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 March 31, 2020

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 Governance 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

As of April 30, 2020, 1,008,198,947 ordinary shares, par value $0.0001 per share, were outstanding, of which 850,615,805 ordinary shares were held in the form of 65,431,985 American Depositary Shares, each representing 13 ordinary shares.

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 every Interactive Data File required to be submitted 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 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	☐	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 ☒

BeiGene, Ltd.

Quarterly Report on Form 10-Q

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 March 31, 2020 $ (unaudited)	As of December 31, 2019 $ (audited)
Assets			
Current assets:			
Cash and cash equivalents		1,957,101	618,011
Short-term restricted cash	4	282	288
Short-term investments	4	1,417,097	364,728
Accounts receivable, net	10	65,620	70,878
Inventories	5	28,775	28,553
Prepaid expenses and other current assets	10	126,312	90,238
Total current assets		3,595,187	1,172,696
Long-term restricted cash	4	2,435	2,476
Property, plant and equipment, net	6	240,331	242,402
Operating lease right-of-use assets		91,509	82,520
Intangible assets, net	8	5,563	5,846
Deferred tax assets	9	37,937	37,894
Other non-current assets	10	94,250	68,455
Total non-current assets		472,025	439,593
Total assets		4,067,212	1,612,289
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		98,364	122,488
Accrued expenses and other payables	10	179,331	163,556
Tax payable	9	19,535	13,454
Operating lease liabilities, current portion		14,597	10,814
Research and development cost share liability, current portion	3	128,672	—
Short-term bank loan	11	11,298	—
Total current liabilities		451,797	310,312
Non-current liabilities:			
Long-term bank loan	11	81,913	83,311
Shareholder loan	12	157,278	157,384
Operating lease liabilities, non-current portion		32,967	25,833
Deferred tax liabilities		10,368	10,532
Research and development cost share liability, non-current portion	3	460,528	—
Other long-term liabilities	10	45,305	46,562
Total non-current liabilities		788,359	323,622
Total liabilities		1,240,156	633,934
Commitments and contingencies	19		
Equity:			
Ordinary shares, US$0.0001 par value per share; 9,500,000,000 shares authorized; 1,007,976,816 and 801,340,698 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively		101	79
Additional paid-in capital		5,138,239	2,925,970
Accumulated other comprehensive loss	16	(6,548)	(8,001)
Accumulated deficit		(2,319,578)	(1,955,843)
Total BeiGene, Ltd. shareholders' equity		2,812,214	962,205
Noncontrolling interest		14,842	16,150
Total equity		2,827,056	978,355
Total liabilities and equity		4,067,212	1,612,289

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 March 31, 2020	Three Months Ended March 31, 2019
		$	$
Revenues			
Product revenue, net	13	52,059	57,421
Collaboration revenue	3	—	20,412
Total revenues		52,059	77,833
Expenses			
Cost of sales - product		14,149	15,261
Research and development		304,302	178,351
Selling, general and administrative		107,081	57,645
Amortization of intangible assets		283	331
Total expenses		425,815	251,588
Loss from operations		(373,756)	(173,755)
Interest income, net		6,690	4,477
Other income, net		3,681	1,728
Loss before income taxes		(363,385)	(167,550)
Income tax expense	9	1,554	519
Net loss		(364,939)	(168,069)
Less: net loss attributable to noncontrolling interests		(1,204)	(429)
Net loss attributable to BeiGene, Ltd.		(363,735)	(167,640)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	14	(0.36)	(0.22)
Weighted-average shares outstanding, basic and diluted	14	1,005,347,581	774,750,255
Net loss per American Depositary Share ("ADS"), basic and diluted		(4.70)	(2.81)
Weighted-average ADSs outstanding, basic and diluted		77,334,429	59,596,173

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

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 March 31,	
	2020	2019
	$	$
Net loss	(364,939)	(168,069)
Other comprehensive (loss)/ income, net of tax of nil:		
Foreign currency translation adjustments	(4,349)	3,755
Unrealized holding gain, net	5,698	685
Comprehensive loss	(363,590)	(163,629)
Less: comprehensive loss attributable to noncontrolling interests	(1,308)	(535)
Comprehensive loss attributable to BeiGene, Ltd.	(362,282)	(163,094)

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

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	Three months ended March 31, 2020	2019
		$	$
Operating activities:			
Net loss		(364,939)	(168,069)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		7,750	3,416
Share-based compensation expenses	15	38,255	26,392
Provision for doubtful accounts		2,022	—
Unrealized gain on equity securities	4	(6,964)	—
Acquired in-process research and development		43,000	29,000
Amortization of research and development cost share liability		(27,634)	—
Non-cash interest expense		2,572	1,858
Deferred income tax benefits		(206)	(983)
Other items, net		(1,105)	(3,218)
Changes in operating assets and liabilities:			
Accounts receivable		3,236	(17,920)
Inventories		(222)	3,102
Prepaid expenses and other current assets		(36,075)	(5,772)
Operating lease right-of-use assets		(8,990)	(1,588)
Other non-current assets		(2,710)	(10,212)
Accounts payable		(21,450)	(20,364)
Accrued expenses and other payables		15,775	(8,790)
Tax payable		6,080	969
Deferred revenue		—	(2,238)
Operating lease liabilities		10,917	1,550
Other long-term liabilities		(1,256)	892
Net cash used in operating activities		(341,944)	(171,975)
Investing activities:			
Purchases of property, plant and equipment		(21,533)	(21,828)
Purchases of investments		(1,307,179)	(487,354)
Proceeds from sale or maturity of investments		256,743	710,598
Purchase of in-process research and development		(43,000)	(29,000)
Net cash (used in) provided by investing activities		(1,114,969)	172,416
Financing activities:			
Proceeds from sale of ordinary shares, net of cost		2,162,407	—
Proceeds from research and development cost share liability		616,834	—
Proceeds from long-term bank loan	11	—	36,695
Proceeds from short-term bank loan	11	11,298	—
Proceeds from option exercises and employee share purchase plan		11,629	6,269
Net cash provided by financing activities		2,802,168	42,964
Effect of foreign exchange rate changes, net		(6,212)	4,265
Net increase in cash, cash equivalents, and restricted cash		1,339,043	47,670
Cash, cash equivalents, and restricted cash at beginning of period		620,775	740,713
Cash, cash equivalents, and restricted cash at end of period		1,959,818	788,383
Supplemental cash flow information:			
Cash and cash equivalents		1,957,101	764,492
Short-term restricted cash		282	14,900
Long-term restricted cash		2,435	8,991
Income taxes paid		531	360
Interest paid		1,136	888
Supplemental non-cash information:			
Acquisitions of equipment included in accounts payable		26,412	32,462

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

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

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

(Unaudited)

	Attributable to BeiGene, Ltd.							
	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total	Noncontrolling Interests	Total
	Shares	Amount						
		$	$	$	$	$	$	$
Balance at December 31, 2019	801,340,698	79	2,925,970	(8,001)	(1,955,843)	962,205	16,150	978,355
Issuance of ordinary shares in connection with collaboration	206,635,013	21	2,162,386	—	—	2,162,407	—	2,162,407
Use of shares reserved for share option exercises	(3,705,468)	—	—	—	—	—	—	—
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	3,706,573	1	11,628	—	—	11,629	—	11,629
Share-based compensation	—	—	38,255	—	—	38,255	—	38,255
Other comprehensive income	—	—	—	1,453	—	1,453	(104)	1,349
Net loss	—	—	—	—	(363,735)	(363,735)	(1,204)	(364,939)
Balance at March 31, 2020	1,007,976,816	101	5,138,239	(6,548)	(2,319,578)	2,812,214	14,842	2,827,056
Balance at December 31, 2018	776,263,184	77	2,744,814	1,526	(1,007,215)	1,739,202	14,445	1,753,647
Use of shares reserved for share option exercises	(916,383)	—	—	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	2,066,383	1	6,268			6,269		6,269
Share-based compensation	—	—	26,392	—	—	26,392	—	26,392
Other comprehensive income	—	—	—	4,546	—	4,546	(106)	4,440
Net loss	—	—	—	—	(167,640)	(167,640)	(429)	(168,069)
Balance at March 31, 2019	777,413,184	78	2,777,474	6,072	(1,174,855)	1,608,769	13,910	1,622,679

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

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 global, commercial-stage biotechnology company focused on discovering, developing, manufacturing and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. The Company started as a research and development company in Beijing in 2010. Over the last ten years, it has developed into a fully-integrated global biotechnology company, with significant commercial, manufacturing, and research and development capabilities.

The Company has built substantial commercial capabilities in China and the United States and is currently marketing both internally-developed drugs and in-licensed drugs. In the United States, the Company markets BRUKINSA™ (zanubrutinib) for adult patients with mantle cell lymphoma ("MCL") who have received at least one prior therapy. In China, the Company markets tislelizumab for patients with classical Hodgkin’s Lymphoma ("cHL") who have received at least two prior therapies and for patients with locally advanced or metastatic urothelial carcinoma ("UC"), a form of bladder cancer, with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. As of May 1, 2020, the Company has filed three additional new or supplementary new drug applications ("sNDA") for regulatory approvals in China for its internally-developed products and is planning for launches in these additional products or indications in 2020 and beyond. The Company's in-licensed portfolio includes ABRAXANE®, REVLIMID® and VIDAZA®, which it has been marketing in China since 2017 under a license from Celgene Logistics Sàrl, a Bristol Myers Squibb (“BMS”) company. The Company plans on launching additional in-licensed products in China from its collaborations, including XGEVA® (denosumab), KYPROLIS® (carfilzomib) and BLINCYTO® (blinatumomab) from Amgen Inc. ("Amgen"), and SYLVANT® (siltuximab) and QARZIBA® ▼ (dinutuximab beta), from EUSA Pharma ("EUSA").

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of March 31, 2020, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2019, the condensed consolidated statements of cash flows for the three months ended March 31, 2020 and 2019, and the condensed consolidated statements of shareholders' equity for the three months ended March 31, 2020 and 2019, 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, 2019 (the "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 months ended March 31, 2020 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 its interests in its joint venture, BeiGene Biologics Co., Ltd. ("BeiGene Biologics") and MapKure, LLC, under the voting model and recognizes the minority shareholders' equity interest as a noncontrolling interest in its condensed consolidated financial statements.

Use of estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating variable consideration in product sales and collaboration revenue arrangements, identifying separate accounting units and the standalone selling price of each performance obligation in the Company's revenue arrangements, estimating the fair value of net assets acquired in business combinations, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets, estimating uncertain tax positions, measurement of right-of-use assets and lease liabilities 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 June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses*. Subsequently, the FASB issued ASU 2019-05, *Financial Instruments- Credit Losses (Topic 326): Targeted Transition Relief* and *ASU 2019-11 Codification Improvements to Topic 326, Financial Instruments-Credit Losses* (collectively, the "Credit Loss ASUs"). The Credit Loss ASUs change the methodology to be used to measure credit losses for certain financial instruments and financial assets, including trade receivables. The new methodology requires the recognition of an allowance that reflects the current estimate of credit losses expected to be incurred over the life of the financial asset. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The Company adopted the standard on January 1, 2020. Based on the composition of the Company's trade receivables and investment portfolio, the adoption of this standard did not have a material impact on the Company's financial position or results of operations upon adoption. The Company has updated its accounting policy for trade accounts receivable and is providing additional disclosure about its allowance for credit losses, as required by the standard, upon adoption.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurement*. The update eliminates, modifies, and adds certain disclosure requirements for fair value measurements. The added disclosure requirements and the modified disclosure on the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented. All other changes to disclosure requirements in this update should be applied retrospectively to all periods presented upon their effective date. The Company adopted this standard on January 1, 2020. There was no material impact to the Company's financial position or results of operations upon adoption.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This update requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to defer and recognize as an asset. This guidance should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted this standard on January 1, 2020. There was no material impact to the Company's financial position or results of operations upon adoption.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance should be applied retrospectively to the date of initial application of Topic 606. The Company adopted this standard on January 1, 2020. There was no material impact to the Company's financial position or results of operations upon adoption.

New accounting standards which have not yet been adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, *Income taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on

income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, and all other amendments should be applied prospectively. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the condensed 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, 2019.

Accounts Receivable and Allowance for Credit Losses

Trade accounts receivable are recorded at their invoiced amounts, net of trade discounts and allowances as well as an allowance for credit losses. The allowance for credit losses reflects the Company's current estimate of credit losses expected to be incurred over the life of the receivables. The Company considers various factors in establishing, monitoring, and adjusting its allowance for credit losses including the aging of receivables and aging trends, customer creditworthiness and specific exposures related to particular customers. The Company also monitors other risk factors and forward-looking information, such as country specific risks and economic factors that may affect a customer's ability to pay in establishing and adjusting its allowance for credit losses. Accounts receivable are written off after all collection efforts have ceased.

Except for the changes to the Company's significant accounting policies related to the adoption of the Credit Loss ASUs, there have been no other material changes to the Company's significant accounting policies as of and for the three months ended March 31, 2020, 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.

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 March 31, 2020 and December 31, 2019:

As of March 31, 2020	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Short-term investments (Note 4):			
U.S. treasury securities	1,417,097	—	—
Cash equivalents:			
U.S. treasury securities	251,505	—	—
Money market funds	1,144,458	—	—
Other non-current assets:			
Equity securities (Note 4)	7,592	4,372	—
Total	2,820,652	4,372	—

As of December 31, 2019	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Short-term investments (Note 4):			
U.S. treasury securities	364,728	—	—
Cash equivalents			
U.S. treasury securities	16,442	—	—
Money market funds	50,461	—	—
Total	431,631	—	—

The Company's equity securities consist of holdings in common stock and warrants to purchase additional shares of common stock of Leap Therapeutics, Inc. ("Leap"), which were acquired in connection with a strategic collaboration and license agreement entered into in January 2020. The common stock investment in Leap, a publicly-traded biotechnology company, is measured and carried at fair value and classified as Level 1. The warrants to purchase additional shares of common stock in Leap are classified as a Level 2 investment and are measured using the Black-Scholes option-pricing valuation model, which utilizes a constant maturity risk-free rate and reflects the term of the warrants, dividend yield and stock price volatility, that is based on the historical volatility of similar companies.

The Company had no liabilities measured and recorded at fair value on a recurring basis as of March 31, 2020 or December 31, 2019.

3. Collaborative Arrangements

The Company enters into collaborative arrangements for the research and development, manufacture and/or commercialization of drug products and drug candidates. To date, these collaborative arrangements have included out-licenses of internally-developed drug candidates to other parties, in-licenses of drug products and drug candidates from other parties, and profit and cost sharing arrangements.

Amgen

On October 31, 2019, the Company entered into a global strategic oncology collaboration with Amgen (the "Amgen Collaboration Agreement") for the commercialization and development in China, excluding Hong Kong, Taiwan and Macao, of Amgen's XGEVA, KYPROLIS, and BLINCYTO, and the joint global development of a portfolio of oncology assets in

Amgen’s pipeline, with BeiGene responsible for development and commercialization in China. On January 2, 2020, following approval by the Company's shareholders and satisfaction of other closing conditions, the agreement became effective.

Under the agreement, the Company is responsible for the commercialization of XGEVA, KYPROLIS and BLINCYTO in China for five or seven years. Amgen is responsible for manufacturing of the products globally and will supply the products to the Company at an agreed upon price. The Company and Amgen will share equally in the China commercial profits and losses during the commercialization period. Following the commercialization period, the Company has the right to retain one product and is entitled to receive royalties on sales in China for an additional five years on the products not retained. XGEVA was approved in China in 2019 for patients with giant cell tumor of the bone and a supplemental new drug application has been filed for prevention of skeletal-related events in cancer patients with bone metastases. Additionally, new drug applications have been filed in China for KYPROLIS as a treatment for patients with multiple myeloma and BLINCYTO a as a treatment for adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL).

Amgen and the Company are also jointly developing a portfolio of Amgen oncology pipeline assets under the collaboration. In April 2020, two Amgen oncology pipeline assets were removed from the collaboration due to portfolio prioritization, and the parties expect that the development plan for the assets in the portfolio will continue to evolve over time. The Company is responsible for conducting clinical development activities in China and co-funding global development costs by contributing cash and development services up to a total cap of $1,250,000. Amgen is responsible for all development, regulatory and commercial activities outside of China. For each pipeline asset that is approved in China, the Company will receive commercial rights for seven years from approval. The Company has the right to retain approximately one out of every three approved pipeline assets, other than AMG 510, for commercialization in China. The Company and Amgen will share equally in the China commercial profits and losses during the commercialization period. The Company is entitled to receive royalties from sales in China for pipeline assets returned to Amgen for five years after the seven-year commercialization period. The Company is also entitled to receive royalties from global sales of each product outside of China (with the exception of AMG 510).

The Amgen Collaboration Agreement is within the scope of ASC 808, as both parties are active participants and are exposed to the risks and rewards dependent on the commercial success of the activities performed under the agreement. The Company is the principal for product sales to customers in China during the commercialization period and will recognize 100% of net product revenue on these sales. Amounts due to Amgen for its portion of net product sales will be recorded as cost of sales. Cost reimbursements due to or from Amgen under the profit share will be recognized as incurred and recorded to cost of sales; selling, general and administrative expense; or research and development expense, based on the underlying nature of the related activity subject to reimbursement. Costs incurred for the Company's portion of the global co-development funding are recorded to research and development expense as incurred.

In connection with the collaboration, a Share Purchase Agreement ("SPA") was entered into by the parties on October 31, 2019. On January 2, 2020, the closing date of the transaction, Amgen purchased 15,895,001 of the Company's ADSs for $174.85 per ADS, representing a 20.5% ownership stake in the Company. Per the SPA, the cash proceeds shall be used as necessary to fund the Company's development obligations under the Amgen Collaboration Agreement. Pursuant to the SPA, Amgen also received the right to designate one member of the Company's board of directors.

In determining the fair value of the common stock at closing, the Company considered the closing price of the common stock on the closing date of the transaction and included a lack of marketability discount because the shares are subject to certain restrictions. The fair value of the shares on the closing date was determined to be $132.74 per ADS, or $2,109,902 in the aggregate. The Company determined that the premium paid by Amgen on the share purchase represents a cost share liability due to the Company's co-development obligations. The fair value of the cost share liability on the closing date was determined to be $601,857 based on the Company's discounted estimated future cash flows related to the pipeline assets. The total cash proceeds of $2,779,241 were allocated based on the relative fair value method, with $2,162,407 recorded to equity and $616,834 recorded as a research and development cost share liability. The cost share liability is being amortized proportionately as the Company contributes cash and development services to its total co-development funding cap.

Amounts recorded related to the cash proceeds received from the Amgen collaboration for the three months ended March 31, 2020 were as follows:

	Three Months Ended March 31, 2020
	$
Fair value of equity issued to Amgen	2,162,407
Fair value of research and development cost share liability	616,834
Total cash proceeds	2,779,241

Amounts recorded related to the Company's portion of the co-development funding on the pipeline assets for the three months ended March 31, 2020 were as follows:

	Three Months Ended March 31, 2020
	$
Research and development expense	28,366
Amortization of research and development cost share liability	27,634
Total amount due to Amgen for BeiGene's portion of the development funding	56,000
Total amount of development funding payable in cash	56,000
Total amount of development funding paid with development services	—
Remaining portion of development funding cap at March 31, 2020	1,194,000

At March 31, 2020, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of March 31, 2020
	$
Research and development cost share liability, current portion	128,672
Research and development cost share liability, non-current portion	460,528
Total research and development cost share liability	589,200

There were no product sales or commercial profit share payments related to the Amgen collaboration during the three months ended March 31, 2020.

Celgene Corporation, a Bristol Myers Squibb company ("BMS")

On July 5, 2017, the Company entered into a license agreement with Celgene Corporation, now BMS, pursuant to which the Company granted to the BMS parties an exclusive right to develop and commercialize the Company’s investigational PD-1 inhibitor, tislelizumab, 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”). The Company entered into a mutual agreement with BMS to terminate the Amended and Restated PD-1 License Agreement effective June 14, 2019 in advance of the acquisition of Celgene by BMS.

The following table summarizes total collaboration revenue recognized related to the BMS collaboration for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
	$	$
Reimbursement of research and development costs	—	18,174
Research and development service revenue	—	2,238
Total	—	20,412

For the three months ended March 31, 2019, the Company recognized collaboration revenue of $20,412 related to its former collaboration with BMS. The Company recognized $18,174 of research and development reimbursement revenue for the three months ended March 31, 2019 for the clinical trials that Celgene had opted into. The $2,238 of research and development services revenue for the three months ended March 31, 2019, reflected the recognition of upfront consideration that was allocated to research and development services at the time of the collaboration and was recognized over the term of the respective clinical studies for the specified indications.

In-Licensing Arrangements

The Company has in-licensed the rights to develop, manufacture and, if approved, commercialize multiple development stage drug candidates and drug products globally or in specific territories. These arrangements typically include non-refundable, upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost sharing arrangements, royalty payments, and profit sharing.

Upfront and development milestones paid under these arrangements for the three months ended March 31, 2020 and 2019 are set forth below. All upfront and development milestones were expensed to research and development expense. There have been no regulatory or commercial milestones paid under these arrangements to date.

	Three Months Ended March 31,	
	2020	2019
Research and development payments to Collaboration Partners	$	$
Upfront payments	43,000	10,000
Milestone payments	5,000	—
Total	48,000	10,000

EUSA Pharma

On January 13, 2020, the Company entered into an exclusive development and commercialization agreement with EUSA Pharma ("EUSA") for the orphan biologic products SYLVANT® (siltuximab) and QARZIBA® (dinutuximab beta) in China. Under the terms of the agreement, EUSA granted the Company exclusive rights to SYLVANT in greater China and to QARZIBA in mainland China. Under the agreement, the Company will fund and undertake all clinical development and regulatory submissions in the territories, and will commercialize both products once approved. EUSA received a $40,000 upfront payment and will be eligible to receive payments upon the achievement of regulatory and commercial milestones up to a total of $160,000. EUSA will also be eligible to receive tiered royalties on future product sales. The upfront payment was expensed to research and development expense during the three months ended March 31, 2020 in accordance with the Company's acquired in-process research and development expense policy.

Other

In addition to the collaborations discussed above, the Company has entered into additional collaborative arrangements during the three months ended March 31, 2020 and 2019. The Company may be required to pay additional amounts upon the achievement of various development, regulatory and commercial milestones under these agreements. The Company may also incur significant research and development costs if the related product candidates advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay milestones and royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

4. Restricted Cash and Investments

Restricted Cash

The Company's restricted cash balance of $2,717 as of March 31, 2020 primarily consists of RMB-denominated cash deposits held in designated bank accounts for collateral for letters of credit. The Company classifies restricted cash as current or non-current based on the term of the restriction.

Short-Term Investments

Short-term investments as of March 31, 2020 consisted of the following available-for-sale debt securities:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
	$	$	$	$
U.S. treasury securities	1,410,129	6,968	—	1,417,097
Total	1,410,129	6,968	—	1,417,097

Short-term investments as of December 31, 2019 consisted of the following available-for-sale debt securities:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
	$	$	$	$
U.S. treasury securities	363,440	1,288	—	364,728
Total	363,440	1,288	—	364,728

As of March 31, 2020, the Company's available-for-sale debt securities consisted entirely of short-term U.S. treasury securities, which were determined to have zero risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of March 31, 2020.

Equity Method Investment

In January 2020, the Company purchased $5,000 of Series B mandatorily convertible, non-voting preferred stock of Leap in connection with a strategic collaboration and license agreement the Company entered into with Leap. The Series B shares were subsequently converted into shares of Leap common stock and warrants to purchase additional shares of common stock upon approval of Leap's shareholders in March 2020. Upon conversion, the Company's ownership interest in the outstanding common stock of Leap is 13.4%. Inclusive of the shares of common stock issuable upon the exercise of the currently exercisable warrants, the Company's interest is approximately 23.7%. The Company determined that it has the ability to exercise significant influence over the operating and financial policies of Leap based on our ownership percentage and collaborative relationship, and the investment represents an equity method investment upon conversion. The Company elected to apply the fair value option to the equity method investment, and measure the investment in the common stock and warrants at fair value, with changes in fair value recorded to other income. The fair value of the common stock and warrants was $7,592 and $4,372, respectively, as of March 31, 2020. During the three months ended March 31, 2020, the Company recorded an unrealized gain of $6,964 in the statement of operations.

5. Inventories

The Company's inventory balance consisted of the following:

	As of	
	March 31, 2020	December 31, 2019
	$	$
Work in process	444	—
Finished goods	28,331	28,553
Total inventories	28,775	28,553

6. Property, plant and equipment

Property, plant and equipment are recorded at cost and consisted of the following:

	As of	
	March 31, 2020	December 31, 2019
	$	$
Laboratory equipment	49,059	47,154
Leasehold improvements	23,866	24,008
Building	107,992	109,514
Manufacturing equipment	65,123	62,775
Software, electronics and office equipment	14,688	14,705
Property, plant and equipment, at cost	260,728	258,156
Less accumulated depreciation	(43,375)	(36,709)
Construction in progress	22,978	20,955
Property, plant and equipment, net	240,331	242,402

As of March 31, 2020 and December 31, 2019, construction in progress ("CIP") of $22,978 and $20,955, respectively, was primarily related to the buildout of additional capacity at the Guangzhou manufacturing facility. Subsequent phases of the Guangzhou factory buildout will continue to be recorded as CIP until they are placed into service.

Depreciation expense for the three months ended March 31, 2020 and 2019 was $7,467 and $3,085, respectively.

7. Guangzhou Biologics Business

Manufacturing legal entity structure

BeiGene (Shanghai) Co., Ltd. ("BeiGene Shanghai"), originally established as a wholly-owned subsidiary of BeiGene (Hong Kong) Co., Limited ("BeiGene HK"), and currently a wholly-owned subsidiary of BeiGene Biologics, as described below, provides clinical development services for BeiGene affiliates and is the clinical trial authorization ("CTA") holder and marketing authorization application ("MAA") holder for tislelizumab in China.

In March 2017, BeiGene HK, a wholly-owned subsidiary of the Company, and Guangzhou GET Technology Development Co., Ltd. (now Guangzhou High-tech Zone Technology Holding Group Co., Ltd.) (“GET”) entered into a definitive agreement to establish a commercial-scale biologics manufacturing facility in Guangzhou, Guangdong Province, PRC.

In March 2017, BeiGene HK and GET entered into an Equity Joint Venture Contract (the “JV Agreement”). Under the terms of the JV Agreement, BeiGene HK made an initial cash capital contribution of RMB200,000 and a subsequent contribution of one or more biologics assets in exchange for a 95% equity interest in BeiGene Biologics. GET made a cash capital contribution of RMB100,000 to BeiGene Biologics, representing a 5% equity interest in BeiGene Biologics. In addition, on March 7, 2017, BeiGene Biologics entered into a contract with GET, under which GET agreed to provide a RMB900,000 loan (the “Shareholder Loan”) to BeiGene Biologics (see Note 12). In September 2019, BeiGene Biologics completed the first phase of construction of a biologics manufacturing facility in Guangzhou, through a wholly-owned subsidiary, BeiGene Guangzhou Biologics Manufacturing Co., Ltd. ("BeiGene Guangzhou Factory"), to manufacture biologics for the Company and its subsidiaries.

In April 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. In the second quarter of 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 was paid in June 2019. In April 2017, GET made cash capital contributions of RMB100,000 into BeiGene Biologics, and BeiGene Biologics drew down the Shareholder Loan of RMB900,000 from GET (as further described in Note 12).

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 to BeiGene Biologics, as required by the JV agreement, such that the CTA holder and MAA holder for tislelizumab in China was controlled by 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 the PRC. Upon the transfer of equity in BeiGene Shanghai, BeiGene HK's equity interest in BeiGene Shanghai became 95%. As of March 31, 2020, the Company and GET held 95% and 5% equity interests in BeiGene Biologics, respectively.

As of March 31, 2020, the Company had $83,126 of cash and cash equivalents and $1,961 of restricted cash held by BeiGene Biologics to be used to build the commercial-scale biologics facility and to fund research and development of the Company's biologics drug candidates in China.

Commercial distribution legal entity structure

BeiGene (Guangzhou) Co., Ltd. ("BGC"), a wholly-owned subsidiary of BeiGene HK, was organized on July 11, 2017. In September 2018, BGC acquired 100% of the equity interests of Baiji Shenzhou (Guangzhou) Pharmaceuticals Co., Ltd. (formerly known as Huajian Pharmaceuticals Co., Ltd.), which subsequently changed its name to BeiGene Pharmaceuticals (Guangzhou) Co., Ltd. ("BPG"). BPG owns drug distribution licenses necessary to distribute pharmaceutical products in China. The Company acquired these drug distribution licenses through the acquisition of BPG, which was accounted for as an asset acquisition, as it is difficult to obtain a newly issued domestic drug distribution license in China.

Commercial supply agreement and facility expansion

In January 2018, the Company entered into a commercial supply agreement with Boehringer Ingelheim Biopharmaceuticals (China) Ltd. ("Boehringer Ingelheim") for tislelizumab, which is being manufactured at Boehringer Ingelheim's facility in Shanghai, China as part of a Marketing Authorization Holder ("MAH") project pioneered by the Company and Boehringer Ingelheim. Under the terms of the commercial supply agreement, Boehringer Ingelheim has agreed to manufacture tislelizumab in China under an exclusive multi-year arrangement, with contract extension possible. In addition, the Company obtained certain preferred rights for future capacity expansion by Boehringer Ingelheim in China.

In October 2018, the Company entered into a binding letter of intent ("LOI") with Boehringer Ingelheim to increase the amount of tislelizumab supplied under the agreement through the expansion of Boehringer Ingelheim's facility to add a second bioreactor production line. Under the terms of the binding LOI, the Company provided initial funding for the facility expansion and may make additional payments for contingency costs. This initial funding payment and any subsequent contingency payments will be credited against future purchases of tislelizumab over the term of the supply agreement.

The payment was recorded as a noncurrent asset since it is considered a long-term prepayment for future product costs that will provide future benefit to the Company through credits on purchases of tislelizumab from Boehringer Ingelheim over the life of the supply agreement.

8. Intangible Assets

Intangible assets as of March 31, 2020 and December 31, 2019 are summarized as follows:

	As of					
	March 31, 2020			December 31, 2019		
	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	(1,937)	5,563	7,500	(1,750)	5,750
Trading license	816	(816)	—	816	(720)	96
Total finite-lived intangible assets	8,316	(2,753)	5,563	8,316	(2,470)	5,846

Product distribution rights consist of distribution rights on the approved cancer therapies licensed from BMS, ABRAXANE, REVLIMID, and VIDAZA acquired as part of the BMS transaction in 2017. The Company is amortizing the product distribution rights over a period of 10 years which is the term of the agreement. The trading license represents the Guangzhou drug distribution license acquired on September 21, 2018. The Company amortized the drug distribution trading license over the remainder of the initial license term through February 2020.

Amortization expense of intangible assets for the three months ended March 31, 2020 and 2019 was $283 and $331, respectively.

As of March 31, 2020, expected amortization expense for the unamortized finite-lived intangible assets is approximately $563 for the remainder of 2020, $750 in 2021, $750 in 2022, $750 in 2023, $750 in 2024, and $2,000 in 2025 and thereafter.

9. Income Taxes

Income tax expense was $1,554 and $519, respectively, for the three months ended March 31, 2020 and 2019. The income tax expense for the three months ended March 31, 2020 was primarily attributable to income reported in certain China subsidiaries as adjusted for certain non-deductible expenses offset by the tax benefit of deferred U.S. stock-based compensation deductions. The resulting current U.S. tax was reduced by windfall stock compensation deductions, research and development tax credits and other special tax deductions. The income tax expense for the three months ended March 31, 2019 was primarily attributable to income reported in the U.S. and certain China subsidiaries offset by U.S. research and development tax credits and other special tax deductions.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law on March 27, 2020. The CARES Act removes certain net operating loss deduction and carry-back limitations originally imposed by the Tax Cuts and Jobs Act of 2017. Specifically, the Company may now carry back net operating losses (NOLs) originating in 2018 and 2019 to 2017 and 2016, resulting in an increase to the Company's income tax receivable of $5,586 as of March 31, 2020. The enactment of the CARES Act did not have a material effect on our income tax expense.

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 March 31, 2020, it is more likely than not that deferred tax assets will not be realized for the Company’s subsidiaries in Australia and Switzerland, for certain subsidiaries in China, and for all U.S. tax credit carry-forwards.

As of March 31, 2020, the Company had gross unrecognized tax benefits of $5,003. 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 $369 in the three months ended March 31, 2020 primarily due 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 March 31, 2020 and December 31, 2019, 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, is required to file income tax returns in multiple jurisdictions globally. As of March 31, 2020, Australia tax matters are open to examination for the years 2013 through 2020, China tax matters are open to examination for the years 2014 through 2020, Switzerland tax matters are open to examination for the years 2017 through 2020, and U.S. federal tax matters are open to examination for years 2015 through 2020. Various U.S. states and other non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2010 through 2020.

10. Supplemental Balance Sheet Information

The roll-forward of the allowance for credit losses related to trade accounts receivable for the three months ended March 31, 2020 consists of the following activity:

	Allowance for Credit Losses
	$
Balance as of December 31, 2019	—
Current period provision for expected credit losses	2,022
Amounts written-off	—
Recoveries of amounts previously written-off	—
Balance as of March 31, 2020	2,022

Prepaid expenses and other current assets consist of the following:

	As of	
	March 31, 2020	December 31, 2019
	$	$
Prepaid research and development costs	75,867	69,715
Prepaid taxes	17,392	9,498
Other receivables	6,414	—
Interest receivable	5,941	1,932
Prepaid insurance	4,298	—
Prepaid manufacturing costs	3,525	—
Other	12,875	9,093
Total	126,312	90,238

Other non-current assets consist of the following:

	As of	
	March 31, 2020	December 31, 2019
	$	$
Goodwill	109	109
Prepayment of property and equipment	20,421	10,289
Prepayment of facility capacity expansion activities (1)	25,963	24,881
Prepaid VAT	32,396	29,967
Rental deposits and other	3,397	3,209
Long-term investment (Note 4)	11,964	—
Total	94,250	68,455

(1) Represents payments for facility expansions under commercial supply agreements. The payments will provide future benefit to the Company through credits on future supply purchases as further described in Note 7.

Accrued expenses and other payables consist of the following:

	As of	
	March 31, 2020	December 31, 2019
	$	$
Compensation related	27,272	54,156
External research and development activities related	53,428	62,794
Development funding payable- Amgen	56,000	—
Commercial activities	18,522	25,645
Income tax and other taxes	11,944	9,648
Sales rebates and returns related	4,014	3,198
Professional fees and other	8,151	8,115
Total	179,331	163,556

Other long-term liabilities consist of the following:

	As of	
	March 31, 2020	December 31, 2019
	$	$
Deferred government grant income	45,134	46,391
Other	171	171
Total	45,305	46,562

11. Bank Loans

On April 4, 2018, BeiGene Guangzhou Factory entered into a nine-year loan agreement with China Construction Bank to borrow an RMB denominated loan of RMB580,000 at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan is secured by BeiGene Guangzhou Factory's land use right. Interest expense is paid quarterly until the loan is fully settled. As of March 31, 2020, the Company has fully drawn down $81,913 (RMB580,000) of the loan. The loan interest rate was 4.9% for the three months ended March 31, 2020, and the maturity dates range from 2021 to 2027.

On January 13, 2020, BeiGene Shanghai entered into a one-year loan agreement with China Industrial Bank to borrow up to RMB200,000 at a fixed interest rate of 5.6%. On January 19, 2020, the Company borrowed RMB80,000 of the loan. Interest will be paid quarterly until the loan becomes fully due on January 18, 2021. As of March 31, 2020 the amount outstanding under the loan agreement was $11,298.

Interest expense recognized for the three months ended March 31, 2020 and 2019 was $1,719 and $941, respectively, among which, $66 and $641 was capitalized, respectively.

12. 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 simple interest at a fixed rate of 8% per annum. No interest payment is due or 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 may be repaid or converted, either partially or in full, into 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.

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.

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 is 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 involve 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 months ended March 31, 2020 and 2019, total interest generated from the Shareholder Loan was $2,572 and $2,645, respectively, of which, $0 and $788 was capitalized, respectively.

13. Product Revenue

The Company's product sales are derived from the sale of its internally-developed products BRUKINSA in the U.S. and tislelizumab in China, as well as the sale of ABRAXANE, REVLIMID, and VIDAZA in China under a distribution license from BMS. The table below presents the Company's net product sales for the three months ended March 31, 2020 and 2019.

	Three Months Ended March 31,	
	2020	2019
	$	$
Product revenue – gross	53,188	58,536
Less: Rebates and sales returns	(1,129)	(1,115)
Product revenue – net	52,059	57,421

The following table disaggregates net product sales by product for the three months ended March 31, 2020 and March 31, 2019:

	Three Months Ended March 31,	
	2020	2019
	$	$
Tislelizumab	20,526	—
BRUKINSA™	717	—
ABRAXANE®	17,145	27,134
REVLIMID®	7,628	23,584
VIDAZA®	6,043	6,703
Total net product revenue	52,059	57,421

The following table presents the roll-forward of accrued sales rebates and returns for the three months ended March 31, 2020 and March 31, 2019:

	Sales Rebates and Returns
	$
Balance as of December 31, 2019	4,749
Accrual	1,115
Payments	(2,498)
Balance as of March 31, 2019	3,366
Balance as of December 31, 2019	3,198
Accrual	1,129
Payments	(313)
Balance as of March 31, 2020	4,014

14. Loss Per Share

Loss per share was calculated as follows:

	Three Months Ended March 31,	
	2020	2019
	$	$
Numerator:		
Net loss attributable to BeiGene, Ltd.	(363,735)	(167,640)
Denominator:		
Weighted average shares outstanding, basic and diluted	1,005,347,581	774,750,255
Net loss per share attributable to BeiGene, Ltd., basic and diluted	(0.36)	(0.22)

The effects of all share options, restricted shares and restricted share units were excluded from the calculation of diluted loss per share, as their effect would have been anti-dilutive during the three months ended March 31, 2020 and 2019.

15. Share-Based Compensation Expense

2016 Share Option and Incentive Plan

On January 14, 2016, in connection with the Company's initial public offering ("IPO") on the NASDAQ Stock Market, 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 March 31, 2020, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,152,236. The 2016 Plan formerly provided 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, 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. In August 2018, in connection with the Company's IPO on the Stock Exchange of Hong Kong Limited ("HKEx"), the board of directors of the Company approved an amended and restated 2016 Plan to remove this “evergreen” provision and implement other changes required by the HKEx rules. In December 2018, the board of directors approved a second amended and restated 2016 Plan to increase the number of shares authorized for issuance by 38,553,159 ordinary shares, as well as amend the cap on annual compensation to independent directors and make other changes. 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 three months ended March 31, 2020, the Company granted options for 462,449 ordinary shares and restricted share units for 1,880,554 ordinary shares under the 2016 Plan. As of March 31, 2020, options and restricted share units for ordinary shares outstanding under the 2016 Plan totaled 90,600,885 and 25,109,448, 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. In August 2018, in connection with the Hong Kong IPO, the board of directors of the Company approved an amended and restated 2018 Plan to implement changes required by the HKEx rules.

During the three months ended March 31, 2020, the Company did not grant any options or restricted share units under the 2018 Plan. As of March 31, 2020, options and restricted share units for ordinary shares outstanding under the 2018 Plan totaled 79,404 and 2,228,174, respectively.

2018 Employee Share Purchase Plan

On June 6, 2018, the shareholders of the Company approved the 2018 Employee Share Purchase Plan (the "ESPP"). Initially, 3,500,000 ordinary shares of the Company were reserved for issuance under the ESPP. In August 2018, in connection with the Hong Kong IPO, the board of directors of the Company approved an amended and restated ESPP to remove an "evergreen" share replenishment provision originally included in the plan and implement other changes required by the HKEx rules. In December 2018, the shareholders of the Company approved a second amended and restated ESPP to increase the number of shares authorized for issuance by 3,855,315 ordinary shares to 7,355,315 ordinary shares. In June 2019, the board of directors adopted an amendment to revise the eligibility criteria for enrollment in the plan. 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 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.

On February 28, 2020, the Company issued 425,425 ordinary shares to employees for aggregate proceeds of $4,048 under the ESPP. The purchase price of the shares was $123.71 per ADS, or $9.52 per ordinary share, which was discounted in accordance with the terms of the ESPP from the closing price on NASDAQ on February 28, 2020 of $158.35 per ADS, or $12.18 per ordinary share.

On August 30, 2019, the Company issued 233,194 ordinary shares to employees for aggregate proceeds of $2,192 under the ESPP. The purchase price of the shares was $122.19 per ADS, or $9.40 per ordinary share, which was discounted in accordance with the terms of the ESPP from the closing price on NASDAQ on August 30, 2019 of $143.75 per ADS, or $11.06 per ordinary share.

On February 28, 2019, the Company issued 154,505 ordinary shares to employees for aggregate proceeds of $1,385 under the ESPP. The purchase price of the shares was $116.49 per ADS, or $8.96 per ordinary share, which was discounted in accordance with the terms of the ESPP from the closing price on NASDAQ on February 28, 2019 of $137.05 per ADS, or $10.54 per ordinary share.

The following table summarizes total share-based compensation expense recognized for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
	$	$
Research and development	20,399	15,771
Selling, general and administrative	17,856	10,621
Total	38,255	26,392

16. Accumulated Other Comprehensive Income

The movement of accumulated other comprehensive income was as follows:

	Foreign Currency Translation Adjustments	Unrealized Gains on Available-for-Sale Securities	Total
	$	$	$
Balance as of December 31, 2019	(9,291)	1,290	(8,001)
Other comprehensive (loss)/ income before reclassifications	(4,245)	6,938	2,693
Amounts reclassified from accumulated other comprehensive income	—	(1,240)	(1,240)
Net-current period other comprehensive (loss)/ income	(4,245)	5,698	1,453
Balance as of March 31, 2020	(13,536)	6,988	(6,548)

17. Shareholders' Equity

Share Purchase Agreement

On January 2, 2020, the Company sold 15,895,001 ADSs, representing a 20.5% ownership stake in the Company, to Amgen for aggregate cash proceeds of $2,779,241, or $174.85 per ADS, pursuant to the SPA executed in connection with the Amgen Collaboration Agreement.

18. Restricted Net Assets

The Company's ability to pay dividends may depend on the Company receiving distributions of funds from its PRC subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by the Company's PRC subsidiaries only out of the subsidiary's retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the condensed consolidated financial statements prepared in accordance with GAAP differ from those reflected in the statutory financial statements of the Company's PRC subsidiaries.

In accordance with the company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the board of directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's PRC subsidiaries were established as domestic enterprises and therefore are subject to the above-mentioned restrictions on distributable profits.

During the three months ended March 31, 2020 and 2019, no appropriation to statutory reserves was made because the PRC subsidiaries had substantial losses during these periods.

As a result of these PRC laws and regulations, including the requirement to make annual appropriations of at least 10% of after-tax income and set aside as general reserve fund prior to payment of dividends, the Company's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulations in the PRC may further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of dividends, loans and advances. As of March 31, 2020 and December 31, 2019, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to $102,494 and $109,633, respectively.

19. Commitments and Contingencies

Purchase Commitments

As of March 31, 2020, the Company had purchase commitments amounting to $117,325, of which $96,686 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $20,639 related to binding purchase obligations of inventory from BMS. The Company does not have any minimum purchase requirements for inventory from BMS.

Capital commitments

The Company had capital commitments amounting to $60,645 for the acquisition of property, plant and equipment as of March 31, 2020, which were mainly for BeiGene Guangzhou Factory's manufacturing facility in Guangzhou, China.

Co-development funding commitment

Under the Amgen Collaboration Agreement, the Company is responsible for co-funding global development costs for the Amgen oncology pipeline assets up to a total cap of $1,250,000. The Company is funding its portion of the co-development costs by contributing cash and development services. As of March 31, 2020, the Company's remaining co-development funding commitment was $1,194,000.

Other Business Agreements

The Company enters into agreements in the ordinary course of business with contract research organizations ("CROs") to provide research and development services. These contracts are generally cancelable at any time by us with prior written notice.

The Company also enters into collaboration agreements with institutions and companies to license intellectual property. The Company may be obligated to make future development, regulatory and commercial milestone payments and royalty

payments on future sales of specified products associated with its collaboration agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on the Company's balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in the Company's financial statements.

20. Segment and geographic information

The Company operates in one segment: pharmaceutical products. 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.

Net product revenues by geographic area 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 area are presented as follows:

	Three Months Ended March 31,	
	2020	2019
	$	$
PRC	51,342	57,421
United States	717	13,268
Other	—	7,144
Total	52,059	77,833

21. Subsequent Event

On April 13, 2020, the Company's board of directors adopted an amendment to the 2016 Plan to increase the number of authorized shares by 57,200,000 ordinary shares and to extend the term of the plan through April 13, 2030, subject to approval of the Company's shareholders at the annual meeting to be held on June 17, 2020.

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 (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," "ongoing," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. These forward-looking statements, include, but are not limited to, statements regarding: our ability to successfully commercialize our approved drugs and to obtain approvals in additional indications and territories for our drugs; our ability to successfully commercialize our in-licensed drugs in China and any other drugs we may in-license; our ability to successfully develop and commercialize oncology assets licensed from Amgen in China pursuant to our global strategic oncology collaboration with Amgen; our ability to further develop sales and marketing capabilities and launch new drugs, if approved; our ability to maintain and expand regulatory approvals for our drugs and drug candidates, if approved; the pricing and reimbursement of our drugs and drug candidates, if approved; 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; our plans, expected milestones and the timing or likelihood of regulatory filings and approvals; the implementation of our business model, strategic plans for our business, drugs, 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; 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, the People's Republic of China ("China" or "PRC"), 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; our ability to manufacture and supply, or have manufactured and supplied, drug candidates for clinical development and drugs for commercial sale; the rate and degree of market access and acceptance and reimbursement for our drugs and drug candidates, if approved; developments relating to our competitors and 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 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; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations; 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 global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. We started as a research and development company in Beijing in 2010. Over the last ten years, we have developed into a fully-integrated global biotechnology company, with significant commercial, manufacturing, and research and development capabilities.

We have built substantial commercial capabilities in China and the United States and are currently marketing both internally-developed drugs and in-licensed drugs. In the United States, we market BRUKINSA™ (zanubrutinib) for adult patients with mantle cell lymphoma ("MCL") who have received at least one prior therapy. In China, we market tislelizumab for patients with classical Hodgkin's Lymphoma ("cHL") who have received at least two prior therapies and for patients with locally advanced or metastatic urothelial carcinoma ("UC"), a form of bladder cancer, with PD-L1 high expression whose

disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. As of May 1, 2020, we filed three additional new or supplementary new drug applications ("sNDA") for regulatory approvals in China for our internally-developed products and are planning for launches in these additional drugs or indications in 2020 and beyond. Our in-licensed portfolio includes ABRAXANE®, REVLIMID® and VIDAZA®, which we have been marketing in China since 2017 under a license from Celgene Logistics Sàrl, a Bristol Myers Squibb company ("BMS"). We plan on launching additional in-licensed products in China from our collaborations, including XGEVA® (denosumab), KYPROLIS® (carfilzomib) and BLINCYTO® (blinatumomab) from Amgen Inc. ("Amgen"), and SYLVANT® (siltuximab) and QARZIBA® ▼ (dinutuximab beta), from EUSA Pharma ("EUSA").

We have built deep clinical development capabilities, including a more than 1,100-person global clinical development team that is running over 60 ongoing or planned clinical trials in more than 35 countries that have enrolled over 7,500 patients and healthy subjects. We are conducting late-stage clinical trials of BRUKINSA and tislelizumab, including 26 registration or registration-enabling trials in 15 discrete cancer indications. Our internal research capabilities have yielded another late-stage asset, pamiparib, and five other internally-developed drug candidates that are currently in early-stage clinical development. In addition, we have been able to leverage our capabilities and China's rising importance as a clinical science center to expand our clinical and pre-clinical portfolio with in-licensed drug candidates. We are also working with high-quality contract manufacturing organizations ("CMOs") to manufacture our internally-developed commercial and clinical products in China and globally and have built state-of-the-art small molecule and biologic manufacturing facilities in China to support the launches and potential future demand of our internally-developed products.

Based on the strength of our China-inclusive global development and commercial capabilities, we have entered into collaborations with leading pharmaceutical and biotechnology companies to develop and commercialize innovative medicines in China and the Asia-Pacific region. In October 2019, we entered into a strategic collaboration with Amgen pursuant to which we have agreed to collaborate on the commercialization of Amgen's oncology products XGEVA, KYPROLIS and BLINCYTO in China, and the global development and future commercialization in China of a portfolio of Amgen's clinical- and late pre-clinical-stage pipeline products, including AMG 510, Amgen's first-in-class investigational KRAS G12C inhibitor. In April 2020, two of Amgen's oncology pipeline assets were removed from the collaboraiton due to portfolio prioritization, and the parties expect that the development plan for the assets in the portfolio will continue to evolve over time.

Recent Developments

Recent Business Developments

On April 29, 2020, we announced plans to collaborate with Atreca, Inc. ("Atreca") and IGM Biosciences, Inc. ("IGM") to help address the COVID-19 pandemic. We, along with Atreca and IGM, plan to leverage our combined technology and expertise in an effort to discover, develop, and manufacture novel immunoglobulin M ("IgM") and immunoglobulin A ("IgA") antibodies targeting SARS-CoV-2 for the potential treatment or prophylaxis of COVID-19.

On April 20, 2020, we announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration ("NMPA") has accepted an sNDA of tislelizumab in combination with two chemotherapy regimens for first-line treatment of patients with advanced squamous non-small cell lung cancer ("NSCLC").

On April 13, we announced that the Phase 3 trial evaluating our anti-PD-1 antibody tislelizumab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with non-squamous NSCLC met its primary endpoint, demonstrating a statistically significant improvement in progression-free survival ("PFS") compared to pemetrexed and platinum chemotherapy alone at the planned interim analysis, as assessed by independent review committee ("IRC"). The safety profile of tislelizumab in combination with pemetrexed and platinum chemotherapy was consistent with the known risks of each study treatment, and no new safety signals were identified.

On April 10, 2020, we announced that tislelizumab received approval from the NMPA as a treatment for patients with locally advanced or metastatic UC with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This is the second indication approved for tislelizumab, and the first in a solid tumor indication.

On March 25, 2020, we announced that the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to BeiGene by Celgene Corporation, a BMS company. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of ABRAXANE in mainland China. Because of the suspension, we are no longer currently able to sell ABRAXANE in China. We are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On

March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE.

Coronavirus Disease 2019 (COVID-19)

We expect that the worldwide health crisis of COVID-19 will continue to have a negative impact on our operations globally, including clinical trial recruitment and participation, regulatory interactions and inspections, and commercial revenue, particularly in the first half of 2020 and possibly longer depending on the scope and duration of the disruption. While we have experienced decreased demand for our commercial products, we continue to execute on our clinical development, regulatory and commercialization goals and are working to minimize delays and disruptions.

Recent Regulatory Developments

PRC Drug Regulation

On April 27, 2020, the NMPA and PRC National Health Commission jointly issued a new version of China's Good Clinical Practice ("GCP"), which will come into effect on July 1, 2020 and replace the previous GCP issued by the NMPA in 2003. The new GCP incorporates many aspects of ICH-GCP E6 R2 and aims to improve the conduct of clinical trials by setting more specific and strict requirements for various aspects of clinical study, including human subject protection, roles and responsibilities of sponsors, ethics committees and sites, quality management, and compensation and indemnification of trial subjects and investigators. For example, the new GCP continues to permit clinical trial sponsors to outsource certain tasks in clinical studies to third parties, such as contract research organizations, and sponsors must be ultimately responsible for the quality of those third parties' work. The new GCP clarifies that all medical judgements or clinical decisions shall be made by clinicians; the ways and information of subject enrollment shall be approved by the ethics committee. The new GCP also includes some provisions that are not in ICH GCP, such as the sample retention in bioequivalence studies, a record of the informed consent process in the medical record of the subject, and complimentary supply of investigational products to subjects in clinical trials. Under the new GCP, sponsors are also responsible for continuously evaluating the risks of investigational products, including analyzing safety-related information and promptly reporting any suspected unexpected serious adverse reactions to the regulatory authorities. We plan to review our current clinical study practices in China in light of the new GCP to ensure that our business complies with the new rules.

On March 30, 2020, the NMPA issued the Measures for the Administration and Supervision of Drug Manufacturing (the "Drug Manufacturing Measures") and the Measures for the Administration of Drug Registration (the "Drug Registration Measures"), both of which will become effective on July 1, 2020. These measures reflect the changes adopted by the newly amended Drug Administration Law of the PRC (the "DAL") by further detailing the procedural and substantive requirements for the key regulatory concepts established by the DAL. For example, despite the cancellation of the GMP certification requirement, the Drug Manufacturing Measures continue to emphasize the GMP rules as the fundamental standards for drug manufacturing. To implement the market authorization holder ("MAH") system nationwide, the NMPA imposes qualification requirements on the MAH in these measures, including that a MAH must establish a quality assurance system and be responsible for product release. The Drug Registration Measures clarify the review and approval procedures and provide detailed requirements for four expedited approval mechanisms, namely, the breakthrough therapy process, conditional approval process, priority review process, and special approval process. Drugs eligible for conditional approvals or considered breakthrough therapies will be eligible for priority review, with the goal of providing shortened approval timelines and more flexibility in providing supplementary information during the review process. These measures also reflect the enhancement of administrative penalties on violations. We plan to continue to closely monitor the implementation of the DAL, the Drug Registration Measures and the Drug Manufacturing Measures to ensure that our business complies with the new rules.

Components of Operating Results

Revenue

We began generating product revenue in September 2017 through our in-license agreement with BMS to distribute the approved cancer therapies ABRAXANE, REVLIMID and VIDAZA in China. Following FDA approval on November 14, 2019, we launched our first internally-developed drug, BRUKINSA, in the United States. We launched our second internally-developed drug, tislelizumab, in March 2020 in China.

Revenues from product sales are recognized when there is a transfer of control from the Company to the customer. The Company determines transfer of control based on when the product is delivered, and title passes to the customer. Revenues from product sales are recognized net of variable consideration resulting from rebates, chargebacks, trade discounts and allowances, sales returns allowances and other incentives. Provisions for estimated reductions to revenue are provided for in the same period the related sales are recorded and are based on contractual terms, historical experience and trend analysis. We

expect revenue from our internal product sales to increase throughout 2020. We plan on launching additional in-licensed products from our collaborations with Amgen and EUSA in 2020 and 2021, and continue to expand our efforts to promote our existing commercial products.

To date, we also recorded revenue from our 2017 collaboration and license agreement with BMS for tislelizumab, which was terminated in June 2019. Under this agreement, we received an upfront payment related to the license fee, which was recognized upon the delivery of the license right. Additionally, the portion of the upfront payment related to the reimbursement of undelivered research and development services was deferred and recognized over the performance period of the collaboration arrangement. We recognized the remainder of the deferred research and development services revenue balance upon termination of the collaboration agreement. We also received research and development reimbursement revenue for the clinical trials that BMS opted into until the termination of the collaboration agreement. Pursuant to the terms of the termination agreement, we received a one-time payment of $150 million in June 2019, which was recognized in full at that time because we had no further performance obligations under the collaboration.

Expenses

Cost of Sales

Cost of sales includes the cost of products purchased from BMS and distributed in China and the costs to manufacture our internally-developed commercial products. Costs to manufacture inventory in preparation for commercial launch of a product incurred prior to regulatory approval are expensed to research and development expense as incurred. Cost of sales for newly launched products will not be recorded until the initial pre-launch inventory is depleted and additional inventory is manufactured.

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 ("CROs"), CMOs, and consultants that conduct and support clinical trials and preclinical studies;
- costs of comparator drugs in certain of our clinical trials;
- manufacturing costs related to pre-commercial activities;
- 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;
- in-process research and development costs expensed as part of collaboration agreements entered into; 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 internally-developed drugs and drug candidates:

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

- BGB-A1217, an investigational humanized monoclonal antibody against TIGIT; and
- BGB-11417, an investigational small molecular inhibitor of Bcl-2.

Research and development activities also include costs associated with in-licensed drug candidates, including:

- sitravatinib, an investigational, spectrum-selective kinase inhibitor in clinical development by Mirati Therapeutics, Inc. ("Mirati");
- ZW25 and ZW49, two bispecific antibody-based product candidates targeting HER2, under development by Zymeworks Inc.;
- BA3071, an investigational CAB-CTLA-4 antibody, under development by BioAtla LLC;
- R&D expense related to the co-development of pipeline assets under the Amgen collaboration agreement. Our total cost share obligation to Amgen is split between R&D expense and a reduction to the R&D cost share liability.

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 drugs and drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our drugs and drug candidates, if approved. This is due to the numerous risks and uncertainties associated with developing such drugs and drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety and efficacy profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing and other required approvals from applicable regulatory authorities;
- successfully launching and commercializing our drugs and drug candidates, if and when approved, whether as monotherapies or in combination with our internally-developed drugs and drug candidates or third-party products;
- market acceptance, pricing and reimbursement;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drugs and drug candidates;
- continued acceptable safety and efficacy 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 would significantly change the costs, timing and viability associated with the development of that drug or 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 drugs and drug candidates as treatments for various cancers and as we move these drugs and drug candidates into additional clinical trials, including potential pivotal trials. There are numerous factors associated with the successful commercialization of any of our drugs and 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 and commercial 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 tislelizumab and BRUKINSA and the preparation for potential launch and commercialization of our in-licensed products from our collaborations with Amgen and EUSA and internally-developed drugs and 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 drugs and drug candidates as treatments for various cancers and the initiation of clinical trials for potential new indications or 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 incur significant legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company with our American Depositary Shares ("ADSs") and ordinary shares listed for trading on The NASDAQ Global Select Market and The Hong Kong Stock Exchange, respectively.

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, Net

Other income consists primarily of government grants and subsidies received that involve no conditions or continuing performance obligations by us, realized and unrealized gains and losses related to foreign currency exchange rates, unrealized gains and losses on equity securities, and realized gains and losses on the sale of investments.

Results of Operations

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(dollars in thousands)			
Revenues				
Product revenue, net	$ 52,059	$ 57,421	$ (5,362)	(9.3)%
Collaboration revenue	—	20,412	(20,412)	(100.0)%
Total revenues	52,059	77,833	(25,774)	(33.1)%
Expenses				
Cost of sales - product	14,149	15,261	(1,112)	(7.3)%
Research and development	304,302	178,351	125,951	70.6 %
Selling, general and administrative	107,081	57,645	49,436	85.8 %
Amortization of intangible assets	283	331	(48)	(14.5)%
Total expenses	425,815	251,588	174,227	69.3 %
Loss from operations	(373,756)	(173,755)	(200,001)	115.1 %
Interest income, net	6,690	4,477	2,213	49.4 %
Other income, net	3,681	1,728	1,953	113.0 %
Loss before income taxes	(363,385)	(167,550)	(195,835)	116.9 %
Income tax expense	1,554	519	1,035	199.4 %
Net loss	(364,939)	(168,069)	(196,870)	117.1 %
Less: Net loss attributable to noncontrolling interest	(1,204)	(429)	(775)	180.7 %
Net loss attributable to BeiGene, Ltd.	$ (363,735)	$ (167,640)	$ (196,095)	117.0 %

Comparison of the Three Months Ended March 31, 2020 and 2019

Revenue

Total revenue decreased to $52.1 million for the three months ended March 31, 2020, from $77.8 million for the three months ended March 31, 2019, primarily due to the cessation of collaboration revenue following the termination of the BMS collaboration agreement in the second quarter of 2019. The following table summarizes the components of revenue for the three months ended March 31, 2020 and 2019, respectively:

	Three Months Ended March 31,		Changes	
	2020	2019	$	%
	(dollars in thousands)			
Product revenue	$ 52,059	$ 57,421	$ (5,362)	(9.3)%
Collaboration revenue:				
Reimbursement of research and development costs	—	18,174	(18,174)	(100.0)%
Research and development service revenue	—	2,238	(2,238)	(100.0)%
Total	$ 52,059	$ 77,833	$ (25,774)	(33.1)%

Net product revenues consisted of the following:

	Three Months Ended March 31,		Changes	
	2020	2019	$	%
	(dollars in thousands)			
Tislelizumab	$ 20,526	$ —	$ 20,526	NM
BRUKINSA™	717	—	717	NM
ABRAXANE®	17,145	27,134	(9,989)	(36.8)%
REVLIMID®	7,628	23,584	(15,956)	(67.7)%
VIDAZA®	6,043	6,703	(660)	(9.8)%
Total product revenue	$ 52,059	$ 57,421	$ (5,362)	(9.3)%

Net product revenue, which related to sales of tislelizumab (since its launch in March 2020), ABRAXANE, REVLIMID and VIDAZA in China, and sales of BRUKINSA in the United States, decreased 9.3% to $52.1 million for the three months ended March 31, 2020, compared to $57.4 million in the prior year period due to decreased product sales of ABRAXANE, REVLIMID and VIDAZA, partially offset by the initial sales of tislelizumab in China and BRUKINSA in the United States. Product revenues in the first quarter of 2020 were negatively impacted by the COVID-19 pandemic, increased generic competition, and the suspension of ABRAXANE in China by the NMPA in March 2020, which limited our ability to sell our inventory of ABRAXANE to our distributor prior to the end of the quarter. Product revenues in the first quarter of 2020 were positively impacted by sales of our internally-developed products, tislelizumab and BRUKINSA. Product revenue for tislelizumab reflects sales since its launch in China in March 2020, including launch inventory build at distributors.

During the first quarter of 2020, we recognized revenue related to sales of ABRAXANE that was subsequently recalled from the market by BMS. We have not reduced the net revenue that was recognized on sales of ABRAXANE that was recalled in the first quarter of 2020 since we do not expect to refund any of the revenue to our customer. We expect product revenue from our licensed products to decrease due to the NMPA's suspension of ABRAXANE importation, sales and use in China in March 2020 and the subsequent voluntary recall of ABRAXANE by BMS, as well as the decreased demand for our other licensed products due to the impact of COVID-19 and increased competition from generic products. We do not expect revenue from ABRAXANE until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE and qualified drug is manufactured and available for sale in China. We do not know when the NMPA suspension of ABRAXANE will be lifted and when we will be able to re-commence sales of ABRAXANE.

We did not have any collaboration revenue for the three months ended March 31, 2020 due to the termination of the collaboration agreement with BMS for tislelizumab in the second quarter of 2019.

Cost of Sales

Cost of sales decreased to $14.1 million for the three months ended March 31, 2020 from $15.3 million for the three months ended March 31, 2019, primarily due to a decreased volume of in-licensed sales compared to the prior year period.

Research and Development Expense

Research and development expense increased by $126.0 million, or 70.6%, to $304.3 million for the three months ended March 31, 2020 from $178.4 million for the three months ended March 31, 2019. The following table summarizes external clinical, external non-clinical and internal research and development expense for the three months ended March 31, 2020 and 2019, respectively:

	Three Months Ended March 31,		Changes	
	2020	2019	$	%
	(dollars in thousands)			
External cost of clinical-stage programs	$ 94,899	$ 78,701	$ 16,198	20.6%
Upfront license fees and milestones	48,000	10,000	38,000	380.0%
External cost of non-clinical-stage programs	11,835	10,057	1,778	17.7%
Amgen co-development expense[1]	28,366	—	28,366	NM
Internal research and development expenses	121,202	79,593	41,609	52.3%
Total research and development expenses	$ 304,302	$ 178,351	$ 125,951	70.6%

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended March 31, 2020 totaled $56.0 million, of which $28.4 million was recorded as R&D expense. The remaining $27.6 million was recorded as a reduction of the R&D cost share liability.

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

- Increases of approximately $4.5 million and $6.0 million, respectively, for zanubrutinib and tislelizumab. The expense increases were primarily due to the continued enrollment and expansion of pivotal clinical trials;
- An increase of $38.0 million related to license fees under collaboration agreements, including $33.0 million of increased upfront payments compared to the same period last year, as well as a $5.0 million milestone payment accrued in the first quarter of 2020;
- External spending for our non-clinical-stage programs was primarily related to manufacturing costs for pre-commercial activities and costs associated with our preclinical candidates and an increase of $28.4 million related to expense recognized on co-development fees to Amgen.

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

- $13.0 million increase of employee salary and benefits, which was primarily attributable to hiring more research and development personnel to support our expanding research and development activities;
- $4.6 million increase of share-based compensation expense, primarily attributable to our increased headcount, resulting in more awards being expensed related to the growing employee population;
- $14.8 million increase of materials and reagent expenses, mainly in connection with the in-house manufacturing of drug candidates used for clinical purposes;
- $0.9 million increase of consulting fees, which was mainly attributable to increased scientific, regulatory and development consulting activities, in connection with the advancement of our drug candidates; and
- $8.3 million increase of facilities, depreciation, office expense, rental fees, and other expenses to support the growth of our organization.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $49.4 million, or 85.8%, to $107.1 million for the three months ended March 31, 2020, from $57.6 million for the three months ended March 31, 2019. The increase was primarily attributable to the following:

- $20.8 million increase of employee salary and benefits, which was primarily attributable to the hiring of more personnel to support our growing organization, including the expansion of our commercial organizations in China and the United States;
- $7.2 million increase of share-based compensation expense, primarily attributable to our increased headcount, resulting in more awards being expensed related to the growing employee population;
- $10.1 million increase of professional fees and consulting for general and administrative activities, including legal, recruiting, information technology, tax, accounting and audit services, mainly in connection with our growing business;
- $4.0 million increase in external selling and marketing expenses, including market access studies, meeting and seminar expenses, promotional activities, and sponsorship and grant expenses; and
- $5.2 million increase in facility expenses, rental fees, office expenses, and other administrative expenses, primarily attributable to the global expansion of our business, including the expansion of our commercial operations in China and the United States.

Interest Income, Net

Interest income, net increased by $2.2 million, or 49.4%, to $6.7 million for the three months ended March 31, 2020, from $4.5 million for three months ended March 31, 2019. The increase in interest income was primarily attributable to interest income on cash and short-term investment balances exceeding interest expense on our long-term debt.

Other Income, Net

Other income, net increased to $3.7 million of net other income for the three months ended March 31, 2020, from $1.7 million of net other income for the three months ended March 31, 2019. The increase was mainly attributable to unrealized gains on equity securities and realized gains on sales of available-for-sale securities, offset by foreign currency exchange losses.

Income Tax Expense

Income tax expense was $1.6 million for the three months ended March 31, 2020, as compared to an income tax expense of $0.5 million for the three months ended March 31, 2019. The income tax expense for the three months ended March 31, 2020 was primarily attributable to income reported in certain China subsidiaries offset by the tax benefit of deferred U.S. stock-based compensation deductions. The resulting current U.S. tax was reduced by windfall stock-based compensation deductions, research and development tax credits and other special tax deductions. The income tax expense for the three months ended March 31, 2019 was primarily attributable to income reported in the United States and certain China subsidiaries, offset by U.S. research and development tax credits and other special tax deductions.

Liquidity and Capital Resources

Since our inception in 2010, we have incurred annual net losses and negative cash flows from our operations. Substantially all of our operating 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 $364.9 million and $168.1 million, respectively, for the three months ended March 31, 2020 and 2019. As of March 31, 2020, we had an accumulated deficit of $2.3 billion. Our primary use of cash is to fund our research and development activities and to support the commercialization of our products in China and the United States and planned additional product launches. Our operating activities used $341.9 million and $172.0 million during the three months ended March 31, 2020 and 2019, respectively. We have financed our operations principally through proceeds from public and private offerings of our securities and proceeds from our collaboration agreements, together with product sales since September 2017.

As of March 31, 2020, we had cash, cash equivalents, restricted cash, and short-term investments of $3.4 billion, including approximately $85.1 million of cash, cash equivalents and restricted cash held by our joint venture, BeiGene Biologics, to continue phased construction of our commercial biologics facility in Guangzhou, China and to fund research and development

of our biologics drug candidates in China. Restricted cash of $2.7 million primarily consists of RMB-denominated cash deposits pledged in designated bank accounts as collateral for bank loans and letters of credit.

The following table provides information regarding our cash flows for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 620,775	$ 740,713
Net cash used in operating activities	(341,944)	(171,975)
Net cash (used in) provided by investing activities	(1,114,969)	172,416
Net cash provided by financing activities	2,802,168	42,964
Net effect of foreign exchange rate changes	(6,212)	4,265
Net increase in cash, cash equivalents, and restricted cash	1,339,043	47,670
Cash, cash equivalents and restricted cash at end of period	$ 1,959,818	$ 788,383

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 $341.9 million of cash in the three months ended March 31, 2020, which resulted principally from our net loss of $364.9 million, and an increase in our net operating assets and liabilities of $34.7 million, offset by non-cash charges of $57.7 million related primarily to stock-based compensation expense, depreciation and amortization and other non-cash charges. The increase in our net operating assets and liabilities was primarily due to an increase of $36.1 million in prepaid expenses and other current assets primarily related to prepayments to CROs for clinical trials, an increase of $9.0 million in operating lease right-of-use assets, a decrease of $5.7 million in accounts payable and accrued expenses related to payments for external research and development costs, and an increase in other non-current assets, all of which had a negative impact on operating cash flow. These cash uses were partially offset by an increase in operating lease liabilities of $10.9 million and a net decrease of $3.2 million in accounts receivable, net, on products sales from our collaboration with BMS, all of which had a positive impact on operating cash flows. Our non-cash charges and other adjustments to our net loss during the three months ended March 31, 2020 primarily consisted of $38.3 million of share-based compensation expense, $43.0 million of acquired in-process research and development related to license agreements in the period, and $7.8 million of depreciation and amortization expense, offset by $27.6 million for amortization of a research and development cost share liability related to the Amgen collaboration, and $7.0 million of gains from an equity investment.

Operating activities used $172.0 million of cash in the three months ended March 31, 2019, which resulted principally from our net loss of $168.1 million and an increase in our net operating assets and liabilities of $60.4 million, offset by non-cash charges of $56.5 million related primarily to stock-based compensation expense, depreciation and amortization and other non-cash charges. The increase in our net operating assets and liabilities was primarily due to an increase of $17.9 million related to collections on product sales from our collaboration with BMS, a decrease of $29.2 million in accounts payable and accrued expenses related to payments for external research and development costs, an increase of $10.2 million in other non-current assets primarily related to rental deposit payments, an increase of $8.3 million in prepaid expenses and other current assets primarily related to prepayments to CROs for clinical trials, and a decrease of $2.2 million in deferred revenue, all of which had a negative impact on operating cash flow. These cash uses were partially offset by a decrease of $3.1 million in inventories, a decrease of $2.5 million in unbilled receivables related to the BMS collaboration, an increase of $1.0 million in taxes payable, and an increase of $0.9 million in other long-term liabilities, all of which had a positive impact on operating cash flows. Our non-cash charges and other adjustments to our net loss during the three months ended March 31, 2019 primarily consisted of $26.4 million of share-based compensation expense, $29.0 million of acquired in-process research and development related to our license agreement with Ambrx Inc. and termination of the collaboration agreement with Merck KGaA, Darmstadt Germany, $3.4 million of depreciation and amortization expense, and $1.9 million of non-cash interest expense, offset by $2.4 million of bond discount amortization, $1.0 million related to deferred tax benefits, and $0.8 million of disposal gain on available-for-sale securities.

Investing Activities

Investing activities used $1.1 billion of cash in the three months ended March 31, 2020, consisting of $1.3 billion in purchases of investment securities, $43.0 million of acquired in-process research and development, capital expenditures of $21.5 million, and cash paid for an equity investment of $5.0 million, all of which were offset by sales and maturities of investment securities of $256.7 million.

Investing activities provided $172.4 million of cash in the three months ended March 31, 2019, consisting of sales and maturities of investment securities of $710.6 million, which was offset by $487.4 million in purchases of investment securities, $29.0 million of acquired in-process research and development related to the license agreement with Ambrx and termination of the collaboration agreement with Merck KGaA, Darmstadt Germany, and capital expenditures of $21.8 million primarily related to our Guangzhou and Suzhou manufacturing facilities.

Financing Activities

Financing activities provided $2.8 billion of cash in the three months ended March 31, 2020, consisting primarily of $2.8 billion received from our collaboration with Amgen, of which $2.2 billion was recorded as equity, and $0.6 billion was recorded as a research and development cost share liability. Additionally, we received $11.6 million from the exercise of employee share options and proceeds issuance of shares through our employee share purchase plan, and $11.3 million from proceeds of a short-term bank loan.

Financing activities provided $43.0 million of cash in the three months ended March 31, 2019, consisting of $36.7 million from a long-term bank loan to fund our Guangzhou manufacturing facility, and $6.3 million from the exercise of employee share options.

Effects of Exchange Rates on Cash

We have substantial operations in the PRC, which generate a significant amount of RMB-denominated cash (from product sales) and require a significant amount of RMB-denominated cash to pay our obligations. Since the reporting currency of the Company is the U.S. dollar, periods of volatility may have a significant impact on our consolidated cash balances.

Operating Capital Requirements

We have exclusive rights to distribute and promote BMS’s approved cancer therapies in China, for which we began recognizing revenue in the third quarter of 2017. On November 14, 2019, we received accelerated approval from the FDA for BRUKINSA as a treatment for MCL in adult patients who have received at least one prior therapy; and on December 26, 2019, we received regulatory approval from the NMPA for tislelizumab as a treatment for patients with cHL who have received at least two prior therapies. We launched BRUKINSA in the United States in November 2019 and launched tislelizumab in China in March 2020. However, we do not expect to generate significant revenue from product sales of our internally-developed drugs and drug candidates unless and until we obtain regulatory approvals for additional indications of our currently approved drugs. We anticipate that we will continue to generate losses for the foreseeable future as we continue the development of, and seek regulatory approvals for, our drugs and drug candidates, commercialize our approved products and prepare for commercialization and begin to commercialize any future 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 as well as our internally-developed products that are either approved or in late-stage clinical trials. We may need additional funding prior to generating sufficient cash from operations to fund our continuing operations.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of March 31, 2020, 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, and the shared development costs of a portfolio of Amgen's oncology pipeline products and additional in-licensed drug candidates; our other ongoing and planned clinical trials; regulatory filing and registration of our late-stage drug candidates; expansion of our commercial operations in China and the U.S. and the launch of our in-licensed commercial drug portfolio and late-stage 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 expect in our current operating plan. Because of the numerous risks and uncertainties associated with the development and commercialization of our drugs and 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 drugs and drug candidates.

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

- our ability to successfully commercialize our internally-developed and in-licensed drugs;
- 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 drugs and drug candidates we pursue;
- the costs of establishing or expanding 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;
- 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 may be required to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, strategic alliances, licensing arrangements, government grants and other available sources. Under the rules of the U.S. Securities and Exchange Commission ("SEC"), 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, prior to which time we plan to file another shelf registration statement that will be effective 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 collaboration agreements, 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 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 March 31, 2020:

	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	$ 53,562	$ 16,614	$ 24,888	$ 11,825	$ 235
Purchase commitments	117,325	34,299	44,433	20,067	18,526
Debt obligations	250,490	11,298	1,412	178,463	59,317
Co-development funding commitment	1,194,000	268,750	633,500	291,750	—
Capital commitments	60,645	60,645	—	—	—
Total	$ 1,676,022	$ 391,606	$ 704,233	$ 502,105	$ 78,078

Operating Lease Commitments

We lease office or manufacturing facilities in Beijing, Shanghai, Suzhou, Guangzhou and other cities in China, and office facilities in the United States in California, Maryland, Massachusetts and New Jersey, and in Basel, Switzerland 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 aggregate future minimum payments under these non-cancelable operating leases are summarized in the table above.

Purchase Commitments

As of March 31, 2020, purchase commitments amounted to $117.3 million, of which $96.7 million related to minimum purchase requirements for supply purchased from CMOs and $20.6 million related to binding purchase obligations of inventory from BMS. We do not have any minimum purchase requirements for inventory from BMS.

Debt Obligations

Short-term Bank Loan

On January 13, 2020, BeiGene Shanghai entered into a one-year loan agreement with China Industrial Bank to borrow up to RMB200.0 million at a fixed interest rate of 5.6%. On January 19, 2020, the Company borrowed RMB80.0 million of the loan. Interest will be paid quarterly until the loan becomes fully due on January 18, 2021. As of March 31, 2020 the amount outstanding under the loan agreement was $11.3 million.

Long-term Bank Loan

On April 4, 2018, BeiGene Guangzhou Biologics Manufacturing Co., Ltd. ("BeiGene Guangzhou Factory") entered into a nine-year loan agreement with China Construction Bank to borrow RMB580.0 million at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan is secured by BeiGene Guangzhou Factory’s land use right. Interest expense will be paid quarterly until the loan is fully settled. As of March 31, 2020, we have drawn down the entire $81.9 million (RMB580.0 million) in aggregate principal amount of this loan. Maturity dates range from 2021 to 2027.

Shareholder Loan

On March 7, 2017, BeiGene Biologics Co., Ltd. ("BeiGene Biologics") entered into a Shareholder Loan Contract with Guangzhou GET Technology Development Co., Ltd. (now Guangzhou High-tech Zone Technology Holding Group Co., Ltd.) (“GET”), pursuant to which, GET provided a shareholder loan to BeiGene Biologics in the principal amount of RMB900.0 million at a fixed 8% 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 RMB900.0 million from GET.

Co-development funding commitment

Under the Amgen collaboration, the Company is responsible for co-funding global development costs for the Amgen oncology pipeline assets up to a total cap of $1,250,000. The Company is funding its portion of the co-development costs by

contributing cash and development services. As of March 31, 2020, the Company's remaining co-development funding commitment was $1,194,000.

Capital Commitments

We had capital commitments amounting to $60.6 million for the acquisition of property, plant and equipment as of March 31, 2020, which was primarily for BeiGene Guangzhou Factory's manufacturing facility in Guangzhou, China.

Other Business Agreements

We enter into agreements in the ordinary course of business with CROs to provide research and development services. These contracts are generally cancelable at any time by us with prior written notice.

We also enter into collaboration agreements with institutions and companies to license intellectual property. We may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with its collaboration agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on our balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in our financial statements.

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 ("GAAP"). The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. These include, but are not limited to, estimating the useful lives of long-lived assets, estimating variable consideration in product sales and collaboration revenue arrangements, estimating the incremental borrowing rate for operating lease liabilities, identifying separate accounting units and the standalone selling price of each performance obligation in the Company's revenue arrangements, assessing the impairment of long-lived assets, share-based compensation expenses, realizability of deferred tax assets and the fair value of financial instruments. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies as of and for the three months ended March 31, 2020, 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, 2019.

For new accounting policies adopted during the three months ended March 31, 2020 , 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.

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 $2.0 billion and $618.0 million, restricted cash of $2.7 million and $2.8 million, and short-term investments of $1.4 billion and $364.7 million at March 31, 2020 and December 31, 2019, respectively. At March 31, 2020, the majority of our cash and cash equivalents is held in U.S. treasury securities and U.S. money market funds. We also have cash and cash equivalent deposits with various major reputable financial institutions located both within and outside 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. At March 31, 2020, our short-term investments consisted of U.S. treasury securities. We believe that the U.S. treasury securities are of high credit quality and continually monitor the credit worthiness of these institutions.

The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significant increasing risk. Our primary exposure to market risk relates to fluctuations in the interest rates which are affected by changes in the general level of PRC and U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We estimate that a hypothetical 100-basis point change in market interest rates would impact the fair value of our investment portfolio as of March 31, 2020 by $5.4 million.

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

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange prices. From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For the RMB against U.S. dollars, there was depreciation of approximately 1.7% in the three months ended March 31, 2020 and depreciation of approximately 1.3% in the year ended December 31, 2019, 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 receivables, earnings or losses. Further, volatility in exchange rate fluctuations may have a significant impact on the foreign currency translation adjustments recorded in other comprehensive income (loss).

Currency Convertibility Risk

A significant portion of our expenses, 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 (the "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 three months ended March 31, 2020.

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 (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 March 31, 2020, 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 quarter ended March 31, 2020 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 we believe 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 our ADSs or ordinary shares. 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 our ADSs and ordinary shares 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 on Form 10-K for the year ended December 31, 2019.*

Risks Related to Commercialization of Our Drugs and Drug Candidates

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 or generic products to ours. If our drugs and drug candidates do not achieve an adequate level of acceptance, the sales of our drugs may be limited and we may not generate significant product 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 safe and effective treatments;
- government agencies, professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations, and organizations publishing guidelines and recommendations recommending our drugs and reimbursement;
- the potential and perceived advantages of our drugs and drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of 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, third-party payors, 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 launching and marketing our internally-developed drugs and third-party drugs. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our drugs and third-party drugs, we may not be able to generate substantial product sales revenue.

In 2017, in connection with our strategic collaboration with Celgene Logistics Sàrl, a Bristol Myers Squibb company ("BMS"), we were granted an exclusive license in the People's Republic of China ("PRC" or "China"), excluding Hong Kong, Macau and Taiwan, to commercialize BMS's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®, and acquired BMS's commercial operations in China, excluding certain functions. We started marketing BMS's approved drugs in September 2017.

In October 2019, we entered into a strategic collaboration with Amgen with respect to its commercial-stage oncology products XGEVA® (which received approval from the National Medical Products Administration ("NMPA") and was made available in China in September 2019), KYPROLIS® and BLINCYTO® and a portfolio of clinical- and late-preclinical-stage oncology pipeline products, and the agreement became effective on January 2, 2020. In April 2020, two Amgen oncology pipeline assets were removed from the collaboration due to portfolio prioritization, and the parties expect that the development plan for the assets in the portfolio will continue to evolve over time. In connection with this strategic collaboration, we are authorized to commercialize the oncology products of Amgen in China for five or seven years and have the option to retain one of the three oncology products to commercialize for as long as the product is sold in China. For each pipeline product that is approved in China, we will also have the right to commercialize the pipeline product for seven years in China and the right to retain approximately one of every three approved pipeline assets, other than AMG 510, for commercialization in China.

In November 2019, our BTK inhibitor BRUKINSA™ (zanubrutinib) received accelerated approval from the FDA as a treatment for mantle cell lymphoma ("MCL") in adult patients who have received at least one prior therapy and we launched BRUKINSA in the United States soon after approval. In December 2019, our anti-PD-1 antibody tislelizumab received approval from the NMPA as a treatment for patients with classical Hodgkin's Lymphoma ("cHL") who have received at least two prior therapies and we launched tislelizumab in China in March 2020. In April 2020, tislelizumab received approval from the NMPA as a treatment for patients with locally advanced or metastatic urothelial carcinoma ("UC"), a form of bladder cancer, with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

We continue to build our salesforce in China and the United States to commercialize our internally-developed drugs (including BRUKINSA and tislelizumab) and third-party drugs, and any additional drugs or drug candidates that we may develop or in-license, which will require significant capital expenditures, management resources and time.

We have limited experience in commercializing our internally-developed drugs, such as BRUKINSA and tislelizumab, and third-party drugs, such as ABRAXANE, REVLIMID, and VIDAZA, which we license from BMS, and XGEVA, KYPROLIS and BLINCYTO, which we have the right to commercialize under our strategic collaboration with Amgen. For example, we have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our drugs. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, our ability to successfully commercialize our drug may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in launching drugs.

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.

There can be no assurance that we will be able to further develop and successfully maintain internal sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any drug, and as a result, we may not be able to generate substantial 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. For example, both BRUKINSA and tislelizumab face substantial competition, and some of our products face or are expected to face competition from generic therapies. 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 U.S. Food and Drug Administration ("FDA"), NMPA, European Medicines Agency ("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 have and 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 drugs and 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 drugs and 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 drugs and 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.

If we are not able to continue to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drugs and 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 new drug application ("NDA") or biologics license application ("BLA") must include significant information regarding the chemistry, manufacturing and controls ("CMC") for the drug candidate. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA or BLA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that a submission will be accepted for filing and review by the FDA.

We have limited experience in obtaining regulatory approval for our drug candidates. For example, we have limited experience in preparing the required materials for regulatory submission and 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 substantial experience in obtaining regulatory approvals.

Regulatory authorities outside of the United States, such as the NMPA 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, China and Europe, 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, NMPA 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.

We have limited manufacturing capability and must rely on third-party manufacturers to manufacture our commercial products and clinical supplies, and if they fail to meet their obligations, the development and commercialization of our drugs and drug candidates could be adversely affected.

We have limited manufacturing capabilities and experience. Our drugs and drug candidates are composed of multiple components and require specialized formulations for which scale-up and manufacturing could be difficult. We have limited experience in such scale-up and manufacturing, requiring us to depend on a limited number of third parties, who may not be able to deliver in a timely manner, or at all. In order to develop drugs and drug candidates, apply for regulatory approvals, and commercialize our drugs and drug candidates, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our contract manufacturers to meet our delivery time requirements or provide adequate amounts of material to meet our needs.

We currently rely on third-party manufacturers to produce commercial quantities of drugs we are marketing, including in-licensed drugs and our internally-developed drugs, BRUKINSA and tislelizumab. In addition, if any of our other drug candidates or in-licensed drugs or drug candidates becomes approved for commercial sale, we will need to expand our internal capacity or establish additional third-party manufacturing capacity. Manufacturing partner requirements may require us to fund capital improvements, perhaps on behalf of third parties, to support the scale-up of manufacturing and related activities. We may not be able to establish scaled manufacturing capacity for an approved drug in a timely or economic manner, if at all. If we or our third-party manufacturers are unable to provide commercial quantities of such an approved drug, we will have to successfully transfer manufacturing technology to a different manufacturer. Engaging a new manufacturer for such an approved drug could require us to conduct comparative studies or utilize other means to determine bioequivalence of the new and prior manufacturers' products, which could delay or prevent our ability to commercialize such an approved drug. If we or any of these manufacturers is unable or unwilling to increase its manufacturing capacity or if we are unable to establish alternative arrangements on a timely basis or on acceptable terms, the development and commercialization of such an approved drug may be delayed or there may be a shortage in supply. Any inability to manufacture our drugs, drug candidates, in-licensed drugs and drug candidates or future approved drugs in sufficient quantities when needed could seriously harm our business and our financial results.

Manufacturers of our approved drugs, if any, must comply with good manufacturing practice ("GMP") requirements enforced by the FDA, NMPA, EMA and other comparable foreign health authorities through facilities inspection programs. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our approved drugs may be unable to comply with these GMP requirements and with other FDA, NMPA, EMA, state, and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of

product approval. If the safety of any quantities supplied is compromised due to a manufacturer's failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our drugs, which would seriously harm our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE in mainland China. As a result, there has been a disruption in ABRAXANE supply in China and we are working closely with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE. We do not know when the NMPA suspension of ABRAXANE will be lifted and we will be able to re-commence sales of ABRAXANE. As such, we do not expect revenue from ABRAXANE until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE and qualified drug is manufactured and available for sale in China.

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 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. Our operations are 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 are 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 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 third-party payor, not just governmental payors, but also private insurers. These laws are enforced by various state agencies and through private actions. 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 that restrict the payments made to healthcare providers and other potential referral sources. Several states and local laws also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and require the registration of pharmaceutical sales representatives. State laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. 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, individual imprisonment, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws.

In addition, the approval, commercialization, and other activities related to any of our drugs and drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws such as those mentioned above,

among other non-U.S. laws. As with the state equivalents mentioned above, some of these non-U.S. laws may be broader in scope. Data privacy and security laws and regulations in non-U.S. jurisdictions may also be more stringent than those in the United States (such as the European Union ("EU"), which adopted the General Data Protection Regulation, which became effective in May 2018).

If any of the physicians or other providers or entities with whom we 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 development and/or 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 strategy. For example, in connection with our collaboration with Amgen we have been granted the right to commercialize three of Amgen's oncology products in China for five or seven years and will have the option to retain one of the three oncology products to commercialize for as long as the product is sold in China. We have also agreed to collaborate with Amgen on the global development and commercialization in China of a portfolio of Amgen oncology pipeline products. In April 2020, two Amgen oncology pipeline assets were removed from the collaboration due to portfolio prioritization, and the parties expect that the development plan for the assets in the portfolio will continue to evolve over time. We initially intend to focus on opportunities in China, in particular. If we fail to obtain licenses or enter into collaborative arrangements with third parties in other markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- 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, including the loss of normal trade status between China and the United States;
- 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 other anti-bribery and corruption laws; and
- business interruptions resulting from geo-political actions, including trade disputes, war and terrorism, disease or public health epidemics, such as the coronavirus impacting China and elsewhere, 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 Clinical Development and Regulatory Approval of Our Drugs and Drug Candidates

We depend substantially on the success of the clinical development of our drugs and drug candidates. If we are unable to successfully complete clinical development, obtain additional regulatory approvals and commercialize our drugs and drug candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business depends on the successful development, regulatory approval and commercialization of our drugs and drug candidates for the treatment of patients with cancer, such as BRUKINSA, for which we obtained FDA approval for the treatment for MCL in adult patients who have received at least one prior therapy, and tislelizumab, for which we obtained NMPA approval for the treatment of patients with cHL who have received at least two prior therapies and of patients with previously treated locally advanced or metastatic UC, and other drug candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development of our drugs and drug candidates. The success of our drugs and drug candidates depends 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 ("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 valid patent, trade secret or other intellectual property rights of third parties;
- successfully launching our drugs and drug candidates, if and when approved;
- obtaining favorable reimbursement from third-party payors for drugs and drug candidates, if and when approved;
- competition with other products;
- continued acceptable safety profile following regulatory approval; and
- manufacturing or obtaining sufficient supplies of our drugs, drug candidates and any competitor drug products that may be necessary for use in clinical trials for evaluation of our drug candidates and commercialization of our drugs.

If we do not achieve and maintain 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 additional regulatory approvals for and/or to successfully commercialize our drugs and 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.

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.

Even if our future clinical trial results show favorable efficacy and impressive durability of anti-tumor 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 ("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 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 current GMP, or obtaining sufficient quantities of a drug candidate for use in a clinical trial or for commercialization; 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 drugs and drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates or commercialization of our drugs 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 warning labels or restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Significant clinical trial, manufacturing or regulatory 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.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol, competition from competing companies, and natural disasters or public health epidemics, such as the coronavirus impacting China and elsewhere.

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 delay or prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Risks Related to Extensive Government Regulation

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

All jurisdictions in which we conduct or intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We initially intend to focus our activities in the major markets of the United States, China, EU, and other select countries. 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. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE in mainland China. As a result, there has been a disruption in ABRAXANE supply in China and we are working closely with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE. Additionally, although we obtained FDA approval of BRUKINSA for the treatment of adult patients with MCL who have received at least one prior therapy and NMPA approval of tislelizumab for patients with cHL who have received at least two prior therapies and for patients with previously treated locally advanced or metastatic UC, the FDA and NMPA could later suspend or withdraw these approvals. In order to market approved products in any given jurisdiction, we must comply with numerous and varying regulatory requirements of such jurisdiction regarding safety, efficacy and quality. In any event, the receipt of FDA, NMPA or other regulatory approval does not assure ultimate success of our commercialization efforts for our drugs.

The approval processes of regulatory authorities in the United States, China, Europe 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 FDA, the NMPA, the EMA, and other comparable regulatory authorities is unpredictable and 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 be delayed or 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;

- reporting or 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;
- failure to satisfy regulatory conditions regarding endpoints, patient population, available therapies and other requirements for our clinical trials in order to support marketing approval on an accelerated basis or at all;
- 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, NMPA, EMA or a comparable regulatory authority may require more information, including additional preclinical, 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.

Our development activities and regulatory filings also could be harmed or delayed by a shutdown of the U.S. government, including the FDA, or other governments and regulatory authorities.

We believe that our drug candidates' designation in China as Category 1 products should confer certain regulatory advantages to 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 NMPA, 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 NMPA, which is a favored category for regulatory review and approval.

The NMPA 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 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 regulatory exclusivity for NMPA-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 commonly referred to as the "Hatch-Waxman Amendments," 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. The Hatch-Waxman Amendments also have 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 months. Finally, the Hatch-Waxman Amendments provide 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. The Economic and Trade Agreement Between the United States of America and the People's Republic of China announced in January 2020 (the "Trade Agreement") also provides for patent linkage systems and patent term extension systems. To be implemented, this framework will require adoption of legislation and regulations. To date, the NMPA has issued several draft implementing regulations in this regard for public comment but no regulations have been formally issued, and these concepts were not included in the revised Drug Administration Law that became effective on December 1, 2019 and contains significant other changes to the drug regulatory landscape in China. 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, NMPA and EMA inspections, which may result in a longer and costlier current GMP inspection and approval process by the FDA, NMPA or EMA for our Chinese manufacturing processes and third-party contract manufacturers.

To obtain FDA, NMPA and EMA approval for our drug candidates in the United States, China and Europe, we will need to undergo strict pre-approval inspections of our manufacturing facilities, which we have located in China, or the manufacturing facilities of our contract manufacturers located in China and elsewhere. Historically, some manufacturing facilities in China have had difficulty meeting the FDA's, NMPA's or EMA's standards. When inspecting our or our contractors' Chinese manufacturing facilities, the FDA, NMPA or EMA might cite GMP 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, NMPA or EMA notes deficiencies as a result of its inspection, it will generally reinspect the facility to determine if the deficiency has been remediated to its satisfaction. The FDA, NMPA or EMA 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, NMPA and EMA as to our compliance with GMP in a timely basis, marketing approval for our drug candidates 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 ("AEs") caused by our drugs and 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, NMPA, EMA or other comparable regulatory authorities, or could result in limitations or withdrawal following approvals. If the conduct or results of our trials or patient experience following approval reveal a high and unacceptable severity or prevalence of AEs, our trials could be suspended or terminated and the FDA, NMPA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates or require us to cease commercialization following approval.

Numerous drug-related AEs and serious AEs ("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 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 our press releases and scientific and medical presentations released from time to time we disclose clinical results for our drug candidates, including the occurrence of AEs and SAEs. Each such disclosure 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 ("IRAEs") have been associated with treatment with checkpoint inhibitors such as tislelizumab, including immune-mediated pneumonitis, colitis, 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 implement a Risk Evaluation Mitigation Strategy ("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 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 drugs and 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. For example, BRUKINSA and tislelizumab will continue to be subject to post-approval development and regulatory requirements, which may limit how they are manufactured and marketed, and could materially impair our ability to generate revenue. As such, we and our third-party manufacturers will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. Additionally, to the extent we want to make certain changes to the approved products, product labeling, or manufacturing processes, we will need to submit new applications or supplements to regulatory authorities for approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, EMA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to GMP regulations. As such, we and our contract manufacturers are and will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA or BLA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The failure to comply with these requirements could have a material adverse effect on our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE in mainland China. As a result, there has been a disruption in ABRAXANE supply in China and we are working closely with

BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply.

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, NMPA, EMA or comparable regulatory authorities may also require a REMS program or comparable program as a condition of approval of our drug candidates or following approval, as is the case with REVLIMID. In addition, if the FDA, NMPA, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, establishment registration, as well as continued compliance with GMP and good clinical practice ("GCP") for any clinical trials that we conduct post-approval.

The FDA, NMPA, EMA 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, NMPA, EMA 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, NMPA, EMA 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, NMPA, 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, NMPA, 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 are able to obtain accelerated approval of any of our drug candidates, as we have done with the initial approval of BRUKINSA in the United States, 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 NMPA 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, NMPA, 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 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, or we may experience disruptions in the commercialization of our approved drugs. For example, we have in-licensed drug candidates from third parties to conduct clinical trials in combination with our drug candidates. We may rely on those third parties to manufacture the in-licensed drug candidates and may not have control over their manufacturing process. If these third parties encounter any manufacturing difficulties, disruptions or delays and are not able to supply sufficient quantities of drug candidates, our drug combination study program may be delayed.

Reimbursement may be limited or unavailable for our drugs and 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. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. The EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

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 and results of operations.

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 on adequate terms, or at all, from government health administration authorities, private health insurers and other organizations. In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

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. The principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

Coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable regulatory authorities in other countries. 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 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.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be

sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug 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 product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (“ASP”) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Furthermore, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries, proposed bills or announced plans intended to, among other things, bring more transparency to drug pricing, set patient spending caps, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer’s patient programs, reform government program reimbursement methodologies for drug products, and allow import of lower-priced drugs from other countries. While some proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be.

In the United States, since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act (the “ACA”), and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Additionally, the current administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. It is not clear what effect these measures may have on our business if we receive coverage for our drugs and drug candidates

In China, drug prices are typically lower than in the United States and Europe, and until recently, the market has been dominated by generic drugs. The PRC Ministry of Human Resources and Social Security or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List (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 or provincial reimbursements lists, or if they are, that they will be included at a price that allows us to be commercially successful. Products included in the NRDL have been typically generic and essential drugs. Innovative drugs similar to our drugs and 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.

In addition, in January 2019, the Chinese government launched a national program for volume-based, centralized drug procurement with minimum quantity commitments in an attempt to negotiate lower prices from drug manufacturers and reduce the price of drugs. The program was initially rolled out in 11 pilot cities and was expanded nationwide in September 2019. Under the program, one of the key determining factors for a successful bid is the price. The government will award a contract to the lowest bidders who are able to satisfy the quality and quantity requirements. The successful bidders will be guaranteed a sale volume for at least a year. A volume guarantee gives the winner an opportunity to gain or increase market share. The volume guarantee is intended to make manufacturers more willing to cut their prices to win a bid. It may also enable manufacturers to lower their distribution and commercial costs. Many types of drugs are covered under the program, including drugs made by international pharmaceutical companies and generics made by domestic Chinese manufacturers. For example, in January 2020, ABRAXANE and its generic forms were included in the program. We won the bid and became one of the three companies who were awarded a government contract, with a price for sales of ABRAXANE under the government contract that

would have been significantly lower than the price that we have been charging in 2019 and into 2020. On March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE in mainland China. As a result, there has been a disruption in ABRAXANE supply in China and we are working closely with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE. Moreover, the program may change how generic drugs are priced and procured in China and is likely to accelerate the replacement of originator drugs with generics. We cannot be sure whether there will be any changes to the program in the future. The implementation of the program may negatively impact our existing commercial operations in China as well as our strategies on how to commercialize our drugs in China, especially if one of our drugs is included in the program but does not win the bid, which could have a material adverse effect on our business, financial condition and results of operations.

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 and drug candidate that we in-license or successfully develop.

There may be significant delays in obtaining reimbursement for approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or other comparable regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. 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, for example those in the EU, 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 drugs and drug candidates and affect the prices we may obtain.

In the United States, China, the EU 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 and drug candidates.

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 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 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 biotechnology 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, developing and operating internal manufacturing capabilities, and the commercialization of our in-licensed and internally-developed drugs. We have limited experience in completing large-scale, pivotal or registrational clinical trials and obtaining, maintaining or expanding regulatory approvals for our drugs and drug candidates. Additionally, we have limited experience in manufacturing, sales, marketing or distribution of pharmaceutical products. We have two internally-developed drugs approved for commercial sale and have only generated limited revenue from internally-developed product sales. Since September 2017, we have generated revenues from the sale of drugs in China licensed from BMS, and since the fourth quarter of 2019, we have generated revenues from our internally-developed products. 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 March 31, 2020 and December 31, 2019, we had an accumulated deficit of $2.3 billion and $2.0 billion, 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 in the near term as we continue and expand our development of, and seek regulatory approvals for, our drug candidates, and our manufacturing facilities, commercialize our drugs and launch new drugs, if approved, maintain and expand regulatory approvals, contribute up to $1.25 billion to the global development of a portfolio of Amgen pipeline assets, and commercialize the drugs that we have licensed from BMS and drugs that we have the right to commercialize under our collaboration with Amgen 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 Hong Kong. We will also incur costs in support of our growth as a commercial-stage global biotechnology 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 our manufacturing activities, the cost of commercializing our 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, development, manufacturing and commercialization efforts, expand our business or continue our operations.

We may 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, scale up and availability of manufacturing resources, 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 used $750.3 million and provided $547.7 million of net cash during the years ended December 31, 2019 and 2018, respectively, and used $341.9 million and $172.0 million of net cash during the three months ended March 31, 2020 and 2019, respectively. We

recorded negative net cash flows from operating activities in 2019 and 2018 primarily due to our net losses of $950.6 million and $674.0 million, respectively. Although we recorded positive net cash flows from operating activities in 2017, primarily due to the upfront fees received from the BMS collaboration, we cannot assure you that we will be able to generate positive cash flows from operating activities in the future. In January 2020, we received gross proceeds of approximately $2.78 billion from the issuance of our ordinary shares in the form of ADSs to Amgen. Under the collaboration with Amgen, we will equally share profits/losses with Amgen for Amgen's oncology products in China during each product's respective commercialization period and will also be eligible to receive royalties on sales of Amgen's products in China or outside of China in the future, based on specified terms.

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 financing 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, contributing to the global development of a portfolio of Amgen pipeline assets, developing our manufacturing capabilities and securing drug supply, and launching and commercializing our and our collaborators' drugs and any additional drug candidates for which we receive regulatory approval, including building and maintaining a commercial organization to address markets in China, the United States and other countries.

Since September 2017, we have generated revenues from the sale of drugs in China licensed from BMS, and since the fourth quarter of 2019, we have generated revenues from our internally-developed products. 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 may not be sufficient to enable us to complete all global development or commercially launch all of our current drugs and drug candidates for the currently anticipated indications and to invest in additional programs. Accordingly, we may 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:

- our ability to successfully market our approved drugs;
- 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 drugs and drug candidates that we may in-license and develop;
- the amount and timing of the development, 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 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, licensing 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 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, the Euro, 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 do not regularly 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 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.

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 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 $2.0 billion, $618.0 million and $712.9 million, restricted cash of $2.7 million, $2.8 million and $27.8 million and short-term investments of $1.4 billion, $364.7 million and $1.1 billion at March 31, 2020, December 31, 2019 and 2018, 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 March 31, 2020 and December 31, 2019, our short-term investments consisted of U.S. Treasury securities.

Although we believe that the U.S. Treasury securities 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 and drugs 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 and drugs from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the drugs, 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 patents and/or 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 applications 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.

In addition, under the 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 National Intellectual Property Administration, or NIPA, for security 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 (the "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 drugs or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drugs or 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, drugs, 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 drugs 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 BMS 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 drugs even if we successfully obtain patent protection. 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 drugs and 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, 2019. 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 or licensed from 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 or the licensors of our patents in order to enforce such patents against 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 drugs or 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. In addition, we may not be able to enforce patents that we in-license from third parties, who may delay or decline to enforce patents in the licensed territory.

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 drugs and 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 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 drugs or 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 drugs or 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.

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 drugs or drug candidates.

Our commercial success depends in part on our avoiding infringement of the valid 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 of our drugs and 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 drugs and 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 drugs and 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 drugs and 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 drugs or 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 and 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 BRUKINSA 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 or drug candidate was to be approved for sale in the United States before the expiration of the relevant patents, we would need a license to commercialize the drug or 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 or drug candidate before the expiration of corresponding patents covering that drug or 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 regulatory exclusivity for any drugs or 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 drugs or drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the 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 yet, and implementation of the patent term extension proposed in the Innovation Opinion and the Trade Agreement 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.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drugs or 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 drugs and 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. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which

may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. 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

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

We rely on third-party distributors to distribute our approved drugs. For example, we rely on a sole third-party distributor to distribute BMS's approved cancer therapies, ABRAXANE, REVLIMID, and VIDAZA, and multiple third-party distributors for the distribution of BRUKINSA and tislelizumab. We also expect to rely on third-party distributors to distribute our other internally-developed drug products, if approved, and the oncology products of Amgen to be commercialized by us in China under the collaboration with Amgen. 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 drugs to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributors, who may fail to distribute our drugs in the manner we contemplate. For example, while we have long-standing business relationship with our sole distributor for the in-licensed products from BMS, the agreement we entered into with our sole distributor can be terminated by both parties upon six months' written notice. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our products to hospitals, medical institutions and sub-distributors, they may terminate their relationship with us. While we believe alternative distributors are readily available, there is a risk that, if the distribution of our drugs is interrupted, our sales volumes and business prospects could be adversely affected.

****We rely on third parties to manufacture at least a portion of our commercial and clinical 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 manufacturing facilities that may be used for clinical-scale manufacturing and processing and are building a biologics manufacturing facility 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. ("Boehringer Ingelheim") and entered into a commercial supply agreement for BRUKINSA with Catalent Pharma Solutions, LLC ("Catalent"). In addition, we rely on BMS

and its third-party manufacturers for supply of ABRAXANE, REVLIMID, and VIDAZA in China. We will be dependent on Amgen for the supply of the drugs that we plan to develop and commercialize in China under the collaboration with Amgen. We have limited experience in manufacturing or processing our drugs and drug candidates on a commercial scale, including BRUKINSA and tislelizumab. Additionally, 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, NMPA, EMA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drugs and drug candidates. This evaluation would require new testing and GMP-compliance inspections by FDA, NMPA, EMA or other comparable regulatory authorities;

- our manufacturers may have little or no experience with manufacturing our drugs and 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 drugs and 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. For example, we encountered supply disruptions of ABRAXANE in 2019, and in 2020 the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS, as further described below;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with GMPs 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. For example, in 2020, based on inspection findings at BMS's contract manufacturing facility in the United States, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS, as further described below;

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

- 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 drug component suppliers may be subject to disruptions in their business, including unexpected demand for or shortage of raw materials or components, cyber-attacks on supplier systems, labor disputes or shortage and 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 development or 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.

For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE in mainland China, including ABRAXANE that we sold to our distributor prior to the recall. During the first quarter of 2020, we recognized revenue related to sales of ABRAXANE that was subsequently recalled from the market by BMS. We have not reduced the net revenue that was recognized on sales of ABRAXANE that was recalled in the first quarter of 2020, since we do not expect to refund any of the revenue to our customer. However, all of the financial payments for the recall have not been completed between the parties and it is possible that we will be required to record costs in future periods in connection with the recall.

There has been a disruption in ABRAXANE supply in China and we are working closely with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an

alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE. Additionally, there are risks that our supplemental import drug application for ABRAXANE, which was accepted by the NMPA in May 2019, as well as our clinical study evaluating tislelizumab in combination with ABRAXANE, may be adversely affected. Until the corrective actions are implemented and accepted by the NMPA or the approval of an alternative manufacturing site is granted, the NMPA may refuse to grant approval of applications for ABRAXANE and/or refuse to grant import certificates for ABRAXANE. We do not know when the NMPA suspension of ABRAXANE will be lifted and we will be able to re-commence sales of ABRAXANE. As such, we do not expect revenue from ABRAXANE until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE and qualified drug is manufactured and available for sale in China.

Currently, the raw materials for our manufacturing activities are supplied by multiple source suppliers, although portions of our supply chain may rely on sole 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. For example, the COVID-19 pandemic could have a broad impact on the production and supplies of active ingredients or other raw materials and result in a potential shortage of supply. If we or our third party manufacturers experience a shortage in supply of active ingredients or other raw materials, we may not be able to continue to supply adequate levels of our drugs to our customers, which would have a negative impact on our business and results of operations.

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 the 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 drugs and 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 GMPs. Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE in mainland China. As a result, there has been a disruption in ABRAXANE supply in China and we are working

closely with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE. In addition to any possible sanctions, we do not expect to recognize revenue from sales of ABRAXANE in China until the suspension on the importation, sales and use of ABRAXANE in China is lifted by the NMPA and qualified drug is manufactured and available for sale in China, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 or impact commercialization or continuous supply of approved drugs. 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. For example, we are working closely with BMS to restore supply of ABRAXANE as soon as possible, including through BMS's application to qualify an alternative manufacturing site for China supply, which requires prior review and approval by the NMPA and is subject to various requirements described above.

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 drugs and 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, NMPA, 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 and other regulatory requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA, 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 GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We could also be subject to government investigation and enforcement actions.

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

Switching or adding additional CROs involves additional cost and 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, among other factors, our ability to identify a collaboration partner and negotiate acceptable terms for a collaboration agreement and to work effectively with collaborators to develop our drugs and 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 have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such 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 research, development and commercialization efforts with respect to our drugs and drug candidates and any future drugs and 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.

In August 2017, we acquired Celgene Corporation's commercial operations in China and an exclusive license to Celgene's (now BMS's) commercial cancer portfolio in China, ABRAXANE, REVLIMID, and VIDAZA (the "BMS China License"). On October 31, 2019, we entered into a strategic collaboration with Amgen with respect to its commercial-stage oncology products XGEVA, KYPROLIS and BLINCYTO and a portfolio of clinical- and late-preclinical-stage oncology pipeline products. We are authorized to commercialize the three oncology products in China for five or seven years and have the option to retain one of the three oncology products to commercialize for as long as the product is sold in China. For each pipeline product that is approved in China, we have the right to commercialize the pipeline product for seven years in China and the right to retain approximately one of every three approved pipeline assets, other than AMG 510, for commercialization in China.

Our strategic collaborations with Amgen and BMS involve numerous risks. For our collaboration with Amgen, we cannot be certain that we will achieve the financial and other benefits that led us to enter into the collaboration. Moreover, we may not achieve the revenue and cost synergies expected from our collaborations with Amgen or BMS for their commercial products in China, 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. Lastly, strategic collaborations can be terminated for various reasons. For example, our strategic collaboration with Celgene for the development and commercialization of tislelizumab, which we entered into in connection with the BMS China License in 2017, was terminated in June 2019 in advance of the acquisition of Celgene by BMS, and we received a $150 million payment and regained global rights to tislelizumab. The termination of the collaboration agreement for tislelizumab did not impact the BMS China License, which remains in effect.

Additionally, from time to time, we may enter into joint ventures with other companies. Establishment of a joint venture involves significant risks and uncertainties, including (i) our ability to cooperate with our strategic partner, (ii) our strategic partner having economic, business, or legal interests or goals that are inconsistent with ours, and (iii) the potential that our strategic partner may be unable to meet its economic or other obligations, which may require us to fulfill those obligations alone.

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 drugs and 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 drugs and 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 or drug candidate, we can expect to relinquish some or all of the control over the future success of that drug or drug candidate to the third party. For any drugs or drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than us, and any agreement that we do enter may result in the anticipated benefits.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drugs and 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 drugs and 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 drugs and drug candidates; and
- collaborators may own or co-own intellectual property covering our drugs and drug candidates 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 and drug candidates 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 be able to fulfill all of our contractual obligations in a timely manner or achieve the revenue, specific net income or other goals that justify 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 drugs and drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

Risks Related to Our Industry, Business and Operations

Our future success depends on our ability to retain 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 of directors; and the other principal members of our management and scientific teams. Although we have formal employment agreements or offer letters 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 or offer letters with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel 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 and executing our discovery, clinical development, manufacturing 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, manufacturing 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 2019, we had 2,070 employees, and we ended the year with 3,359 employees, an increase of approximately 62%. As of March 31, 2020, we had approximately 3,600 employees. Most of our employees are full-time. As our research, development, manufacturing 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 develop and 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, 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, manufacture and commercialize our drugs and drug candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals.

We incur significant costs as a result of operating as a public company in the United States and Hong Kong, 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 and Hong Kong, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the listing rules of the Nasdaq Stock Market ("Nasdaq"), and The Stock Exchange of Hong Kong Limited (the "HKEx"), and incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), together with rules implemented by the SEC and applicable market regulators, and the listing rules of the Nasdaq and HKEx. 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.

For example, 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 in 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, HKEx 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.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For example, in connection with the Amgen transaction, we issued to Amgen a total of 206,635,013 ordinary shares in the form of ADSs, representing 20.5% of the issued share capital of the Company after giving effect to the share issuance, which resulted in Amgen becoming our largest shareholder and the ownership of our existing shareholders being diluted.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (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 (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 the PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (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 (the "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 (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.

We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (the "CFIUS") and other agencies, including the Foreign Investment Risk Review Modernization Act (the "FIRRMA"), adopted in August 2018.

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 CFIUS, the SAMR, the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether those complementary businesses we may acquire in the future would be deemed to be in an industry that raises “national defense and security” or “national security” concerns.

However, CFIUS, MOFCOM or other government agencies may publish explanations in the future determining that certain of the complementary business is in an industry subject to the security review, in which case our future acquisitions in the United States and 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 and corruption 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 (the "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 and corruption laws of other jurisdictions, particularly China. The anti-bribery laws in China generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. As our business has expanded, the applicability of the FCPA and other anti-bribery and corruption 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 United States, PRC or other countries’ anti-corruption and 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 United States, 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.

Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Our procedures and controls to monitor anti-bribery and corruption 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 and corruption laws, our reputation could be harmed and we could incur criminal or civil penalties, including but not limited to imprisonment, criminal and civil fines, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs, 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.

If we or our CROs or contract manufacturing organizations ("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 or insurance coverage. 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 that 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 information technology systems, or those used by our CROs, CMOs, or other collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization programs.

Despite the implementation of security measures, our internal information technology systems and those of our CROs, CMOs and other collaborators, contractors and consultants are vulnerable to damage from internal or external events, such as computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures, which compromise the confidentiality, integrity and availability of the systems. 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 research, development, manufacturing, gaining regulatory approval for our drug candidates and commercialization efforts 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 cause loss of data, damage to system and data and leave us unable to utilize key business systems or access important data needed to operate our business, including conducting research and development, gaining regulatory approval for our drug candidates or manufacturing and selling our products. Our CROs, CMOs or other collaborators, contractors or consultants may face similar risks, and service disruptions or security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential 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, 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, business email compromise attacks, or 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 respond to these threats or breaches and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. 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. In addition, there can be no assurance that our internal information technology systems or those of our CROs, CMOs and other collaborators, contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

In the United States, we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels. Numerous laws and regulations, including security breach notification laws, health information privacy laws, and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/679 ("GDPR"), which became effective in May 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including, but not limited to, requirements relating to having legal bases for processing personal information, including personal health data, relating to identifiable individuals and transferring such information outside the European Economic Area (including to the United States), providing information to those individuals regarding the data processing of their personal information, implementing safeguards to keep personal information secure and confidential, having data processing agreements with third parties who process personal information, acquiring consent of the individuals to whom the personal data relates, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, and recordkeeping. The GDPR imposes strict rules on the transfer of personal data to countries outside the European Economic Area, including the United States, and also imposes restrictions on cross-border data transfers. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20 million or up to 4% of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. Despite our best efforts to comply, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. National laws of member states of the EU are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the Cyber Security Law of the PRC (the "Cyber Security Law"), which became effective in June 2017, created China's first national-level data protection for "network operators," which may include all

organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Drafts of some of these measures have now been published, including the draft rules on cross-border transfer of personal information published by the China Cyberspace Administration in 2017 and 2019, which may, upon enactment, require security review before transferring human health-related data out of China. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the Regulation on the Administration of Human Genetic Resources promulgated by the State Council (the "HGR Regulation"), which became effective on July 1, 2019, applies to activities that involve sampling, biobanking, use of HGR materials and associated data, in China, and provision of such to foreign parties. The HGR Regulation prohibits both onshore or offshore entities established or actually controlled by foreign entities and individuals from sampling or biobanking any China HGR in China and require approval for the sampling of certain HGR and biobanking of all HGR by Chinese parties. Approval for any export or cross-border transfer of the HGR material is also required. The HGR Regulation also requires that foreign parties should ensure the full participation of Chinese parties in international collaborations and all records and data must be shared with the Chinese parties. If the Chinese parties fail to comply with data protection laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, it could result in a loss of our confidential information and subject us to litigation and government enforcement actions. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our entities and responsible persons from further HGR projects. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

We expect that these areas will receive greater attention and focus from regulators going forward and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under global data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including the GDPR and Cyber Security Law. In addition, a data breach affecting personal information, including health information, could result in significant management resources, legal and financial exposure and reputational damage that could potentially have an adverse effect on our business.

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

In March 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (the "Scientific Data Measures"), which provides a broad definition of scientific data and relevant rules for the management of scientific data in China. 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 that 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 preclinical 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 condition 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.

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, CMOs, suppliers and other contractors and consultants, could be subject natural or man-made disasters, public health epidemics or other 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 such business interruptions, government shutdowns or withdrawn funding. The occurrence of any of these business interruptions 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 disasters, public health epidemics or other business interruptions. Damage or extended periods of interruption to our or our vendors' corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, public health epidemics or other events could cause us to delay or cease development or commercialization of some or all of our drugs and drug candidates. Although we maintain 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. For example, the COVID-19 outbreak could negatively impact our business and our financial performance. Our clinical development and commercial efforts could be delayed or otherwise negatively impacted, as patients may be reluctant to go to the hospitals to receive treatment. Additionally, the commercial or clinical supply of our drugs and drug candidates could be negatively impacted due to reduced operations or a shutdown of our or our third-party manufacturing facilities, distribution channels and transportation systems, or shortages of raw materials and drug product.

****Our business and results of operations could be adversely affected by public health crises and natural catastrophes or other disasters outside of our control in the locations in which we, our suppliers, CROs, CMOs and other contractors operate.***

Our global operations expose us to risks associated with public health crises, such as epidemics and pandemics, natural catastrophes, such as earthquakes, hurricanes, typhoons, or floods, or other disasters such as fires, explosions and terrorist activity or war that are outside of our control, including government reactions due to such events. Our business operations and those of our suppliers, CROs, CMOs and other contractors may potentially suffer interruptions caused by any of these events.

In December 2019, the COVID-19 began to impact the population in China and since January 2020, the COVID-19 outbreak has been spreading around the world. The continued spread of COVID-19 has negatively impacted our business and results of operations, including commercial sales, regulatory interactions and inspections, and clinical trial recruitment and participation. In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring many employees to work remotely. We have already suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the United States, China, Europe and other geographies where we or our third party suppliers and contract manufacturers or contract research organizations operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, our results of operations and financial condition.

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 United States 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 or drug candidate; and a decline in our 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 product liability coverage which we believe to be sufficient in light of our current products and clinical programs, the amount of such insurance coverage may not be adequate, and 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 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 or disputes, 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; laws and regulations on foreign investment in the United States under the jurisdiction of the CFIUS and other agencies, including the FIRRMA adopted in August 2018; the effects of applicable local tax regimes and potentially adverse tax consequences; the impact of public health epidemics on employees, our operations and the global economy, such as the COVID-19 outbreak impacting the world; restrictions on international travel and commerce; and significant adverse changes in local currency exchange rates. For example, the withdrawal of the United Kingdom from the EU effective on January 31, 2020, commonly referred to as "Brexit," may cause increased economic volatility, affecting our operations and business. In addition, on July 27, 2017, the United Kingdom Financial Conduct Authority, which regulates London Interbank Offered Rate ("LIBOR"), announced that it will no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator after 2021, and it is anticipated that LIBOR will be phased out and replaced by 2022. While various replacement reference rates have been proposed, an alternative reference rate to LIBOR has not yet been widely adopted. As such, the replacement of LIBOR could have an adverse effect on the market for, or value of, LIBOR-linked financial instruments.

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, Guangzhou, and Suzhou, China. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction or expansion, regulatory evaluation and/or approval of our facilities are delayed, we may not be able to manufacture sufficient quantities of our drugs and drug candidates, 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.

In addition to the similar manufacturing risks described in "Risks Related to Our Reliance on Third Parties," our manufacturing facilities will be subject to inspection in connection with clinical development and new drug approvals and ongoing, periodic inspection by the FDA, NMPA, EMA or other comparable regulatory agencies to ensure compliance with GMP and other regulatory requirements. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or 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. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, NMPA, 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 GMP regulations and other requirements of the FDA, NMPA, 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 supply commercial quantities for our marketed products, produce our drugs in the quantities that we believe will be required to meet anticipated market demand, and to supply clinical drug material to support the continued growth of our clinical programs, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production, which will require substantial additional expenditures and various regulatory approvals and permits. 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. 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, plant 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 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 interruption or failure of our manufacturing facilities or processes.

Future operating results could be negatively affected by changes in tax rates, the adoption of new tax legislation in the jurisdictions in which we operate, or exposure to additional tax liabilities.

The nature of our international operations subjects us to local, state, regional and national tax laws in jurisdictions around the world. Our future tax expense could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities or changes in tax laws or their interpretation. Additionally, tax rules governing cross-border activities are continually subject to modification as a result of both coordinated actions by governments and unilateral measures designed by individual countries, both intended to tackle concerns over base erosion and profit shifting (BEPS) and perceived international tax avoidance techniques. For example, the Cayman Islands has enacted the International Tax Co-operation (Economic Substance) Law (2020 Revision) (the "Economic Substance Law"), which originally

took effect on January 1, 2019, and which is accompanied by Guidance on Economic Substance for Geographically Mobile Activities (Version 2.0; April 30, 2019) published by the Cayman Islands Tax Information Authority. The Economic Substance Law embraces a global initiative to combat BEPS and demonstrates the continued commitment of the Cayman Islands to international best practice. The Economic Substance Law provides that relevant entities that existed before January 1, 2019 and that had been conducting relevant activities by that date must comply with the economic substance requirements from July 1, 2019, and relevant entities that are established from January 1, 2019 onwards have to comply with the requirements from the date they commence the relevant activity. Although we believe that we currently are not required to comply with the economic substance requirements under the Economic Substance Law, we cannot predict any changes to the legislation or its interpretation in the future. If we are subject to compliance with the economic substance requirements in the future, our business and results of operations could be negatively impacted if we are required to make changes to our business in order to gain compliance or if we fail to comply.

We have received tax rulings from various governments that have jurisdictional authority over our operations. If we are unable to meet the requirements of such agreements, or if they expire or are renewed on less favorable terms, the result could negatively impact our future earnings. Additionally, the European Commission has opened formal investigations into specific tax rulings granted by several countries to specific taxpayers. While we believe that our rulings are different than those being discussed, the ultimate resolution of such activities cannot be predicted and could also have an adverse impact on future operating results.

If we are not able to successfully develop and commercialize Amgen's oncology products in China, the expected benefits of the collaboration will not materialize.

We have a Collaboration Agreement with Amgen pursuant to which we and Amgen have agreed to collaborate on (i) the commercialization of Amgen's oncology products XGEVA, KYPROLIS and BLINCYTO in China, and (ii) the global development and commercialization in China of a portfolio of Amgen clinical- and late-preclinical-stage pipeline products. In April 2020, two Amgen oncology pipeline assets were removed from the collaboration due to portfolio prioritization, and the parties expect that the development plan for the assets in the portfolio will continue to evolve over time. The Amgen transaction involves numerous risks, including unanticipated costs and diversion of our management's attention from our other drug discovery and development business. There can be no assurance that we will be able to successfully develop and commercialize Amgen's oncology products in China, which could disrupt our business and harm our financial results.

Moreover, we may not achieve the revenue and cost synergies expected from the Amgen transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from the Amgen transaction may be offset by increases in other expenses, operating losses or problems in our business unrelated to the Amgen transaction. As a result, there can be no assurance that such synergies will be achieved.

Risks Related to Our Doing Business in the PRC

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

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, which we expect will continue. While we believe our strategies regarding pharmaceutical research, development, manufacturing and commercialization in China are aligned with the Chinese government's policies, they may in the future diverge, requiring a change in our strategies. Any such change may result in increased compliance costs on our business or cause delays in or prevent the successful research, development, manufacturing 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. 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. Reports of what have come to be viewed as significant quality-control failures by Chinese vaccine manufacturers have led to enforcement action against officials responsible for implementing national reforms favorable to innovative drugs (such as ours). While not directly affecting us, this macro-industry event could cause state or private resources to be diverted away from fostering innovation and be redirected toward regulatory enforcement, which could adversely affect our research, development, manufacturing and commercialization activities and increase our compliance cost.

Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments 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 or changes in government relations between China and the United States or other governments, such as the ongoing trade war between the United States and China. 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, or if relations between China and the United States or other governments deteriorate, 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 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.

The Foreign Investment Law of the PRC (the "Foreign Investment Law") and the Implementing Rules to the Foreign Investment Law of the PRC (the "Implementing Rules") came into force on January 1, 2020. The Foreign Investment Law and the Implementing Rules embody an expected regulatory trend to rationalize China's foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Foreign Investment Law and its Implementing Rules are drafted at a level of general principle, there is a reasonable possibility that various other new regulations and legislative changes will be issued to implement the Foreign Investment Law. There are still uncertainties with respect to the interpretation and implementation of the Foreign Investment Law and the Implementing Rules. For example, the Foreign Investment Law and its Implementing Rules provide that foreign invested entities established according to the previous laws regulating foreign investment prior to the implementation of the Foreign Investment Law may maintain their structure and corporate governance within a five-year transition period. It is uncertain whether the PRC governmental authorities may require us to adjust the structure and corporate governance of certain of our PRC subsidiaries in such transition period. Failure to take timely and appropriate measures to meet any of these or similar regulatory compliance requirements could materially affect our current corporate governance practices and business operations and our compliance costs may increase significantly.

Additionally, the NMPA'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 plans and investments in offshore companies by PRC residents may subject the PRC plan participants and PRC-resident 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 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 or rights to acquire equity 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 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 ("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 or other rights to acquire equity fail to register the employee equity plans or their exercise of options or vesting of equity awards, or such PRC-resident beneficial owners fails to register or amend their 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 their own behalf in the future, the instruments governing the debt may restrict their 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 March 31, 2020 and December 31, 2019, these restricted assets totaled $102.5 million and $109.6 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 the U.S. dollar in the fourth quarter of 2016, China's People's Bank of China ("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 (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%.

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 (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. The State Administration of Taxation (the "SAT") promulgated SAT Circular 9 in February 2018, which became effective from April 2018 and stipulates that in determining whether a non-resident enterprise has the status as a beneficial owner, comprehensive analysis shall be conducted based on the factors listed therein and the actual circumstances of the specific case shall be taken into consideration. Specifically, it expressly excludes an agent or a designated payee from being considered as a "beneficial owner." 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 ("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 ("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 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).

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 ("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 ("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, 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.

Local governments in the PRC have 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 grants and subsidies recognized in the income statement for the three months ended March 31, 2020 and 2019, and the years ended December 31, 2019 and 2018 were $2.4 million, $0.2 million, $6.2 million and $4.4 million, 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 (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.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China’s, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate an auditor report issued by a foreign public accounting firm. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges (“EQUITABLE”) Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges such as the NASDAQ Global Market of issuers included on the SEC’s list for three consecutive years. Enactment of this legislation or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of our ADSs and ordinary shares could be adversely affected. It is unclear if this proposed legislation will be enacted. Furthermore, there has been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. If any such policies were to materialize, the resulting legislation, if it were to apply to us, would likely have a material adverse impact on our business and the price of our ADSs and ordinary shares.

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

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

our industry; 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 us, our executive officers and directors or our shareholders; general economic and market conditions and overall fluctuations in the United States or Hong Kong equity markets; changes in accounting principles; trade disputes or U.S.-China government relations; and changes or developments in the United States, PRC, EU or global regulatory environment.

In addition, the stock market, in general, and pharmaceutical and biotechnology companies, in particular, 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 HKEx 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, and vice versa. Because of the different characteristics of the U.S. and Hong Kong equity markets, the historic market prices of our ADSs and ordinary shares may not be indicative of the performance of our securities going forward.

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, particularly in our industry in recent years. 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.***

The price of our ordinary shares and/or ADSs 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 April 30, 2020, 1,008,198,947 ordinary shares, par value $0.0001 per share, were outstanding, of which 850,615,805 ordinary shares were held in the form of 65,431,985 ADSs, each representing 13 ordinary shares.

We filed a registration statement on Form S-3 (the ‘‘Initial Registration Statement’’) with the SEC on behalf of certain shareholders on May 26, 2017, 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. On May 9, 2019, we filed a Post-Effective Amendment No. 1 to the Initial Registration Statement on behalf of certain shareholders. By the Post-Effective Amendment No. 1, an additional 50,550,132 ordinary shares, are registered, for a total of 303,514,337 ordinary shares offered by certain selling shareholders named in the Post-Effective Amendment No. 1. 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 and under our employee share purchase plan. 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. Amgen also has specified registration rights upon expiration of a lock-up period.

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, license, 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 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 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 Hong Kong or in the United States 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 outside China or their assets are located outside 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 the above, public shareholders may have more difficulty 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 an annual general meeting is twenty-one calendar days and the minimum notice period required for convening an extraordinary general meeting is fourteen 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.

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 designate courts in the Cayman Islands as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated memorandum and articles of association provide that, unless we consent in writing to the selection of an alternative forum, the courts of Cayman Islands will be the sole and exclusive forum for any derivative action or proceeding brought on behalf of us, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of us to us or our shareholders, any action asserting a claim arising pursuant to any provision of the Companies Law of the Cayman Islands as amended from time to time, or the amended and restated memorandum and articles of association, or any action asserting a claim governed by the internal affairs doctrine (as such concept is recognized under the U.S. laws). This provision may limit a shareholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated memorandum and articles of association inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions.

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 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 may be 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 ("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.

****Dealings in the ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty. There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of the ADSs.***

In connection with the Hong Kong public offering in 2018, we have established a branch register of members in Hong Kong (the "Hong Kong share register"). Our ordinary shares that are traded on the HKEx, including those that may be converted from ADSs, are registered on the Hong Kong share register, and the trading of these ordinary shares on the HKEx are subject to the Hong Kong stamp duty. To facilitate ADS to ordinary share conversion and trading between the NASDAQ and the HKEx, we moved a portion of our issued ordinary shares from our Cayman share register to our Hong Kong share register.

Under the Hong Kong Stamp Duty Ordinance, any person who effects any sale or purchase of Hong Kong stock, defined as stock the transfer of which is required to be registered in Hong Kong, is required to pay Hong Kong stamp duty. The stamp duty is currently set at a total rate of 0.2% of the greater of the consideration for, or the value of, shares transferred, with 0.1% payable by each of the buyer and the seller.

To the best of our knowledge, Hong Kong stamp duty has not been levied in practice on the trading or conversion of ADSs of companies that are listed in both the United States and Hong Kong and that have maintained all or a portion of their ordinary shares, including ordinary shares underlying ADSs, in their Hong Kong share registers. However, it is unclear whether, as a matter of Hong Kong law, the trading or conversion of ADSs of these dual-listed companies constitutes a sale or purchase of the underlying Hong Kong registered ordinary shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. If Hong Kong stamp duty is determined by the competent authority to apply to the trading or conversion of the ADSs, the trading price and the value of your investment in our ADSs or ordinary shares may be affected.

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 (the "Securities Act"), but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by the depositary. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may materially reduce the value of your ADSs.

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

From time to time, we may distribute rights to our shareholders, including rights to acquire securities. Under the deposit agreement, the depositary will not distribute rights to holders of ADSs unless the distribution and sale of rights and the securities to which these rights relate are either exempt from registration under the Securities Act with respect to all holders of ADSs or are registered under the 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 69% of our outstanding ordinary shares as of April 30, 2020. 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" ("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.

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" ("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. Although we believe we are not a CFC now, we may become one or own interests in 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.

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	Amendment No. 2 to Share Purchase Agreement, dated March 17, 2020, by and between Amgen Inc. and the Registrant		8-K (Exhibit 10.1)	3/17/2020	001-37686
10.2†	Employment Apportionment Agreement, dated March 1, 2020, by and between BeiGene (Beijing) Co., Ltd., BeiGene Guangzhou Biologics Manufacturing Co., Ltd. and Xiaobin Wu	X			
10.3†	Independent Director Compensation Policy, as amended	X			
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350	X			
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)	X			

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

*Furnished herewith.

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: May 11, 2020 By: /s/ John V. Oyler
John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: May 11, 2020 By: /s/ Howard Liang
Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)

Exhibit 10.2

EMPLOYMENT APPORTIONMENT AGREEMENT

This Employment Apportionment Agreement (this "Agreement") is made and entered into by and among BeiGene (Beijing) Co., Limited (the "Company"), BeiGene Guangzhou Biologics Manufacturing Co., Ltd. (the "GZ Co."), and Dr. Wu Xiaobin (the "Executive"), on March 1, 2020 (the "Effective Date"). Capitalized terms used but not defined in this Agreement shall have the meanings assigned to them in the Executive Employment Agreement entered into by and between the Company and the Executive, effective as of April 30, 2018 (the "Employment Agreement").

WHEREAS, the Company entered into the Employment Agreement with the Executive effective as of April 30, 2018; and

WHEREAS, the GZ Co., an affiliate of the Company and the Executive wish to establish an employment relationship for the Executive to provide certain service for the GZ Co. and the Company wishes to consent to the establishment of the additional employment relationship between the GZ Co. and the Executive.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, terms, provisions and conditions set forth in this Agreement, the parties hereby agree:

1. Employment. Subject to the terms and conditions set forth in this Agreement, the Executive shall be employed by the GZ Co. to undertake certain work. The Company agrees and consents to the additional employment relationship between the GZ Co. and the Executive. This Agreement constitutes an employment agreement between the GZ Co. and the Executive.

2. Term. The Term of this Agreement shall start from the Effective Date of this Agreement and expire on the termination date of the Employment Agreement, subject to the Executive's timely obtaining and maintenance of requisite visa, work permit and/or residence permit (as applicable) under the relevant PRC laws.

3. Capacity and Performance. Subject to the terms and conditions of Section 3 of the Employment Agreement as well as the Article of Association of the GZ Co., during the Term, the Executive shall serve the GZ Co. as the Legal Representative and Chairman of the Board of Directors, and shall report to the Board of Directors of the GZ Co.

4. Compensation and Benefits. Subject to the terms and conditions of the Employment Agreement, as compensation for all services performed by the Executive for the GZ Co. during the Term and subject to the Executive's performance of his duties and obligations to the GZ Co., pursuant to this Agreement, the GZ Co. shall provide the Executive with compensation and benefits pursuant to the following arrangement:

a) Base Salary. During the Term, the payment of the Base Salary shall be allocated between the Company and the GZ Co. pursuant to this Agreement. In 2020, the Company shall be responsible for 70% of the Base Salary and the GZ Co. shall be responsible for 30% of the Base Salary. To the extent the GZ Co. does not make timely payment of its portion of the Base Salary, the Company shall be obligated to make such payment and the GZ Co. agrees to reimburse the Company any such payment made by the Company on behalf of the GZ Co. as soon as reasonably practicable. Within the first 30 days of each following calendar year, the Company and the GZ Co. shall true up each other based on the final allocation of compensation expenses between the Company and the GZ Co. in the past calendar year and shall assess and re-allocate the payment responsibility of the Base Salary for the current year as necessary. The Executive agrees to such payment allocation arrangement as agreed by the Company and the GZ Co.

b) Other Compensation and Benefits. During the Term, the Executive shall be entitled to participate in or receive compensation or benefits provided by the GZ Co. as set forth in Sections 4 and 5 of the Employment Agreement, except to the extent any such benefit is in a category of benefit otherwise provided to the Executive by the Company or another affiliate of the Company.

c) Business Expenses. During the Term, the GZ Co. shall pay (or promptly reimburse the Executive) for documented, out-of-pocket expenses reasonably incurred by the Executive in the course of performing his duties and responsibilities hereunder, which are consistent with the GZ Co.'s policies in effect from time to time with respect to business expenses, subject to the GZ Co.'s requirements with respect to reporting of such expenses.

5. Termination of Employment. This Agreement and the Executive's employment relationship hereunder shall terminate immediately upon any of the following circumstances occur: (i) the expiration of the Term (i.e. upon termination of the Executive's employment under the Employment Agreement); or (ii) any visa, work permit or other certificate or document

required for the Executive under the applicable PRC laws is expired, terminated or revoked. Furthermore, the GZ Co. shall have the right to shorten the Term of the employment relationship hereunder or terminate this Agreement in advance, with or without reason, provided that the GZ Co. informs the Executive in writing 60 days in advance.

6. Severance Payments and Other Matters Related to Separation under the Employment Agreement. As soon as reasonably practicable after the payment of the Severance Benefits to the Executive by the Company pursuant to the Employment Agreement, the GZ Co. shall reimburse the Company of its portion of such payment calculated based on the allocation determined pursuant to Section 4 of this Agreement. For avoidance of doubt, the portion of the Severance Benefits calculated based on the allocation determined pursuant to Section 4 of this Agreement shall constitute the severance payments that the Executive may be entitled to for termination of this Agreement or the employment relationship hereunder. Furthermore, the Company shall not require the GZ Co. to bear any amount other than its portion as agreed under this Agreement.

7. Withholding. All payments made by the GZ Co. under this Agreement shall be reduced by any tax or other amounts required to be withheld by the GZ Co. under applicable law. In the event the Executive shall participate in the PRC social insurance scheme according to the relevant PRC laws and local regulations, the GZ Co. will withhold and deduct the individual's part of social insurance contributions from the portion of Base Salary payable by the GZ Co. pursuant to law.

8. Conflicting Agreements. The Executive hereby represents and warrants that the execution of this Agreement and the performance of his obligations hereunder will not breach or be in conflict with any other agreement to which the Executive is a party or is bound and that the Executive is not now subject to any covenants against competition or similar covenants or any court order or other legal obligation that would affect the performance of his obligations hereunder. The Executive will not disclose to or use on behalf of the GZ Co. any proprietary information of a third party without such party's consent.

9. Non-disparagement. Executive agrees that he will not, directly or indirectly, individually or in concert with others, engage in any conduct or make any statement that is likely to have the effect of undermining or disparaging the reputation of the GZ Co., or its good will, products, or business opportunities, or that is likely to have the effect of undermining or disparaging the reputation of any officer, director, agent, representative or employee, past or present, of the GZ Co. The GZ Co. agrees that, except for circumstances relating to a termination of Executive's employment by the Company for Cause, its officers, directors and senior management shall not directly or indirectly, individually or in concert with others, engage in any conduct or make any statement that is likely to have the effect of undermining or disparaging the reputation of Executive.

10. Survival. Provisions of this Agreement shall survive any termination if so provided herein or if necessary or desirable to accomplish the purposes of other surviving provisions, including without limitation the obligations of the Executive under Sections 8 and 9 hereof, and obligations of the GZ Co. under Sections 4, 5, 6 and 9.

11. Severability. If any covenants or such other provisions of this Agreement are found to be invalid or unenforceable by a final determination of a court of competent jurisdiction, (a) the remaining terms and provisions hereof shall be unimpaired, and (b) the invalid or unenforceable term or provision hereof shall be deemed replaced by a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision hereof.

12. Waiver and Amendments. Any waiver, alteration, amendment, or modification of any of the terms of this Agreement shall be valid only if made in writing and signed by each of the parties hereto. No waiver by either of the parties hereto of their rights hereunder shall be deemed to constitute a waiver with respect to any subsequent occurrences or transactions hereunder unless such waiver specifically states that it is to be construed as a continuing waiver.

13. Notices. Every notice or other communication relating to this Agreement shall be in writing, and shall be mailed to or delivered to the party for whom or which it is intended at such address as may from time to time be designated by it in a notice mailed or delivered to the other party as herein provided; provided, that unless and until some other address be so designated, all notices and communications by the Executive to the GZ Co. or the Company shall be mailed or delivered to the GZ Co. or the Company at its principal executive office, and all notices and communications by the GZ Co. or the Company to the Executive may be given to the Executive personally or may be mailed to the Executive at the Executive's last known address, as reflected in the GZ Co. or the Company's records. Any notice so addressed shall be deemed to be given or received (a) if delivered by hand, on the date of such delivery, (b) if mailed by courier or by overnight mail, on the first business day following the date of such mailing, and (c) if mailed by registered or certified mail, on the third business day after the date of such mailing.

14. Entire Agreement. This Agreement constitutes the entire understanding and agreement of the parties hereto regarding the employment of the Executive by the GZ Co. This Agreement and the Employment Agreement supersede all prior negotiations, discussions, correspondence, communications, understandings, and agreements between the parties relating to the subject matter of this Agreement and the Employment Agreement.

15. Section Headings. The headings of the sections and subsections of this Agreement are inserted for convenience only and shall not be deemed to constitute a part thereof or affect the meaning or interpretation of this Agreement or of any term or provision hereof.

16. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument. The execution of this Agreement may be by actual or facsimile signature.

17. Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the PRC, without regard to conflicts of laws principles thereof. The parties hereby consent to the jurisdiction of any court in Beijing, China. Accordingly, with respect to any such court action, the Executive hereby (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

[Signature Page to Follow]

IN WITNESS WHEREOF, this Agreement has been executed as a sealed instrument by the Company and the GZ Co., by their duly authorized representatives, and by the Executive, as of the date first above written.

EXECUTIVE

/s/ Wu Xiaobin

Dr. Wu Xiaobin

BEIGENE GUANGZHOU BIOLOGICS MANUFACTURING CO., LTD.

(Chop)

By: /s/ Jonathan Liu

Name: Jonathan Liu

Its: General Manager

BEIGENE (BEIJING) CO., LIMITED

(Chop)

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Its: Director

Exhibit 10.3

BEIGENE, LTD.

INDEPENDENT DIRECTOR COMPENSATION POLICY

The purpose of this Independent Director Compensation Policy (this "Policy") of BeiGene, Ltd. (the "Company") is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who meet the general independence requirements under NASDAQ Rule 5605(a)(2) and Rule 3.13 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. In furtherance of this purpose, all members of the Board of Directors (the "Board") of the Company who are independent directors under NASDAQ Rule 5605(a)(2) shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership	
For general availability and participation in meetings and conference calls of the Board. No additional compensation for attending individual Board meetings.	$50,000
Additional Annual Retainers for Committee Membership and Service as Chairperson	
Audit Committee Chairperson:	$22,500
Audit Committee member:	$10,000
Compensation Committee Chairperson:	$17,500
Compensation Committee member:	$7,500
Nominating and Corporate Governance Committee Chairperson:	$12,500
Nominating and Corporate Governance Committee member:	$5,000
Commercial Advisory Committee Chairperson:	$16,500
Commercial Advisory Committee member:	$7,500
Scientific Advisory Committee Chairperson:	$16,500
Scientific Advisory Committee member:	$7,500
No additional compensation for attending individual committee meetings.	

All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the independent director. Cash retainers owing to independent directors shall be annualized, meaning that independent directors who join the Board during the calendar year, such amounts shall be pro-rated based on the number of calendar days served by such director.

Equity Retainers

Upon initial election or appointment to the Board: An initial equity grant (the "Initial Grant") on the date of such election or appointment (the "grant date" for the Initial Grant) with an initial value of $300,000 on the grant date, pro-rated based on the number of calendar days to be served from the grant date until the first anniversary of the most recent Annual Meeting.

Annual equity grants: On the date of the Company's Annual Meeting of Shareholders (the "Annual Meeting"), each continuing independent member of the Board who is eligible to receive awards under this Plan will receive an annual equity grant (the "Annual Grant") with an initial value of $300,000 on the date of grant.

Terms and Conditions of Initial Grant and Annual Grant: Each of the Initial Grant and the Annual Grant (together, the "Equity Awards") shall consist of 100% share options ("Options"). The number of Options will be the applicable grant value divided by the per share option value on the date of grant determined in accordance with the Company's standard option valuation practices. The Options will have an exercise price equal to the higher of (i) the fair market value per share of the Company's shares on the date of grant, and (ii) the average fair market value per share of the Company's shares for the five trading days immediately preceding the date of grant. The Equity Awards shall be governed by, and subject to the terms and conditions of, the Company's 2016 Share Option and Incentive Plan (as may be amended from time to time) and

standard form of grant agreements in effect on the date of grant. In addition, the Equity Awards shall vest in full (i.e., in a single installment) upon the earlier to occur of the first anniversary of the date of grant or the date of the next Annual Meeting; provided, however, that all vesting shall cease if the director resigns from the Board or otherwise ceases to serve as a director other than as set forth below or the Board determines that the circumstances warrant continuation of vesting. In addition, all Options shall be exercisable for three years following cessation of service, and all Equity Awards shall accelerate in full upon (i) death, (ii) disability, (iii) termination of service in connection with a change of control of the Company, or (iv) upon a change of control of the Company if the director's service continues and the awards are not assumed by the acquiror at the time of the change of control.

Limitations on Independent Director Compensation

Cash and equity compensation payable to independent directors under this Policy shall be subject to any limits, terms and conditions set forth in any Company policy or equity incentive plan or as otherwise adopted by the Board from time to time.

Expenses

The Company shall reimburse all reasonable out-of-pocket expenses incurred by independent directors in attending Board and committee meetings.

ADOPTED: November 16, 2016
EFFECTIVE: November 16, 2016
AMENDED: June 6, 2018, June 5, 2019 and April 13, 2020*

* Cash retainers for the Commercial Advisory Committee and the Scientific Advisory Committee, which were created on February 26, 2020, shall commence with the second quarter 2020.

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, John V. Oyler, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BeiGene, Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2020

/s/ JOHN V. OYLER

John V. Oyler

Chief Executive Officer and Chairman

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Howard Liang, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BeiGene, Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2020

/s/ HOWARD LIANG

Howard Liang

Chief Financial Officer and Chief Strategy Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of BeiGene, Ltd., an exempted company incorporated in the Cayman Islands with limited liability (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the three months ended March 31, 2020 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 11, 2020

/s/ JOHN V. OYLER

John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Dated: May 11, 2020

/s/ HOWARD LIANG

Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)