $6,780, respectively, for the three and six months ended June 30, 2018. Income tax expense was $201 and $381, respectively, for the three and six months ended June 30, 2017. The income tax benefit for the three and six months ended June 30, 2018 was primarily attributable to the income tax benefit due to the discrete tax benefit on employee stock option exercises, the generation of research and development tax credits and the U.S. Orphan Drug Credit for the U.S. operating subsidiary. The income tax expense for the three and six months ended June 30, 2017 was primarily attributable to U.S. profit offset by the generation of research and development tax credits and the U.S. Orphan Drug Credit.

On a quarterly basis, the Company evaluates the realizability of deferred tax assets by jurisdiction and assesses the need for a valuation allowance. In assessing the realizability of deferred tax assets, the Company considers historical profitability, evaluation of scheduled reversals of deferred tax liabilities, projected future taxable income and tax-planning strategies. Valuation allowances have been provided on deferred tax assets where, based on all available evidence, it was considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. After consideration of all positive and negative evidence, the Company believes that as of June 30, 2018 it continues to be more likely than not the deferred tax assets will not be realized for the Company’s subsidiaries in Australia, China and Switzerland. In addition, as of June 30, 2018, the Company maintained a valuation allowance for certain deferred tax assets in the U.S. primarily related to state tax credit carryforwards, due to the uncertainty regarding their realization.

As of June 30, 2018, the Company had gross unrecognized tax benefits of $1,552. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly change within the next 12 months. The Company’s reserve for uncertain tax positions increased by $370 and $634, respectively, for the three and six months ended June 30, 2018 due to additions related to U.S. federal and state tax credits and incentives.

The Company has elected to record interest and penalties related to income taxes as a component of income tax expense. As of June 30, 2018 and December 31, 2017, the Company's accrued interest and penalties, where applicable, related to uncertain tax positions were not material.

The Company conducts business in a number of tax jurisdictions and, as such, are required to file income tax returns in multiple jurisdictions globally. As of June 30, 2018, China tax matters are open for the years 2012 through 2018 and U.S. federal tax matters are open to examination for years 2015 through 2018. Various U.S. states and other non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2010 through 2018.

12. Supplemental Balance Sheet Information

Prepaid expenses and other current assets consist of the following:

	As of June 30, 2018	December 31, 2017
	$	$
Prepaid research and development costs	41,723	21,156
Prepaid taxes	14,469	9,894
Interest receivable	1,791	1,557
Other	5,310	3,016
Total	63,293	35,623

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Other non-current assets consist of the following:

	As of June 30, 2018 $	December 31, 2017 $
Prepayment of property and equipment	6,306	12,867
Tax on intra-entity contribution of subsidiary	—	28,588
Rental deposits and other	5,146	1,460
Total	11,452	42,915

Accrued expenses and other payables consist of the following:

	As of June 30, 2018 $	December 31, 2017 $
Compensation related	18,201	17,051
External research and development activities related	41,601	18,721
Sales rebates and returns related	687	3,997
Professional fees and other	14,548	9,829
Total	75,037	49,598

Other long-term liabilities consist of the following:

	As of June 30, 2018 $	December 31, 2017 $
Deferred government grant income	21,449	31,804
Other	323	155
Total	21,772	31,959

13. 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 $18,134 at a 7% fixed annual interest rate. As of June 30, 2018, the Company has drawn down the entire $18,134, which is secured by BeiGene (Suzhou)’s equipment with a net carrying amount of $19,585 and the Company’s rights to a PRC patent on a drug candidate. The loan

principal amounts of $9,067 and $9,067 are repayable on September 30, 2018 and 2019, respectively.

On April 4, 2018, BeiGene Guangzhou Factory entered into a nine-year loan agreement with China Construction Bank to borrow a RMB denominated loan of $87,652 (RMB580,000) at a floating interest rate benchmarking RMB loans interest rate of financial institutions in PRC. The Company plans to draw down the entire available amount before December 31, 2019. The loan is secured by BeiGene Guangzhou Factory's land use right with a net carrying amount of $12,132. Interest expense will be paid quarterly until the loan is fully settled. As of June 30, 2018, the Company has drawn down $42,315 in aggregate principal amount of this loan, with loan interest rate of 4.9% for the six months ended June 30, 2018, and the maturity dates are ranging from 2021 to 2027.

As of June 30, 2018, the Company has unused long-term credit availability amounting to $45,337. Interest expense recognized for the three and six months ended June 30, 2018 was $421 and $752, respectively.

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14. 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. 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 six months ended June 30, 2018, total interest expense generated from the Shareholder Loan was $2,329 and $5,609, respectively, among which, $753 and $1,568 was capitalized, respectively.

15. Product Revenue

The Company’s product sales are derived from the sale of ABRAXANE®, REVLIMID®, and VIDAZA® in China under a distribution license from Celgene. The table below presents the Company’s net product sales for the three and six months ended June 30, 2018 and 2017.

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	$	$	$	$
Product revenue – gross	31,670	—	55,155	—
Less: Rebate and sales return	(244)	—	(479)	—
Product revenue – net	31,426	—	54,676	—

The following table presents the rollforward of accrued sales rebates and returns for the six months ended June 30, 2018:

	Sales Rebates and Returns
	$
Balance as of December 31, 2017	3,997
Accrual	479
Payments	(3,789)
Balance as of June 30, 2018	687

16. Net Loss Per Share

Net loss per share was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	$	$	$	$
Numerator:				
Net loss attributable to BeiGene, Ltd.	(156,887)	(60,545)	(261,483)	(111,168)
Denominator:				
Weighted average shares outstanding for computing basic and diluted loss per share	698,506,891	517,663,736	684,586,086	517,054,109
Net loss per share attributable to BeiGene, Ltd., basic and diluted	(0.22)	(0.12)	(0.38)	(0.22)

The effects of all share options, restricted shares and restricted share units were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive during the three and six months ended June 30, 2018 and 2017.

17. Share-Based Compensation Expense

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 June 30, 2018, ordinary shares cancelled or forfeited under the 2011 Plan that were provided back to the 2016 Plan totaled 4,977,646. 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, 2018, 29,603,616 ordinary shares were

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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 six months ended June 30, 2018, the Company granted options for 8,465,886 ordinary shares, 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, and restricted share units for 9,254,232 ordinary shares under the 2016 Plan. As of June 30, 2018, options and restricted share units for ordinary shares outstanding under the 2016 Plan totaled 89,918,184 and 10,526,672, respectively.

2018 Inducement Equity Plan

On June 6, 2018, the board of directors of the Company approved the 2018 Inducement Equity Plan (the "2018 Plan") and reserved 12,000,000 ordinary shares to be used exclusively for grants of awards to individuals that were not previously employees of the Company or its subsidiaries, as a material inducement to the individual's entry into employment with the Company or its subsidiaries within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. The 2018 Plan was approved by the board of directors upon recommendation of the compensation committee, without shareholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. The terms and conditions of the 2018 Plan, and the forms of award agreements to be used thereunder, are substantially similar to the 2016 Plan and the forms of award agreements thereunder. During the six months ended June 30, 2018, the Company granted restricted share units for 527,904 ordinary shares under the 2018 Plan. As of June 30, 2018, restricted share units for ordinary shares outstanding under the 2018 Plan totaled 527,904.

2018 Employee Share Purchase Plan

On June 6, 2018, the shareholders of the Company approved the 2018 Employee Stock Purchase Plan ("ESPP"). Initially, 3,500,000 ordinary shares of the Company are reserved for issuance under the ESPP. In addition, on January 1, 2019 and each January 1 thereafter through January 1, 2028, the number of ordinary shares reserved and available for issuance under the ESPP will be cumulatively increased by the least of (i) 5,000,000 ordinary shares, (ii) 0.5% of the number of ordinary shares issued and outstanding on the immediately preceding December 31, or (iii) such lesser number of ordinary shares as determined by the compensation committee of the Company's board of directors; provided that the aggregate number of ordinary shares reserved and available for issuance under the ESPP may not exceed 10% of the number of ordinary shares issued and outstanding as of the date of shareholder approval. The ESPP allows eligible employees to purchase the Company's ordinary shares (including in the form of ADSs) at the end of each offering period, which will generally be six months, at a 15% discount to the market price of the Company's ordinary shares or ADSs at the beginning or the end of each offering period, whichever is lower, using funds deducted from their payroll during the offering period. Eligible employees are able to authorize payroll deductions of up to 10% of their eligible earnings, subject to applicable limitations.

The first offering under the ESPP is anticipated to begin on September 1, 2018 and would end on February 28, 2019. As of June 30, 2018, no shares have been issued under the ESPP.

The following table summarizes total share-based compensation expense recognized for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	$	$	$	$

Research and development	10,722	4,749	22,774	9,278
Selling, general and administrative	7,919	2,333	13,263	3,796
Total	18,641	7,082	36,037	13,074

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18. 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, 2017	(85)	(395)	(480)
Adjustment to opening balance of accumulated other comprehensive income	263	—	263
Balance as of January 1, 2018	178	(395)	(217)
Other comprehensive income before reclassifications	2,283	1,375	3,658
Amounts reclassified from accumulated other comprehensive income	—	(327)	(327)
Net-current period other comprehensive income	2,283	1,048	3,331
Balance as of June 30, 2018	2,461	653	3,114

19. Noncontrolling Interest

As of June 30, 2018, a noncontrolling interest of $13,471 was recognized in the Company's condensed consolidated balance sheet, representing the capital cash contribution by GET in BeiGene Biologics as of June 30, 2018, offset by comprehensive losses attributable to GET's noncontrolling interest in BeiGene Biologics.

For the three and six months ended June 30, 2018, net losses of $828 and $1,348 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.

Reconciliation for the equity attributable to noncontrolling interests for the six months ended June 30, 2018 is as follows:

	BeiGene, Ltd. Shareholders' Equity	Noncontrolling Interest	Total Equity
	$	$	$
Balance as of January 1, 2018	669,809	14,422	684,231
Net loss	(261,483)	(1,348)	(262,831)
Issuance of ordinary shares in follow-on offering, net of transaction costs	757,587	—	757,587
Share-based compensation	36,037	—	36,037
Exercise of options	10,582	—	10,582
Adjustment to opening balance of equity	(2,666)	375	(2,291)

Other comprehensive income, net of tax of nil:			
Foreign currency translation adjustments	2,283	22	2,305
Unrealized holding gain, net	1,048	—	1,048
Other comprehensive income, net of tax of nil	3,331	22	3,353
Balance as of June 30, 2018	1,213,197	13,471	1,226,668

20. Shareholders' Equity

Follow-on public offerings

On January 22, 2018, the Company completed a follow-on public offering under the Company's effective registration statement on Form S-3 at a price of $101.00 per ADS, or $7.77 per ordinary share. In this offering, the

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Company sold 7,425,750 ADSs representing 96,534,750 ordinary shares. Additionally, the underwriters exercised their option to purchase an additional 495,050 ADSs representing 6,435,650 ordinary shares from the Company. Net proceeds from this offering including the underwriter option after deducting the underwriting discounts and offering expenses were $757,587.

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.

21. 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 June 30, 2018 and December 31, 2017, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to $37,640 and $29,920, respectively.

22. 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 $2,217 and $3,870 for the three and six months ended June 30, 2018, respectively. Total expenses under these operating leases were $725 and $1,421 for the three and six months ended June 30, 2017, respectively.

Future minimum payments under non-cancelable operating leases consist of the following as of June 30, 2018:

	$
Six months ending December 31, 2018	6,103
Year ending December 31, 2019	11,064
Year ending December 31, 2020	9,907
Year ending December 31, 2021	5,784
Year ending December 31, 2022	3,961
Year ending December 31, 2023 and thereafter	1,456
Total	38,275

Capital commitments

The Company had capital commitments amounting to $55,957 for the acquisition of property, plant and equipment as of June 30, 2018, which were mainly for BeiGene Guangzhou Factory's manufacturing facility in Guangzhou, China.

23. Segment and geographic information

The Company operates in one segment. Its chief operating decision maker is the Chief Executive Officer, who makes operating decisions, assesses performance and allocates resources on a consolidated basis.

The Company's long-lived assets are substantially located in the PRC.

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Net product revenues by geographic areas are based upon the location of the customer, and net collaboration revenue is recorded in the jurisdiction in which the related income is expected to be sourced from. Total net revenues by geographic areas are presented as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	$	$	$	$
PRC	32,926	—	56,176	—
U.S.	12,921	—	18,962	—
Other	6,957	—	10,210	—
Total	52,804	—	85,348	—

24. Subsequent Event

On August 8, 2018, the Company completed an IPO on the Stock Exchange of Hong Kong Limited (“HKEx”) and a global offering in which it raised approximately $870,107 in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Effective August 8, 2018, the Company was dual-listed in both the U.S. and Hong Kong.

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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," "can," "continue," "could," "estimate," "expect," "goal," "intend," "may," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these terms or other similar exp although not all forward-looking statements contain these words. These forward-looking statements, include, but are not limited to, statements regarding: the initiation, timing, progress and results of our preclinical studies and clinical trials and our research and development programs; our ability to advance our drug candidates into, and successfully complete, clinical trials; our reliance on the success of our clinical-stage drug candidates; the timing or likelihood of regulatory filings and approvals; the commercialization of our drugs and drug candidates, if approved; our ability to further develop sales and marketing capabilities; the pricing and reimbursement of our drugs and drug candidates, if approved; the implementation of our business model, strategic plans for our business, drug candidates and technology; the scope of protection we (or our licensors) are able to establish and maintain for intellectual property rights covering our drugs, drug candidates and technology; our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties; costs associated with enforcing or defending against intellectual property infringement, misappropriation or violation, 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, revenues, capital requirements and our need for additional financing; the potential benefits of strategic collaboration and licensing agreements and our ability to enter into strategic arrangements; our ability to maintain and establish collaborations or licensing agreements; our reliance on third parties to conduct drug development, manufacturing and other services; the rate and degree of market access and acceptance of our drugs and drug candidates, if approved; developments relating to our competitors and our industry, including competing therapies; the size of the potential markets for our drugs and drug candidates and our ability to serve those markets; our ability to effectively manage our anticipated growth; our ability to attract and retain qualified employees and key personnel; statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance; the future trading price of our ADSs and ordinary shares, 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 commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer. We have three internally-developed late-stage clinical drug candidates: (1) zanubrutinib (BGB-3111), an investigational small molecule inhibitor of Bruton's tyrosine kinase, or BTK, (2) tislelizumab (BGB-A317), an investigational humanized monoclonal antibody against the immune checkpoint receptor PD-1, and (3) pamiparib (BGB-290), an investigational small molecule

inhibitor of PARP1 and PARP2. All three of these drug candidates are currently in Phase 2 or 3 pivotal trials globally and in China, and we expect to file for regulatory approvals in China in 2018 for zanubrutinib and tislelizumab and in the United States in the first half of 2019 for zanubrutinib.

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In addition, we have three internally-developed drug candidates in Phase 1 clinical development: lifirafenib (BGB-283), an investigational RAF dimer protein complex inhibitor;, BGB-A333, an investigational humanized monoclonal antibody against the immune checkpoint receptor ligand PD-L1; and BGB-A425, an investigational humanized monoclonal antibody against T-cell immunoglobulin and mucin-domain containing-3, or TIM-3.

In 2017, we entered into a strategic collaboration with Celgene Corporation, or Celgene, in which we granted Celgene exclusive rights to develop and commercialize tislelizumab for solid tumors in the United States, Europe, Japan, and the rest of the world outside of Asia. We retained rights to tislelizumab for solid tumors in Asia (ex-Japan) and for hematological malignancies and internal combinations globally. In connection with the Celgene collaboration, we obtained an exclusive license to market Celgene's approved cancer therapies ABRAXANE®, REVLIMID®, and VIDAZA® in China, excluding Hong Kong, Macau and Taiwan, which has allowed us to generate product revenue in China since September 2017. We also obtained Celgene's commercial operations and personnel in China, which we expect to expand in preparation for the potential launch of our own internally-developed drug candidates and our other in-licensed drug candidates in China.

We initially started as a research and development organization in Beijing in 2010, and have since become a fully-integrated global biopharmaceutical company with operations in China in Beijing, Guangzhou, Shanghai and Suzhou, operations in the United States in Cambridge, MA; Fort Lee, NJ; and Emeryville and San Mateo, CA, and operations in Basel, Switzerland. In addition, we have a facility in Suzhou for the commercial-scale manufacturing of small molecule drugs and pilot-scale manufacturing of biologics, and another facility under construction in Guangzhou for the commercial-scale manufacturing of biologics.

Recent Developments

On July 22, 2018, we announced preliminary topline results from the independent review of response data from our first pivotal trial for tislelizumab in Chinese patients with Hodgkin's lymphoma (cHL). The single-arm pivotal trial enrolled 70 patients with cHL, and achieved an overall response rate of 72.9%, including a complete response rate of 50%, based on the Lugano 2014 criteria. The frequency and severity of adverse events were generally consistent with the previously reported Phase 1 safety and tolerability data for tislelizumab, or, in the case of certain immune-related events such as hypothyroidism and fever, consistent with previous reports of other PD-1 antibodies for the treatment of cHL. The full results of the trial are expected to be presented at an upcoming medical conference. The cHL data, along with additional follow up data from the clinical trial, are expected to be included in the BLA planned to be filed with the CDA later this year. On July 30, 2018, we filed a Current Report on Form 8-K with the SEC in which we disclosed updated preliminary topline results from this trial in which patients had a minimum of 24 weeks of follow-up, compared to a minimum of 18 weeks of follow-up reported on July 22, 2018. In the updated results with a data cut-off of May 25, 2018, and a median follow-up time of 7.85 months, a review of responses by an independent review committee showed an overall response rate of 85.7%, including 61.4% complete response. In both data sets, the median duration of response had not been reached.

On July 22, 2018, we announced that zanubrutinib was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with Waldenstrom macroglobulinemia (WM). Based on interactions with the FDA, internal review of available data from the global Phase 1 trial of zanubrutinib in patients with WM, and supported by the Fast Track Designation, we are preparing to submit an NDA in the first half of 2019 to pursue an accelerated approval of zanubritinib for patients with WM based on the results from the global Phase 1 study. In addition, we announced that the global Phase 3 head-to-head study of zanubrutinib compared to ibrutinib in patients with WM has completed enrollment.

On July 24, 2018, we announced that the first patient was dosed in a global Phase 3 clinical trial of pamiparib as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who responded to

platinum-based first-line chemotherapy.

On July 24, 2018, we announced that the first patient was dosed in a Phase 3 clinical trial of tislelizumab, combined with chemotherapy, as a potential first-line treatment in Chinese patients with Stage IIIB or IV non-squamous non-small cell lung cancer, or NSCLC.

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On July 27, 2018, we announced a Hong Kong initial public offering and a global offering of 65,600,000 ordinary shares, and the proposed listing of our ordinary shares on the Main Board of The Stock Exchange of Hong Kong Limited, which we refer to as the "HKEx" or the "SEHK".

On August 8, 2018, the Company completed an IPO on the Stock Exchange of Hong Kong Limited ("HKEx") and a global offering in which it raised approximately $870,107 in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Effective August 8, 2018, the Company was dual-listed in both the U.S. and Hong Kong.

Components of Operating Results

Revenue

To date, our revenue has consisted of product sales revenue since September 2017, upfront license fees, reimbursed research and development expenses, research and development service revenue and milestone payments from our strategic collaboration with Celgene for tislelizumab entered in 2017 and our collaboration agreements with Merck KGaA, Darmstadt Germany for pamiparib and lifirafenib entered in 2013. We do not expect to generate significant revenue from internally-developed drug candidates unless and until we successfully complete development and obtain regulatory approval for one or more of our drug candidates, which is subject to significant uncertainty.

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, 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. Despite increased competition from generic products, we expect revenue from product sales to increase in 2018 compared to 2017 levels as we expand our efforts to promote and obtain reimbursement for ABRAXANE®, REVLIMID® and VIDAZA® in China.

We also record revenue from our collaboration and license agreements with Celgene and Merck KGaA, Darmstadt Germany. Under each agreement, we have received upfront payments related to the license fee which was recognized upon the delivery of the license right. Additionally, the reimbursement of remaining undelivered research and development services is recognized over the performance periods of the collaboration arrangement. In the case of the Celgene arrangement, we also receive research and development reimbursement revenue for the clinical trials that Celgene opts into. See Note 3 to our consolidated financial statements included in this Quarterly Report for a description of these agreements.

Expenses

Cost of Revenue

Cost of revenue includes the acquisition costs of our commercial products.

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:

- 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;

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- costs associated with preclinical activities and development activities;
- costs associated with regulatory operations;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel; 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 advancement of our six internally-developed drug candidates mentioned above:

- zanubrutinib, an investigational small molecule inhibitor of BTK;
- tislelizumab, an investigational humanized monoclonal antibody against PD 1;
- pamiparib, an investigational small molecule inhibitor of PARP1 and PARP2;
- lifirafenib, an investigational small molecule inhibitor of both the monomer and dimer forms of BRAF;
- BGB-A333, an investigational humanized monoclonal antibody against PD-L1; and
- BGB-A425, an investigational humanized monoclonal antibody against TIM-3.

We expense research and development costs when we incur them. We record costs for certain 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 expense the manufacturing costs of our internally-developed products that are used in clinical trials as they are incurred, as research and development expense. 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 internally-developed drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our internally-developed drug candidates. This is due to the numerous risks and uncertainties associated with developing such drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- successfully launching and 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;

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- continued acceptable safety profiles of the products following approval;
- competition from competing products; 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, as we continue to support the clinical trials of our drug candidates as treatments for various cancers and as we move these drug candidates into additional clinical trials. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may 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 planned 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 our drug candidates as treatments for various cancers and the initiation of clinical trials for potential new 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 market funds, time deposits, U.S. Treasury securities and U.S. agency securities.

Interest Expense

Interest expense consists primarily of interest on our 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.

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Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(dollars in thousands)							
Revenues								
Product revenue, net	$ 31,426	$ —	$ 31,426	—	$ 54,676	$ —	$ 54,676	—
Collaboration revenue	21,378	—	21,378	—	30,672	—	30,672	—
Total revenues	52,804	—	52,804	—	85,348	—	85,348	—
Expenses								
Cost of sales - product	(6,256)	—	(6,256)	—	(10,806)	—	(10,806)	—
Research and development	(164,251)	(47,245)	(117,006)	248%	(273,951)	(90,018)	(183,933)	204%
Selling, general and administrative	(45,160)	(10,777)	(34,383)	319%	(74,075)	(19,546)	(54,529)	279%
Amortization of intangible assets	(187)	—	(187)	—	(375)	—	(375)	—
Total expenses	(215,854)	(58,022)	(157,832)	272%	(359,207)	(109,564)	(249,643)	228%
Loss from operations	(163,050)	(58,022)	(105,028)	181%	(273,859)	(109,564)	(164,295)	150%
Interest income (expense), net	1,892	(1,982)	3,874	-195%	3,444	(1,796)	5,240	-292%
Other income (expense), net	75	(475)	550	-116%	804	438	366	84%
Loss before income tax expense	(161,083)	(60,479)	(100,604)	166%	(269,611)	(110,922)	(158,689)	143%
Income tax benefit (expense)	3,368	(201)	3,569	-1776%	6,780	(381)	7,161	-1880%
Net loss	(157,715)	(60,680)	(97,035)	160%	(262,831)	(111,303)	(151,528)	136%
Less: Net loss attributable to noncontrolling interest	(828)	(135)	(693)	513%	(1,348)	(135)	(1,213)	899%
Net loss attributable to BeiGene, Ltd.	$ (156,887)	$ (60,545)	$ (96,342)	159%	$ (261,483)	$ (111,168)	$ (150,315)	135%

Comparison of the Three Months Ended June 30, 2018 and 2017

Revenue

Total revenue increased to $52.8 million for the three months ended June 30, 2018, from nil for the three months ended June 30, 2017. The following table summarizes the components of revenue for the three months ended June 30, 2018 and 2017, respectively:

	Three Months Ended June 30,		Changes	
	2018	2017	$	%
Product revenue	$ 31,426	$ —	$ 31,426	—
Collaboration revenue:				
Reimbursement of research and development costs	18,175	—	18,175	—
Research and development service revenue	3,203	—	3,203	—
Total	$ 52,804	$ —	$ 52,804	—

Net product revenue was $31.4 million for the three months ended June 30, 2018, which related to sales of ABRAXANE®, REVLIMID® and VIDAZA® in China. We began recognizing product revenue with sales to our distributors in China in September 2017 following the closing of our strategic collaboration with Celgene. VIDAZA® was launched in China in February 2018. We had no product revenue for the three months ended June 30, 2017.

Collaboration revenue totaled $21.4 million for the three months ended June 30, 2018, and was comprised of $18.2 million for the reimbursement of research and development costs for the clinical trials that Celgene has opted into, $1.7 million related to the recognition of deferred revenue for upfront fees allocated to undelivered research and development services to Celgene and $1.5 million research and development services for achieving a milestone related to our collaboration agreement with Merck KGaA, Darmstadt Germany. There was no collaboration revenue for the three months ended June 30, 2017.

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Cost of Sales

Cost of sales increased to $6.3 million for the three months ended June 30, 2018 from nil for the three months ended June 30, 2017. Cost of sales for the three months ended June 30, 2018 consisted entirely of the cost of products purchased from Celgene and distributed in the PRC. We had no product sales for the three months ended June 30, 2017.

Research and Development Expense

Research and development expense increased by $117.0 million, or 248%, to $164.3 million for the three months ended June 30, 2018 from $47.2 million for the three months ended June 30, 2017. The following table summarizes external clinical, external preclinical and internal research and development expense for the three months ended June 30, 2018 and 2017, respectively:

	Three Months Ended June 30,		Changes	
	2018	2017	$	%
	(dollars in thousands)			
External cost of clinical-stage programs	$ 90,130	$ 22,178	$ 67,952	306%
External cost of preclinical-stage programs	18,545	4,206	14,339	341%
Internal research and development expenses	55,576	20,861	34,715	166%
Total research and development expenses	$ 164,251	$ 47,245	$ 117,006	248%

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 $34.3 million, $31.4 million and $3.7 million, respectively, for zanubrutinib, tislelizumab and pamiparib, partially offset by a decrease of approximately $1.5 million for lifirafenib. The expense increases were primarily due to the expansion of clinical trials for these candidates, including the initiation or continuation of pivotal trials.
· An increase of approximately $14.3 million in external spending for our preclinical-stage programs, primarily related to costs associated with advancing our preclinical candidates toward clinical trials.

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

· $13.7 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;
· $6.0 million increase of share-based compensation expense, primarily attributable to our increased headcount and higher share price;
· $6.7 million increase of materials and reagent expenses, mainly in connection with the in-house manufacturing of drug candidates used for clinical purposes, that were previously outsourced and recorded as external cost;
· $4.8 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our pipeline; and
· $3.5 million increase of facilities, office expense, rental fee and other expenses to support the growth of our organization.

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Selling, General and Administrative Expense

Selling, general and administrative expense increased by $34.4 million, or 319%, to $45.2 million for the three months ended June 30, 2018, from $10.8 million for the three months ended June 30, 2017. The increase was primarily attributable to the following:

· $11.3 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;
· $5.6 million increase of share-based compensation expense, primarily attributable to our increased headcount and higher share price;
· $3.2 million increase of professional fees for legal, consulting, recruiting, accounting and audit services to support our growing business; and
· $14.3 million increase of selling, facility, conference fees, travel expenses, rental fees and other administrative expenses, primarily attributable to the global expansion of our business, including the post-combination cost of our commercial operations in China.

Interest Income (Expense), Net

Interest income (net) increased to $1.9 million for the three months ended June 30, 2018, as compared to the interest expense of $2.0 million for three months ended June 30, 2017. The increase in interest income was primarily attributable to interest income on our larger cash and short-term investment balances.

Other Income (Expense), Net

Other income, net, increased to $0.1 million for the three months ended June 30, 2018, from other expense of $0.5 million for the three months ended June 30, 2017. The increase was mainly attributable to the impact of foreign currency exchange and related net gains.

Income Tax Benefit (Expense)

Income tax benefit was $3.4 million for the three months ended June 30, 2018, as compared with income tax expense of $0.2 million for the three months ended June 30, 2017. The income tax benefit for the three months ended June 30, 2018 was primarily attributable to income tax benefit due to the discrete tax benefit on employee share option exercises and the generation of research and development tax credits and the U.S. Orphan Drug Credit for our U.S. operating subsidiary, partially offset by income tax expense from our commercial operations in China.

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Comparison of the Six Months Ended June 30, 2018 and 2017

Revenue

Total revenue increased to $85.3 million for the six months ended June 30, 2018, from nil for the six months ended June 30, 2017. The following table summarizes the components of revenue for the six months ended June 30, 2018 and 2017, respectively:

	Six Months Ended June 30,		Changes	
	2018	2017	$	%
Product revenue	$ 54,676	$ —	$ 54,676	—
Collaboration revenue:				
Reimbursement of research and development costs	25,730	—	25,730	—
Research and development service revenue	4,942	—	4,942	—
Total	$ 85,348	$ —	$ 85,348	—

Net product revenue was $54.7 million for the six months ended June 30, 2018, which related to sales of ABRAXANE®, REVLIMID® and VIDAZA® in China. We began recognizing product revenue with sales to our distributors in China in September 2017 following the closing of our strategic collaboration with Celgene. VIDAZA® was launched in China in February 2018. We had no product revenue for the six months ended June 30, 2017.

Collaboration revenue totaled $30.6 million for the six months ended June 30, 2018, and was comprised of $25.7 million for the reimbursement of research and development costs for the clinical trials that Celgene has opted into, $3.4 million related to the recognition of deferred revenue for upfront fees allocated to undelivered research and development services to Celgene and $1.5 million research and development services for achieving the milestone related to collaboration agreement with Merck KGaA, Darmstadt Germany. There was no collaboration revenue for the six months ended June 30, 2017.

Cost of Sales

Cost of sales increased to $10.8 million for the six months ended June 30, 2018 from nil for the six months ended June 30, 2017. Cost of sales for the six months ended June 30, 2018 consisted entirely of the cost of products purchased from Celgene and distributed in the PRC. We had no product sales for the six months ended June 30, 2017.

Research and Development Expense

Research and development expense increased by $183.9 million, or 204%, to $274.0 million for the six months ended June 30, 2018 from $90.0 million for the six months ended June 30, 2017. The following table summarizes external clinical, external preclinical and internal research and development expense for the six months ended June 30, 2018 and 2017, respectively:

	Six Months Ended June 30,		Changes	
	2018	2017	$	%

	(dollars in thousands)			
External cost of clinical-stage programs	$ 143,299	$ 46,758	$ 96,541	206%
External cost of preclinical-stage programs	28,331	5,341	22,990	430%
Internal research and development expenses	102,321	37,919	64,402	170%
Total research and development expenses	$ 273,951	$ 90,018	$ 183,933	204%

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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 $35.0 million, $41.2 million and $12.1 million, respectively, for zanubrutinib, tislelizumab and pamiparib, partially offset by a decrease of approximately $1.8 million for lifirafenib. The expense increases were primarily due to the expansion of clinical trials for these candidates, including the initiation or continuation of pivotal trials. In addition, external costs of clinical-stage programs include $10 million of in-process research and development expense related to our in-license of sitravitinib for the Asia (excluding Japan), Australia and New Zealand territories.

· An increase of approximately $23.0 million in external spending for our preclinical-stage programs, primarily related to costs associated with advancing our preclinical candidates toward clinical trials.

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

· $26.0 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;
· $13.5 million increase of share-based compensation expense, primarily attributable to our increased headcount and higher share price;
· $9.9 million increase of materials and reagent expenses, mainly in connection with the in-house manufacturing of drug candidates used for clinical purposes, that were previously outsourced and recorded as external cost;
· $8.8 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our pipeline; and
· $6.2 million increase of facilities, office expense, rental fee and other expenses to support the growth of our organization.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $54.5 million, or 279%, to $74.1 million for the six months ended June 30, 2018, from $19.5 million for the six months ended June 30, 2017. The increase was primarily attributable to the following:

· $20.1 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;
· $9.5 million increase of share-based compensation expense, primarily attributable to our increased headcount and higher share price;
· $4.7 million increase of professional fees for legal, consulting, recruiting, accounting and audit services to support our growing business; and
· $20.2 million increase of selling, facility, conference fees, travel expenses, rental fees and other administrative expenses, primarily attributable to the global expansion of our business, including the post-combination cost of our commercial operations in China.

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Interest Income, Net

Interest income (net) increased to $3.4 million for the six months ended June 30, 2018, as compared to the interest expense of $1.8 million for six months ended June 30, 2017. The increase in interest income was primarily attributable to interest income on our larger cash and short-term investment balances.

Other Income, Net

Other income, net, increased by $0.4 million to $0.8 million for the six months ended June 30, 2018, from $0.4 million for the six months ended June 30, 2017. The increase was mainly attributable to the impact of foreign currency exchange and related net gains.

Income Tax Benefit (Expense)

Income tax benefit was $6.8 million for the six months ended June 30, 2018, as compared with income tax expense of $0.4 million for the six months ended June 30, 2017. The income tax benefit as of June 30, 2018 was primarily attributable to income tax benefit due to the discrete tax benefit on employee share option exercises and the generation of research and development tax credits and the U.S. Orphan Drug Credit for our U.S. operating subsidiary, partially offset by income tax expense from our commercial operations in China.

Liquidity and Capital Resources

Since inception, we have incurred annual net losses and negative cash flows from our operations. Substantially all of our losses have resulted from the funding of our research and development programs and selling, general and administrative expenses associated with our operations. We incurred net losses of $157.7 million and $262.8 million, respectively, for the three and six months ended June 30, 2018, and net losses of $60.7 million and $111.3 million, respectively, for the three and six months ended June 30, 2017. As of June 30, 2018, we had an accumulated deficit of $594.9 million. Our primary use of cash is to fund our research and development activities. Our operating activities used $221.6 million and $87.6 million during the six months ended June 30, 2018 and 2017, respectively. We have financed our operations principally through proceeds from public and private offerings of our securities and proceeds from our collaboration agreements with Celgene and Merck KGaA, Darmstadt Germany. During the six months ended June 30, 2018, we raised $757.6 million, net of underwriting discounts and commissions and offering expenses, from a follow-on public offering of our ADSs. In addition, the June 30, 2018 unbilled receivable balance of $12.7 million reflects research and development reimbursement funding under the Celgene collaboration for expenses incurred through the second quarter of 2018.

On August 8, 2018, the Company completed an IPO on the Stock Exchange of Hong Kong Limited (“HKEx”) and a global offering in which it raised approximately $870,107 in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Effective August 8, 2018, the Company was dual-listed in both the U.S. and Hong Kong.

As of June 30, 2018, we had cash, cash equivalents,restricted cash, and short-term investments of $1,401.2 million, including approximately $145.3 million of cash, cash equivalents, restricted cash and short-term investments held by our joint venture, BeiGene Biologics, to build a commercial biologics facility in Guangzhou, China and to fund research and development of biologics drug candidates in China. Restricted cash of $31.6 million represents secured deposits of BeiGene Guangzhou Factory held in designated bank accounts for issuance of letter of credit, and restricted cash deposits as security for long-term bank loan.

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The following table provides information regarding our cash flows for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	$ (221,638)	$ (87,597)
Net cash (used in) provided by investing activities	(360,220)	113,249
Net cash provided by financing activities	810,484	147,600
Net effect of foreign exchange rate changes	1,783	240
Net increase in cash, cash equivalents, and restricted cash	$ 230,409	$ 173,492

Use of Funds

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, cash equivalents and short-term investments 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.

Operating Activities

Operating activities used $221.6 million of cash in the six months ended June 30, 2018, which resulted principally from our net loss of $262.8 million and an increase in our net operating assets and liabilities of $2.8 million, offset by non-cash charges of $44.0 million. The increase in our net operating assets was primarily due to an increase of $27.7 million in prepaid expenses and other current assets primarily related to prepayments to CROs for clinical trials, a decrease in taxes payable of $8.0 million, an increase in accounts receivables of $3.7 million related to collections on product sales from our collaboration with Celgene, an increase of $3.7 million in other non-current assets primarily related to rental deposits, and a decrease in deferred revenue and other long-term liabilities of $3.6 million, which each had a negative impact on operating cash flow. These factors were partially offset by a increase of $35.7 million in accounts payable and accrued expenses related to payments for external research and development costs, payroll-related costs and selling, general and administrative expenses to support our growing business, a decrease of $4.6 million in inventories and a decrease in unbilled receivable of $3.6 million related to the Celgene collaboration, which each had a positive impact on operating cash flow. Our non-cash charges and other adjustments to our net loss during the six months ended June 30, 2018 primarily consisted of $36.0 million of share-based compensation expense, $10.0 million of acquired in-process research and development related to the license agreement with Mirati, $1.8 million of non-cash interest expense and $4.6 million of depreciation expense, offset by $8.4 million related to deferred tax benefits.

During the six months ended June 30, 2017, operating activities used $87.6 million of cash, which resulted principally from our net loss of $111.3 million, adjusting for non-cash charges of $12.6 million and by cash provided by our operating assets and liabilities of $11.1 million. Our net non-cash charges during the six months ended June 30, 2017 primarily consisted of $13.1 million of share-based compensation expense, $2.2 million of non-cash interest expense and $1.4 million of depreciation expense, offset by $4.1 million related to deferred tax benefits.

Investing Activities

Investing activities used $360.2 million of cash in the six months ended June 30, 2018, which consisted of purchases of investment securities of $1,198.9 million, a purchase of $10.0 million of in-process research and development related to the license agreement with Mirati and capital expenditures of $20.3 million primarily related to our Guangzhou and Suzhou manufacturing facilities, offset by sales and maturities of investment securities of $869.0 million.

Investing activities provided $113.2 million for the six months ended June 30, 2017, which consisted of sale or maturity of available-for-sale securities of $161.9 million, offset by purchases of investment securities of $27.7 million, capital expenditures of $8.9 million and a $12.1 million payment to acquire land use rights in Guangzhou, China.

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Financing Activities

Financing activities provided $810.5 million of cash in the six months ended June 30, 2018, which consisted of $757.6 million of proceeds, net of underwriting discounts and commissions and offering expenses, from our follow-on public offering of ADSs, $42.3 million from a new long-term bank loan and $10.6 million from the exercise of employee stock options.

Financing activities provided $147.6 million in the six months ended June 30, 2017, which related to proceeds from the Shareholder Loan of $132.8 million and the capital contribution in BeiGene Biologics by GET of $14.5 million.

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 for 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 June 30, 2018, 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 our ongoing research and clinical development efforts, including our ongoing and planned pivotal trials for zanubrutinib, tislelizumab and pamiparib, both in China and globally; our other ongoing and planned clinical trials; regulatory filing and registration of our late-stage drug candidates; expansion of commercial operations in China and preparation for launch of our drug candidates globally; business development and manufacturing activities; and working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

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

- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our drug candidates to progress through clinical development successfully;
- the initiation, progress, 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 establishing commercial manufacturing capabilities or securing necessary supplies from third-party manufacturers;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

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- the costs of establishing and expanding our commercial operations and the success of those 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.

Contractual Obligations and Commitments

The following table summarizes our significant contractual obligations as of the payment due date by period at June 30, 2018:

	Payments Due by Period				
	Total	Less Than 1 Year	1–3 Years	3–5 Years	More Than 5 Years
	(in thousands)				
Contractual obligations					
Operating lease commitments	$ 38,275	$ 11,982	$ 18,903	$ 6,658	$ 732
Debt obligations	209,751	9,067	9,140	151,698	39,846
Capital commitments	55,957	55,957	—	—	—
Total	$ 303,983	$ 77,006	$ 28,043	$ 158,356	$ 40,578

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.

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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 $18.2 million at a 7% fixed annual interest rate. As of June 30, 2018, we have drawn down the entire $18.2 million, which is secured by BeiGene (Suzhou)'s equipment with a net carrying amount of $19.6 million and our rights to a PRC patent on a drug candidate. $9.1 million is repayable on each of September 30, 2018 and 2019.

On April 4, 2018, BeiGene Guangzhou Factory entered into a nine-year loan agreement with China Construction Bank to borrow $87.7 million at a floating interest rate benchmarking RMB loans interest rate of financial institutions in PRC. The Company plans to draw down the entire available amount before December 31, 2019. The loan is secured by BeiGene Guangzhou Factory's land use right with a net carrying amount of $12.1 million. Interest expense will be paid quarterly until the loan is fully settled. As of June 30, 2018, the Company has drawn down $42.3 million in aggregate principal amount of this loan, with maturity dates ranging from 2021 to 2027.

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 $56.0 million for the acquisition of property, plant and equipment as of June 30, 2018, 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 other entities 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 or the licensing fees are currently not determinable.

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

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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.

Except for the changes to our critical accounting policies related to the adoption of the Revenue ASUs and ASU 2016-16, and the accounting for the acquisition of in-process research and development expense discussed in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018, there have been no other material changes to our significant accounting policies as of and for the three and six months ended June 30, 2018, as compared to 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 on Form 10-K for the year ended December 31, 2017.

For accounting policies relating to the three and six months ended June 30, 2018 and the related impact on adoption, see "Part I—Item 1. Financial Statements—Notes to the Condensed Consolidated Financial Statements—1. Description of Business, Basis of Presentation and Consolidation and Significant Accounting Policies—Significant accounting policies" in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

See Note 1 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding recent accounting pronouncements.

Recent Government Regulations

The section of our Annual Report on Form 10-K for the year ended December 31, 2017 entitled "Item 1. Business—Government Regulation—PRC Regulation—PRC Drug Regulation" is updated to reflect the regulatory developments in the PRC disclosed in our Quaterly Report on Form 10-Q for the three months ended March 31, 2018 under the caption "Part I, Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Governmental Regulations", which are incorporated by reference herein.

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, cash equivalents, restricted cash and short-term investments. The carrying amounts of cash, cash equivalents, restricted cash and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $438.4 million and $239.6 million, restricted cash of $31.6 and nil, and short-term investments of $931.2 million and $597.9 million at June 30, 2018 and December 31, 2017, respectively. At June 30, 2018, our cash and cash equivalents were deposited with various major reputable financial institutions located within and without 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. Restricted cash represents secured deposits held in designated bank accounts for issuance of letters of credit, and restricted cash deposits as security for long-term bank loan. At June 30, 2018, our short-term investments consisted primarily of U.S. treasury securities and time-denominated 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 significantly 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 and short-term investments, 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

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100-basis point change in market interest rates would impact the fair value of our investment portfolio as of June 30, 2018 by $2.8 million.

We do not believe that our cash, cash equivalents, restricted cash and short-term investments have significant risk of default or illiquidity. While we believe that our cash, cash equivalents, restricted cash and short-term investments do not contain excessive risk, we cannot provide absolute assurance that in the future our 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. Swiss franc, Euro and Hong Kong dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge exposure to such risk.

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange prices. From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For the RMB against U.S. dollars, there was depreciation of approximately 1.7% in the six months ended June 30, 2018 and appreciation of approximately 6.5% in the year ended December 31, 2017, 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 purposes, 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.

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 six months ended June 30, 2018.

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Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation, required by paragraph (b) of Rules 13a-15 or 15d-15, promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act are effective, at a reasonable assurance level, as of June 30, 2018, to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in U.S. Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures.

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 six months ended June 30, 2018 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 we believe, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

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

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

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Risks Related to Clinical Development and Regulatory Approval of Our Drug Candidates

We depend substantially on the success of our drug candidates, which are in clinical development. If we are unable to successfully complete clinical development, obtain regulatory approval and 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, which are still in clinical development, and other drug candidates 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 will depend on several factors, including:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by contract research organizations, or CROs, or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- successfully launching our drug candidates, if and when approved;
    - obtaining favorable reimbursement from third-party payors for drugs, if and when approved;
- competition with other products;
- continued acceptable safety profile following regulatory approval; 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.

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

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difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol.

Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, 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 and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

*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, and initial or interim results of a trial may not be predictive of the final results. 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.

Also, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set for the protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from early trials due to differences in the number of patients, clinical trial sites, countries and regions and populations 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.

Even if our future clinical trial results show favorable efficacy and impressive durability of antitumor responses, not all patients may benefit. For certain drugs, including checkpoint inhibitors, and in certain indications, it is likely that the majority of patients may not respond to the agents at all, some responders may relapse after a period of response and certain tumor types may appear particularly resistant.

If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of 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, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. 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 but not limited to: regulators, institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the

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terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; manufacturing issues, including problems with manufacturing, supply quality, compliance with China's drug Good Manufacturing Practice, current good manufacturing practice, or GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; 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 other unexpected characteristics 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 or not rely on the results of 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; and 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.

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.

Significant clinical trial delays may also increase our development costs and 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. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

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Risks Related to Extensive Government Regulation

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated.

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of the United States, China and other Asian countries, and the European Union. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes—some minor, some significant—that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in each of these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The failure to comply with these regulations could have a material adverse effect on our business.

*The regulatory approval processes of the U.S. Food and Drug Administration, China Drug Administration, European Medicines Agency and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable. 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 U.S. Food and Drug Administration, or FDA, the China Drug Administration, or CDA, the European Medicines Agency, or EMA, and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

Our drug candidates could fail to receive regulatory approval for many reasons, including:

· failure to begin or complete clinical trials due to disagreements with regulatory authorities;

· failure to demonstrate that a drug candidate is safe and effective or that a biologic 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;
· data integrity issues related to our clinical trials;
· disagreement with our interpretation of data from preclinical studies or clinical trials;
· changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
· regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;

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- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The FDA, CDA, EMA or a comparable regulatory authority may require more information, including additional preclinical, chemistry, manufacturing and controls, or CMC, and/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.

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 that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. 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.

*We believe that our drug candidates' designation in China as Category 1 products should confer certain regulatory advantages on us. These advantages may not result in commercial benefits to us as we expect, and they might be changed in the future in a manner adverse to us.

In China, prior to seeking approval from the CDA, a pharmaceutical company needs to determine the drug's registration category, which will determine the requirements for its clinical trial and marketing application. These categories range from Category 1, for drugs incorporating a new chemical entity that has not previously been marketed anywhere in the world, to Category 2, for drugs with new indications, dosage forms or routes of administration and the like, to Categories 3 and 4, for certain generic drugs, to Category 5, for "originator" (what would be known elsewhere as innovative) or generic drugs previously marketed abroad but not yet approved for marketing in China. Therapeutic biologics follow a similar classification system. All of our internally developed drug candidates are classified as Category 1 based on the respective clinical trial approval from the CDA, which is a favored category for regulatory review and approval.

The CDA has adopted several mechanisms for expedited review and approval for drug candidates that apply to Category 1 drug candidates. While we believe that the Category 1 designation of our internally developed clinical stage drug candidates should provide us with a significant regulatory, and therefore commercial, advantage over non-Chinese companies seeking to market products in China, we cannot be sure that this will be the case. The pharmaceutical regulatory environment is evolving quickly, and changes in laws, regulations, enforcement and internal policies could result in the "favored" status of Category 1 products changing, or being eliminated altogether or our products classification in Category 1 changing. We cannot be certain that the advantages we believe will be conferred by our Category 1 classifications will be realized or result in any material development or commercial advantage.

*The absence of patent-linkage, patent-term extension and data and market exclusivity for CDA-approved pharmaceutical products could increase the risk of early generic competition with our products in China.

In the United States, the Federal Food Drug and Cosmetic Act, as amended by the law generally referred to as "Hatch-Waxman," provides the opportunity for patent-term restoration of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. Hatch-Waxman also has a process for patent linkage, pursuant to which FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30

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months. Finally, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the United States to the first applicant to obtain approval of a new chemical entity (as defined) and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after FDA grants marketing approval for the innovative product.

In China, however, there is no currently effective law or regulation providing patent term extension, patent linkage, or data exclusivity (referred to as regulatory data protection). Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. To be implemented, this framework will require adoption of regulations. To date, CDA has issued several draft implementing regulations in this regard for public comment but no regulations have been formally issued. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States until the relevant implementing regulations for extension, patent linkage, or data exclusivity are put into effect officially in China.

Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA inspections, which may result in a longer and costlier current good manufacturing practice inspection and approval process by the FDA for our Chinese manufacturing processes.

To obtain FDA approval for our products in the United States, we will need to undergo strict pre approval inspections of our manufacturing facilities, which we have located in China. Historically, manufacturing facilities in China have had difficulty meeting the FDA's standards. When inspecting our Chinese manufacturing facilities, the FDA might cite cGMP deficiencies, both minor and significant, which we may not be required to disclose. Remediating deficiencies can be laborious and costly and consume significant periods of time. Moreover, if the FDA notes deficiencies as a result of this inspection, it will generally reinspect the facility to determine if the deficiency was remediated to its satisfaction. The FDA may note further deficiencies as a result of its reinspection, either related to the previously identified deficiency or otherwise. If we cannot satisfy the FDA as to our compliance with cGMP in a timely basis, FDA marketing approval for our products could be seriously delayed, which in turn would delay commercialization of our drug candidates.

*Undesirable adverse events caused by our drugs and drug candidates 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 drugs 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, CDA, EMA or other comparable regulatory authority, or could result in limitations or withdrawal following approvals. If results of our trials reveal a high and unacceptable severity or prevalence of AEs, our trials could be suspended or terminated and the FDA, CDA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates.

Numerous drug-related AEs and serious AEs, or SAEs, have been reported in our clinical trials. Some of these events have led to patient death. 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. In our periodic and current reports filed with the SEC and from time to time we disclose clinical results for our drug candidates, including the occurrence of AEs and SAEs. Each such report speaks only as of the date of the data cutoff used in such report, and we undertake no duty to update such information unless required by applicable law. Also, a number of immune-related adverse events, or IRAEs, have been associated with treatment with checkpoint inhibitors, including immune-mediated pneumonitis, colitis,

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hepatitis, endocrinopathies, nephritis and renal dysfunction, skin adverse reactions, and encephalitis. These IRAEs may be more common in certain patient populations (potentially including elderly patients) and may be exacerbated when checkpoint inhibitors are combined with other therapies.

Additionally, undesirable side effects caused by our drugs and drug candidates, or caused by our drugs and drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including:

- regulatory authorities could delay or halt pending clinical trials;
- we may suspend, delay or alter development of the drug candidate or marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a Risk Evaluation Mitigation Strategy, or 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; and
- we could be sued and held liable for harm caused to subjects or patients.

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.

*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 drugs 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, 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, CDA, 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 are and will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any New Drug Application, or NDA, or Biologics License Application, 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 drugs and any approvals that we receive for our drug candidates are and may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug or 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®. In addition, if the FDA, CDA, EMA or a comparable regulatory

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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 Good Clinical Practice, or 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 drugs or drug candidates or with our drug's 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 drugs and 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, CDA, 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, CDA, 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, particularly in China, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of any of our drug candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and may also require post-marketing safety studies. Other comparable regulatory authorities outside the United States, such as the CDA 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.

*If safety, efficacy, or other issues arise with any medical product that is used in combination with our drugs, we may be unable to market such drug or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our drug candidates for use as a combination therapy. If the FDA, CDA, EMA or another comparable regulatory agency revokes its approval of another therapeutic we use in combination with our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical

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trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline or at all.

*Reimbursement may not be available for our drug candidates. Even if we are able to commercialize our drugs and any approved drug candidates, the drugs may become subject to unfavorable pricing regulations or third-party reimbursement practices, 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 our revenues.

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.

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.

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 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. There can be no assurance that our drugs and any 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, although this has been changing in recent years.

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.

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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. 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 develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

We intend to seek approval to market our drug candidates in the United States, China, Europe and in other jurisdictions. In some non-U.S. countries, particularly those in the European Union, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of our drugs will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs 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, the European Union and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare 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. We expect that healthcare reform measures 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 recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies, including modification, repeal, or replacement of all, or certain provisions of, the Affordable Care Act, or ACA. The implications of the ACA, its possible repeal, any legislation that may be proposed to replace the ACA, modifications to the implementation of the ACA, and the political uncertainty surrounding any repeal or replacement legislation for our business and financial condition, if any, are not yet clear.

Risks Related to Commercialization of Our Drugs and 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.

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 drug candidate is safe, pure, and potent, for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA or BLA must 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

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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.

We have not yet demonstrated an ability to file for or receive regulatory approval for our drug candidates. For example, we do not have experience in preparing the required materials for regulatory submission or navigating the regulatory approval process. As a result, our ability to successfully submit an NDA or BLA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

Regulatory authorities outside of the United States, such as the CDA 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.

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, CDA 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.

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 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;

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- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by 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 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; and
- the effectiveness of our sales and marketing efforts.

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

*We have limited experience in marketing third-party drugs and no experience in launching an internally-developed drug candidate. 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.

In connection with our strategic collaboration with Celgene, 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 avadomide (CC-122) in clinical development, and acquired Celgene's commercial operations in China, excluding certain functions. We started marketing Celgene's approved drugs in September 2017. We continue to build our salesforce in China to market these drugs and our 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 have not yet demonstrated an ability to launch and commercialize any of our drug candidates. For example, we do not have experience in building a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our internally-developed drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching drug candidates.

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 of our drugs, 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. We would 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 drugs ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drugs.

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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 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 drugs or developing our drug candidates. 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.

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, CDA, 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.

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.

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.

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 and may prove to be inaccurate or based on imprecise data. 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.

We may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the United States

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and other jurisdictions, 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.

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 to 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 other voluntary industry codes of conduct. 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.

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 applicability 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 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.

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 tislelizumab for hematological cancers globally and for solid tumors in China and the rest of Asia, other than Japan. We initially intend to focus on opportunities in China, in particular. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if these parties are not successful, our revenue-generating growth potential will be adversely

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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;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potential third-party patent rights or potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation;
- 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;
- workforce uncertainty and labor unrest;
- 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; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

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

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a commercial-stage 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, conducting preclinical studies and clinical trials of our drug candidates and the commercialization of our drugs. We have not yet completed large-scale, pivotal or registrational clinical trials, obtained regulatory approvals, or manufactured or had manufactured a commercial scale drug. 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

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have generated revenues from the sale of drugs in China licensed from Celgene. Our limited operating history, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

*We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never become profitable.

Investment in pharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we have incurred losses in each period since our inception, except in the third quarter of 2017, when we were profitable due to revenue recognized from an up-front license fee from Celgene. As of December 31, 2017 and June 30, 2018, we had an accumulated deficit of $330.5 million and $594.9 million, respectively. 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 expenses associated with our operations.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue and expand our development of, and seek regulatory approvals for, our drug candidates, and continue to commercialize the drugs that 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. In addition, we will continue to incur costs associated with operating as a public company in the United States and expect to incur costs associated with being a public company in Hong Kong after the completion of our proposed initial public offering in Hong Kong, or the Offering. We will also incur costs in support of our growth as a commercial-stage global biopharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with 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 failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our 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.

Our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. Our operating activities provided $12.8 million and used $89.5 million of net cash during the years ended December 31, 2017 and 2016, respectively, and used $221.6 million and $87.6 million of net cash during the six months ended June 30, 2018 and 2017, respectively. We recorded negative net cash flows from operating activities in 2016 primarily due to our net loss of $119.2 million. Although we recorded positive net cash flows from operating activities in 2017, we cannot assure you that we will be able to generate positive cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at

all, and if we raise finance by issuing further equity securities your interest in our company may be diluted. If we have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, commercializing our 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.

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While we have generated product revenue in China since September 2017 from sales of our drugs licensed from Celgene, these revenues are not sufficient to support our operations. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that we have sufficient cash, cash equivalents and short-term investments to meet our projected operating requirements for at least the next 12 months. However, we believe that our existing cash, cash equivalents and short-term investments will not be sufficient to enable us to complete all global development or commercially launch all of our current drug candidates for the currently anticipated indications and to invest in additional programs. Accordingly, we will require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. 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 exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- 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 of our drug candidates;
- the number and characteristics of drug candidates that we may in-license and develop;
- the amount and timing of the milestone and royalty payments we receive from our collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our drugs 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 cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities; and
- our headcount growth and associated costs.

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 our ordinary shares and/or ADSs. 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

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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 our ADSs and/or ordinary shares 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 derive revenues, in currencies other than the U.S. dollar or Hong Kong dollar, in particular, the RMB and Australian dollar. 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. 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 proposed or adopted by the People’s Republic of China, or PRC, Australia and other non-U.S. governments. It is difficult to predict how market forces or PRC, Australia, other non-U.S. governments and U.S. 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.

Substantially all of our revenues are denominated in U.S. dollars and RMB, 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 and RMB. Any significant revaluation of the RMB may materially reduce any dividends payable on our ordinary shares and/or ADSs in U.S. dollars. To the extent that we need to convert U.S. dollars 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 RMB into U.S. dollars for the purpose of making payments for dividends on our 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.

The proceeds from the Offering will be received in Hong Kong dollars. As a result, any appreciation of the RMB against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our proceeds from the Offering. Conversely, any depreciation of the RMB may adversely affect the value of, and any dividends payable on, our ordinary shares and/or ADSs in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to obtain the State Administration of Foreign Exchange's approval before converting significant sums of foreign currencies into RMB. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our ordinary shares and/or ADSs in foreign currency terms.

*Our business, profitability and liquidity may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers, and an impairment in the carrying value of our short-term investments could negatively affect our consolidated results of operations.

We are exposed to the risk that our distributors and customers may default on their obligations to us as a result of bankruptcy, lack of liquidity, operational failure or other reasons. As we continue to expand our business, the amount and duration of our credit exposure will be expected to increase over the next few years, as will the breadth of the entities to which we have credit exposure. Although we regularly review our credit exposure to specific distributors and

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customers that we believe may present credit concerns, default risks may arise from events or circumstances that are difficult to detect or foresee.

Also, the carrying amounts of cash and cash equivalents, restricted cash and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $438.4 million, $239.6 million and $87.5 million, restricted cash of $31.6 million, nil and nil and short-term investments of $931.2 million, $597.9 million and $280.7 million at June 30, 2018, December 31, 2017 and 2016, respectively, most of which are deposited in financial institutions outside of China. Although our cash and cash equivalents in China are deposited with various major reputable financial institutions, 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. As of June 30, 2018 and December 31, 2017, our short-term investments consisted primarily of U.S. Treasury securities, U.S. agency securities and time deposits. Although we believe that the U.S. Treasury securities, U.S. agency securities and time deposits are of high credit quality and continually monitor the credit worthiness of these institutions, concerns about, or a default by, one institution in the U.S. market, could lead to significant liquidity problems, losses or defaults by other institutions, which in turn could adversely affect us.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends in large part on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in the United States, the PRC and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, the PRC and, recently, the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all

other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

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In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the State Intellectual Property Office, or SIPO, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States, PRC and other countries. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords, is limited. For example, the approved cancer therapies we have licensed from Celgene in China, ABRAXANE®, REVLIMID®, and VIDAZA®, face or are expected to face competition from generic medications, and we may face similar competition for any approved drug candidates even if we successfully obtain patent protection once the patent life has expired for the drug. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents in court, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in “Part I—Item 1—Business—Intellectual Property” of our Annual Report on Form 10-K for the year ended December 31, 2017, as updated by our Current Report on Form 8-K filed on July 24, 2018. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a

result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against

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third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

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

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

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

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

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

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or

interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even

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outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

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

We are aware of U.S. patents with claims covering certain antibodies that are relevant to tislelizumab for which patents are expected to expire in 2023 or 2024; complexes of irreversible BTK inhibitors that are relevant to zanubrutinib for which the patent is expected to expire in 2027; and the use of PARP inhibitors to treat certain cancers that are relevant to pamiparib for which patents are expected to expire between 2027 and 2031. We are also aware of issued patents in Europe and China relevant to pamiparib. Although we believe that the relevant claims of these patents would likely be held invalid, we can provide no assurance that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims of one or more of these patents were to be upheld upon a validity challenge, and our related drug candidate was to be approved for sale in the United States before the expiration of the

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relevant patents, we would need a license to commercialize the drug candidate in the United States before the expiration of the relevant patents. In addition, depending upon the circumstances, we may need licenses for jurisdictions outside of the United States where we wish to commercialize a particular drug candidate before the expiration of corresponding patents covering that drug candidate. In such cases, we can provide no assurance that we would be able to obtain a license or licenses on commercially reasonable terms or at all, which could materially and adversely affect our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of the ordinary shares and/or ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If we do not obtain patent term extension and data exclusivity for any drug candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, no patent term extension system has been established in the PRC beyond the new pilot program, and implementation of the pilot program may not occur quickly. As a result, the patents we have in the PRC are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or term of any such

extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

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

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

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

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

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

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

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third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications. These license agreements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Risks Related to Our Reliance on Third Parties

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

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

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to the failure to adhere to

our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

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

We expect to rely on third parties to manufacture at least a portion of our clinical and commercial drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

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

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

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, CDA, EMA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by FDA, CDA, EMA or other comparable regulatory authorities;
- our manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drugs and drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with cGMPs and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
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we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates and drugs;

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- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our drugs. In addition, we will rely on third parties to perform certain specification tests on our drugs and drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

Currently, the raw materials for our manufacturing activities are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in our supply of our drugs and drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drugs for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

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

Before a third party can begin commercial manufacture of our drugs and drug candidates, contract manufacturers are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture drug and biological products and our drug candidates, any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a cost-effective manner in order for us to obtain regulatory approval of our drug candidates. If our contract manufacturers do not pass their inspections by the relevant regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates or disruption in sales. In addition, drug and biological manufacturing facilities are continuously subject to inspection by regulatory authorities, before and after drug approval, and must comply with cGMPs. Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that

could seriously harm our business. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial

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suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition.

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

We have entered into collaborations, such as with Celgene and Merck KGaA, Darmstadt Germany, and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

For example, we entered into license agreements with Merck KGaA, Darmstadt Germany, pursuant to which Merck KGaA, Darmstadt Germany has an option to acquire exclusive commercialization rights under our pamiparib PARP program in the PRC if pamiparib does not receive national priority project status in China under its 12th or 13th five-year plan by July 28, 2017. We applied for national priority project status for pamiparib to be effective from the beginning of 2017, and our application is in process and we believe it will be approved. However, there have been unanticipated governmental delays that have impacted the 2017 applicant pool for national project priority status and we expect that we will now receive formal notification in 2018. As such, we intend to discuss with Merck KGaA, Darmstadt Germany the impact of this delay on the PRC PARP license agreement.

Our strategic collaboration with Celgene involves numerous risks. There can be no assurance that we will be able to successfully manage and integrate Celgene’s commercial operations in China and its personnel into our business, which could disrupt our business and harm our financial results. Moreover, we may not achieve the revenue and cost synergies expected from the transaction and our management’s attention may be diverted from our drug discovery and development business. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with Celgene may be offset by costs incurred in integrating Celgene’s commercial operations in China, increases in other expenses, operating losses or problems in the business unrelated to our collaboration with Celgene. As a result, there can be no assurance that these synergies will be achieved.

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

in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than us, and any agreement that we do enter may result in the anticipated benefits.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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*If we fail to maintain an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected.

We rely on a third-party distributor to distribute Celgene's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributor, who may fail to distribute our products in the manner we contemplate. While we have long-standing business relationship with our distributor, the agreement we entered into with our distributor can be terminated by both parties upon six months' written notice. If PRC price controls or other factors substantially reduce the margins our distributor can obtain through the resale of our products to hospitals, medical institutions and sub-distributors, it may terminate its relationship with us. As of the date of this report, we rely on one distributor to distribute our products. While we believe alternative distributors are readily available in China, there is a risk that, if the distribution of our drugs is interrupted, our sales volumes and business prospects could be adversely affected.

*We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data , or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Risks Related to Our Industry, Business and Operations

*Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Xiaodong Wang, Ph.D., our Co-Founder, Chairman of our scientific advisory board, which may from time to time provide us assistance upon our request, and director; John V. Oyler, our Co-Founder, Chief Executive Officer and Chairman of the Board; and the other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided share option, restricted share unit and restricted share grants that vest over time. The value to employees of these

equity grants that vest over time may be significantly affected by movements in the ADS and/or ordinary share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

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Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

*We have significantly increased the size and capabilities of our organization, and we may experience difficulties in managing our growth.

At the beginning of 2017, we had over 320 employees, and we ended the year with approximately 900 employees. As of July 20, 2018, our total employee number reached over 1,300. Most of our employees are full-time. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

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

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*We incur significant costs as a result of operating as a public company in the United States, and our management is required to devote substantial time to compliance requirements, including establishing and maintaining internal controls over financial reporting. We may be exposed to potential risks if we are unable to comply with these requirements.

As a public company in the United States, we are subject to the periodic reporting requirements of the Exchange Act and incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, together with rules implemented by the U.S. Securities and Exchange Commission, or SEC, and applicable market regulators. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We have limited experience complying with Section 404, and such compliance may require that we incur substantial accounting expenses and expend significant management efforts. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, the market price of our ordinary shares and/or ADSs could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC or other applicable regulatory authorities and our business could be harmed.

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

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

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

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In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

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

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

We are subject to the Foreign Corrupt Practices Act, or FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery laws of other jurisdictions, particularly China. As our business has expanded, the applicability of the FCPA and other anti-bribery laws to our operations has increased.

We do not fully control the interactions our employees, distributors and third-party promoters have with hospitals, medical institutions and doctors, and they may try to increase sales volumes of our products through means that constitute violations of the PRC anti-corruption and other related laws. If our employees, distributors or third-party promoters engage in corrupt or other improper conduct that results in violation of applicable anti-corruption laws in the PRC or other jurisdictions, our reputation could be harmed. Furthermore, we could be held liable for actions taken by our employees, distributors or third-party promoters, which could expose us to regulatory investigations and

penalties.

Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

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

We and third parties, such as our CROs or CMOs, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health and safety have been completed. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

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

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage

to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition,

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outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

*If we or parties on whom we rely fail to maintain the necessary licenses for the development, production, sales and distribution of our products, our ability to conduct our business could be materially impaired.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Third parties, such as distributors, third party promoters and third-party manufacturers, on whom we may rely to develop, produce, promote, sell and distribute our products may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

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

Our operations, and those of our third-party research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We partially rely on third-party manufacturers to produce and process our drugs and drug candidates. Our ability to obtain supplies of our drugs and drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business

interruption. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

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*Product liability claims or lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the commercialization of our drugs in China and the clinical testing and any future commercialization of our drug candidates globally. For example, we may be sued if our drugs or drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drugs and drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drugs; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any drug candidate; and a decline in the ADS or ordinary share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our drugs and drug candidates. Although we currently hold $10 million in product liability coverage in the aggregate, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We are subject to the risks of doing business globally.

Because we operate in China and other countries outside of the United States, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain countries; enforcement of anti-corruption and anti-bribery laws, such as the FCPA; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable local tax regimes and potentially adverse tax consequences; and significant adverse changes in local currency exchange rates.

We manufacture and intend to continue to manufacture ourselves at least a portion of our drug candidates and our drugs, if approved. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

We currently have manufacturing facilities in Beijing and Suzhou, China and are building a biologics manufacturing facility in Guangzhou, China. These facilities may encounter unanticipated delays and expenses due to a number of

factors, including regulatory requirements. If construction, regulatory evaluation and/or approval of our new facility is delayed, we may not be able to manufacture sufficient quantities of our drug candidates and our drugs, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources.

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

- achieving adequate or clinical-grade materials that meet FDA, CDA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, CDA, EMA or other comparable regulatory agencies.

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

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

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

In addition to the similar manufacturing risks described in "—Risks Related to Our Reliance on Third Parties," if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates or drugs in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any

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expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates and drugs if there were a catastrophic event or failure of our manufacturing facilities or processes.

Risks Related to Our Doing Business in the PRC

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

A large portion of our business is conducted in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates or drugs in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the Chinese government’s policies, but we cannot ensure that our strategy and approach will continue to be aligned.

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

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors of the PRC. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in the PRC, which may adversely affect our business and results of operation. More generally, if the business environment in the PRC deteriorates from the perspective of domestic or international investment, our business in the PRC may also be adversely affected.

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

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

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the

protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature

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of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

A draft of the proposed Foreign Investment Law is being considered and there are substantial uncertainties with respect to the enactment timetable and the final content of the Foreign Investment Law. If enacted as proposed, the Foreign Investment Law may materially impact our current corporate governance practices and business operations in many aspects and may increase our compliance costs. For instance, the proposed Foreign Investment Law would impose stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable foreign invested entities. Depending on the seriousness of the circumstances, non-compliance with the information reporting obligations, concealment of information or providing misleading or false information could result in monetary fines or criminal charges.

Additionally, the CDA's recent reform of the drug and approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner.

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

*Any failure to comply with PRC regulations regarding our employee equity incentive plans and investments in offshore companies by PRC residents may subject the PRC plan participants and PRC-residents beneficial owners or us to fines and other legal or administrative sanctions.

We and our directors, executive officers and other employees who are PRC residents have participated in our employee equity incentive plans. We are an overseas listed company, and therefore, we and our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted share units, restricted shares, options or other forms of equity incentives are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plan of Overseas Publicly Listed Company, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in the PRC for a continuous period of not less than one year, subject to limited exceptions, are required to register with the State Administration of Foreign Exchange, or the SAFE, through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law.

Some of our existing shareholders, each of whom owns our ordinary shares as a result of exercising share options, are PRC residents under the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37. These shareholders have undertaken to (i) apply to register with local SAFE branch or its delegated commercial bank as soon as possible after exercising their options, and (ii) indemnify and hold harmless us and our subsidiaries against any loss suffered arising from their failure to complete the registration. We do not have control over such

shareholders and our other beneficial owners and cannot assure you that all of our PRC-resident beneficial owners have complied with, and will in the future comply with, SAFE Circular 37 and subsequent implementation rules.

If we or our directors, executive officers or other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted equity awards fail to register the employee equity incentive plans or their exercise of options, or such PRC-resident beneficial owners fails to register or amend their

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SAFE registrations in a timely manner pursuant to SAFE Circular 37, we and such employees and PRC-beneficial owners may be subject to (i) legal or administrative sanctions imposed by the SAFE or other PRC authorities, including fines; (ii) restrictions on our cross-border investment activities; (iii) limits on the ability of our wholly owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us; and (iv) prohibitions on our ability to inject additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions.

*We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each operating subsidiary. As of December 31, 2017 and June 30, 2018, these restricted assets totaled $29.9 million and $37.6 million, respectively.

Our PRC subsidiaries generate primarily all of their revenue in RMB, which is not freely convertible into other currencies. As a result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their RMB revenues to pay dividends to us.

In response to the persistent capital outflow in the PRC and RMB’s depreciation against U.S. dollar in the fourth quarter of 2016, China’s People’s Bank of China, or PBOC, and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments.

The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

The Enterprise Income Tax Law, or the EIT Law, and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to PRC withholding tax at a rate of 10%.

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Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, or the Hong Kong Tax Treaty, BeiGene HK, the shareholder of some of our PRC subsidiaries, may be subject to a withholding tax at a rate of 5% on dividends received from our PRC operating subsidiaries as a Hong Kong tax resident. Pursuant to the Hong Kong Tax Treaty, subject to certain conditions, this reduced withholding tax rate will be available for dividends from PRC entities provided that the recipient can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. BeiGene HK currently does not hold a Hong Kong tax resident certificate from the Inland Revenue Department of Hong Kong and there is no assurance that the reduced withholding tax rate will be available.

*We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and we may therefore be subject to PRC income tax on our worldwide taxable income. Dividends payable to foreign investors and gains on the sale of our ADSs or ordinary shares by our foreign investors may become subject to PRC tax.

Under the EIT Law an enterprise established outside the PRC with “de facto management bodies” within the PRC is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for PRC enterprise income tax, or EIT, purposes. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. The State Administration of Taxation, or the SAT, has subsequently provided further guidance on the implementation of Circular 82.

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

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

However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow and we may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. If we are deemed a PRC resident enterprise, dividends paid on our ordinary shares or ADSs, and any gain realized from the transfer of our ordinary shares or ADSs, may be treated as income derived from sources within the PRC. As a result, dividends paid to non-PRC resident enterprise ADS holders or shareholders may be subject to PRC withholding tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprises ADS holders or shareholders from the transfer of our ordinary shares or ADSs may be subject to PRC tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders).

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

Pursuant to the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7, which was amended by the Announcement on Issues Relating to Withholding at Source of Income Tax on Non-resident Enterprises issued by SAT, or Announcement 37, an "indirect transfer" of "PRC taxable assets," including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a "reasonable commercial purpose" of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in the PRC or if its income mainly derives from the PRC; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be reported on with the enterprise income tax filing of the PRC establishment or place of business being transferred, and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC enterprise income tax at the rate of 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC enterprise income tax pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. As such, the sale of the ADSs or ordinary shares on a public stock exchange will not be subject to PRC enterprise income tax pursuant to Bulletin 7. However, the sale of our ordinary shares or ADSs by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Bulletin 7.

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

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Announcement 37, or Bulletin 7, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

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

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of the PRC. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us,

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without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our ordinary shares and the ADSs. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities or designated banks. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

*Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.

In the past, local governments in the PRC granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations. Government grant and subsidies recognized in the income statement for the years ended December 31, 2016, and 2017, and the six month periods ended June 30, 2018 and 2017 was $1,363,000, $20,957,000, $3,740,000 and $442,000, respectively.

The audit report included in our Annual Report on Form 10-K filed with the SEC is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, investors are deprived of the benefits of such inspection.

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

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

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

In December 2012, the SEC brought administrative proceedings against five accounting firms in China, including our independent registered public accounting firm, alleging that they had refused to produce audit work papers and other

documents related to certain other PRC-based companies under investigation by the SEC. On January 22, 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. The decision is neither final nor legally effective unless and until reviewed and approved by the SEC. On February 12, 2014, four of these PRC-based accounting firms appealed to the SEC against this decision. In February 2015, each of the four PRC-based accounting firms agreed to a censure and to

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pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC. These firms' ability to continue to serve all their respective clients is not affected by the settlement. The settlement requires these firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms' audit documents via the China Securities Regulatory Commission, or the CSRC. If these firms do not follow these procedures, the SEC could impose penalties such as suspensions, or it could restart the administrative proceedings. The settlement did not require these firms to admit to any violation of law and preserves these firms' legal defenses in the event the administrative proceeding is restarted. In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, U.S.-listed companies and the market price of the ADSs and/or ordinary shares may be adversely affected.

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

Risks Related to Our American Depositary Shares and Ordinary Shares

*The trading prices of our ordinary shares and/or ADSs can be volatile, which could result in substantial losses to you.

The trading price of our ordinary shares and/or ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in the PRC that have listed their securities in Hong Kong or the United States may affect the volatility in the price of and trading volumes for our ordinary shares and/or ADSs. Some of these companies have experienced significant volatility. The trading performances of these PRC companies' securities may affect the overall investor sentiment towards other PRC companies listed in Hong Kong or the United States and consequently may impact the trading performance of our ordinary shares and/or ADSs.

In addition to market and industry factors, the price and trading volume for our ordinary shares and/or ADSs may be highly volatile for specific business reasons, including: announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process; announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors; adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities; any adverse changes to our relationship with manufacturers or suppliers; the results of our testing and clinical trials; the results of our efforts to acquire or license additional drug candidates; variations in the level of expenses related to our existing drugs and drug candidates or preclinical, clinical development and commercialization programs; any intellectual property infringement actions in which we may become involved; announcements concerning our competitors or the pharmaceutical industry in general; fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages; variations in our results of operations; announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations; publication of operating or industry metrics by third parties, including government statistical

agencies, that differ from expectations of industry or financial analysts; changes in financial estimates by securities research analysts; media reports, whether or not true, about our business; additions to or departures of our management; fluctuations of exchange rates between the RMB, the U.S. dollar and Hong Kong dollar; release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; sales or perceived potential sales of additional ordinary shares or ADSs by

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us, our executive officers and directors or our shareholders; general economic and market conditions and overall fluctuations in the U.S. or Hong Kong equity markets; changes in accounting principles; and changes or developments in the PRC or global regulatory environment.

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

*The characteristics of the U.S. capital markets and the Hong Kong capital markets are different.

The Nasdaq and The Stock Exchange of Hong Kong Limited have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our ordinary shares and the ADSs representing them might not be the same, even allowing for currency differences. Fluctuations in the price of our ADSs due to circumstances peculiar to its home capital market could materially and adversely affect the price of the ordinary shares. Because of the different characteristics of the U.S. and Hong Kong equity markets, the historic market prices of our ADSs may not be indicative of the performance of our securities (including the ordinary shares) after the Offering.

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

Companies that have experienced volatility in the volume and market price of their shares have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, and, if adversely determined, could have a material adverse effect on our business, financial condition and results of operations.

*Future sales of our ordinary shares and/or ADSs in the public market could cause the ordinary shares and/or ADS price to fall.

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

As of August 8, 2018, 767,163,184 ordinary shares, par value $0.0001 per share, were outstanding, of which 578,529,211 ordinary shares were held in the form of 44,502,247 American Depositary Shares, each representing 13 ordinary shares. Of this amount, 32,746,416 ordinary shares issued to Celgene are subject to a lock-up until September 1, 2018. We have also granted certain registration rights with respect to the shares issued to Celgene in the event that they are not eligible for sale under Rule 144.

In connection with the Offering, our directors and executive officers, certain trusts and parties affiliated with such directors and officers and certain holders of our shares have signed lock-up agreements. Upon completion of the Offering, assuming the underwriters do not exercise their option to purchase additional shares, approximately 81.7% of our outstanding ordinary shares immediately after the Offering will not be subject to lock-up agreements and sold to the public after the Offering from time to time.

We filed a registration statement with the SEC on behalf of certain shareholders, registering 299,279,370 ordinary shares in the form of 23,021,490 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. Furthermore, we have registered or plan to register the offer and sale of all securities that we have issued and may issue in the future under our equity compensation plans, including upon the exercise of share options and vesting of restricted share units. If these additional securities are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares and/or ADSs could decline.

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

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

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

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

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

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

*We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under Hong Kong law or U.S. law, shareholders may have fewer shareholder rights than they would have under Hong Kong law or U.S. law and may face difficulties in protecting your interests.

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our amended and restated memorandum and articles of association (as may be further amended from time to time), the Companies Law (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in Hong Kong and the United States. In particular, the Cayman Islands has a less developed body of securities law than Hong Kong or the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders of these companies with the exception that the shareholders may request a copy of the current amended and restated memorandum and articles of association. Our directors have discretion under our amended and restated articles of association to determine whether or

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not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest. As a Cayman Islands company, we may not have standing to initiate a derivative action in a Hong Kong or U.S. federal court. As a result, you may be limited in your ability to protect your interests if you are harmed in a manner that would otherwise enable you to sue in a United States federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in Hong Kong or U.S. federal courts.

Some of our directors and executive officers reside outside of Hong Kong and the United States and a substantial portion of their assets are located outside of Hong Kong and the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the Cayman Islands or in China in the event that you believe that your rights have been infringed under the securities laws of Hong Kong, the United States or otherwise. To the extent our directors and executive officers reside in China or their assets are located in China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if you are successful in bringing an action, the laws of the Cayman Islands and China may render you unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, Hong Kong or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

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

Your voting rights as a holder of the ADSs are limited by the terms of the deposit agreement. The depositary for the ADSs will give us a discretionary proxy to vote our ordinary shares underlying your ADSs if you do not vote at shareholders' meetings, except in limited circumstances, which could adversely affect your interests.

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

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

- we have failed to timely provide the depositary with our notice of meeting and related voting materials;
- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or

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

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The effect of this discretionary proxy is that, if you fail to give voting instructions to the depositary, you cannot prevent the ordinary shares underlying your ADSs from being voted, absent the situations described above, and it may make it more difficult for you to influence our management. Holders of our ordinary shares are not subject to this discretionary proxy.

*Anti-takeover provisions in our constitutional documents may discourage our acquisition by a third party, which could limit our shareholders' opportunity to sell their shares at a premium.

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

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

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

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

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

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

Fee-shifting articles are relatively new and untested in the Cayman Islands, the United States and Hong Kong. The case law and potential legislative action on fee-shifting articles are evolving and there exists considerable uncertainty

regarding the validity of, and potential judicial and legislative responses to, such articles. The application of our fee-shifting article in connection with claims under the Cayman Islands, the United States or Hong Kong securities laws, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting article in any particular dispute. Consistent with our directors' fiduciary duties to act in the best interests of the Company, the directors may in their sole discretion from time to time decide whether or not to enforce this article. In addition, given the unsettled state of the law related to fee-shifting articles, such as ours, we may incur significant

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additional costs associated with resolving disputes with respect to such articles, which could adversely affect our business and financial condition.

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

Holders of the ADSs may be subject to limitations on transfer of their ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, as amended, or for any other reason, subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares.

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

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

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

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

The depositary of the ADSs has agreed to pay you the cash dividends or other distributions it or the custodian for the ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares that your ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended, or the Securities Act, but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by

the depositary. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may materially reduce the value of your ADSs.

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

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

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

Our directors, executive officers and principal shareholders beneficially owned approximately 60.8% of our outstanding ordinary shares as of April 20, 2018. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and reducing the price of our ordinary shares and/or ADSs. These actions may be taken even if they are opposed by our other shareholders. In addition, these persons could divert business opportunities away from us to themselves or others.

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

A non-U.S. corporation will be classified as a “passive foreign investment company,” (or a “PFIC”) for any taxable year if either (1) 75% or more of its gross income consists of certain types of passive income or (2) 50% or more of the average quarterly value of its assets during such year produce or are held for the production of passive income. Based upon the current and expected composition of our income and assets, we do not presently expect to be a PFIC for the current taxable year. Nevertheless, because our PFIC status must be determined annually with respect to each taxable year and will depend on the composition and character of our assets and income, and the value of our assets (which may be determined, in part, by reference to the market value of our ADSs and ordinary shares, which may be volatile) over the course of such taxable year, we may be a PFIC in any taxable year. If we determine not to deploy significant amounts of cash for active purposes, our risk of being a PFIC may substantially increase. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for the current taxable year or any future taxable year. In addition, it is possible that the Internal Revenue Service may challenge our classification of certain income and assets as non-passive, which may result in our being or becoming a PFIC in the current or subsequent years. Further, U.S. investors should be aware that we determined we were a PFIC for 2016.

If we are a PFIC for any taxable year during a U.S. shareholder’s holding period of the ordinary shares or ADSs, then such U.S. shareholder may incur significantly increased United States income tax on gain recognized on the sale or other disposition of the ordinary shares or ADSs and on the receipt of distributions on the ordinary shares or ADSs to the extent such distribution is treated as an “excess distribution” under the United States federal income tax rules. In addition, such holders may be subject to burdensome reporting requirements.

Further, if we are classified as a PFIC for any year during which a U.S. shareholder holds our ordinary shares or ADSs, we will generally continue to be treated as a PFIC for all succeeding years during which such U.S. shareholder holds such ordinary shares or ADSs. Each U.S. shareholder should consult its tax advisor regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the ordinary shares and ADSs.

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*If you are a "Ten Percent Shareholder," you may be subject to adverse U.S. federal income tax consequences if we are classified as a Controlled Foreign Corporation.

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes is generally required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Each Ten Percent Shareholder is also required to include in gross income its "global intangible low-taxed income," which is determined by reference to the income of CFCs of which such Ten Percent Shareholder is a Ten Percent Shareholder. Ten Percent Shareholders that are corporations may be entitled to a deduction equal to the foreign portion of any dividend when a dividend is paid. A non-U.S. corporation will generally be classified as a CFC for U.S federal income tax purposes if Ten Percent Shareholders own in the aggregate, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a U.S. person (as defined by the Internal Revenue Code of 1986, as amended), who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote of such corporation or 10% of the value of all classes of stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. We may currently be a CFC and/or we may become one in the future. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

See the Exhibit Index below for a list of the exhibits filed as part of, or incorporated by reference into, this Quarterly Report, which Exhibit Index is incorporated herein by reference.

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EXHIBIT INDEX

Exhibit No.	Exhibit Description	Filed/Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.1†	Executive Employment Agreement, dated April 28, 2018, by and between BeiGene (Beijing) Co., Ltd. and Xiaobin Wu	X			
10.2†	BeiGene, Ltd. 2018 Employee Share Purchase Plan		8-K (Exhibit 10.1)	06/08/2018	001-37686
10.3†	BeiGene, Ltd. 2018 Inducement Equity Plan		8-K (Exhibit 10.2)	06/08/2018	001-37686
10.4†	Form of Non-Qualified Share Option Agreement under the BeiGene, Ltd. 2018 Inducement Equity Plan		8-K (Exhibit 10.3)	06/08/2018	001-37686
10.5†	Form of Restricted Share Unit Award Agreement under the BeiGene, Ltd. 2018 Inducement Equity Plan	X			
10.6†	BeiGene, Ltd. Independent Director Compensation Policy, as amended		8-K (Exhibit 10.5)	06/08/2018	001-37686
10.7†	Forms of Restricted Share Unit Award Agreement and Share Option Agreement under the BeiGene, Ltd. 2016 Share Option and Incentive Plan	X			
10.8†	Consulting Agreement, dated July 24, 2018, by and between the Registrant and Xiaodong Wang	X			
31.1	Certification of Principal Executive Officer Required Under Rule 13a 14(a) and 15d 14(a) of the Securities Exchange Act of 1934, as amended	X			
31.2	Certification of Principal Financial Officer Required Under Rule 13a 14(a) and 15d 14(a) of the Securities Exchange Act of 1934, as amended	X			

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Exhibit No.	Exhibit Description	Filed/Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a 14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Loss; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to the Condensed Consolidated Financial Statements	X			

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

*Furnished herewith.

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SIGNATURES

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

BEIGENE, LTD.

Date: August 9, 2018 By: /s/ John V. Oyler
John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: August 9, 2018 By: /s/ Howard Liang
Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)