BeiGene, Ltd.
百濟神州有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

OVERSEAS REGULATORY ANNOUNCEMENT – FORM 10-Q

This announcement is issued pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Please refer to the attached for the document which has been published by BeiGene, Ltd. on the website of the U.S. Securities and Exchange Commission on November 9, 2023 (U.S. Eastern Time).

By order of the Board
BeiGene, Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, November 10, 2023

As of the date of this announcement, the Board of Directors of the Company consists of Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang as Non-executive Director, and Dr. Margaret Han Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Anthony C. Hooper, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders and Mr. Qingqing Yi as Independent Non-executive Directors.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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 listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

As of November 1, 2023, 1,359,497,624 ordinary shares, par value $0.0001 per share, were outstanding, of which 871,833,599 ordinary shares were held in the form of 67,064,123 American Depositary Shares, each representing 13 ordinary shares, and 115,055,260 were RMB 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

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BEIGENE, LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

	Note	As of September 30, 2023	As of December 31, 2022
		$ (unaudited)	$ (audited)
Assets			
Current assets:			
Cash and cash equivalents		3,067,336	3,869,564
Short-term restricted cash	4	11,548	196
Short-term investments	4	106,989	665,251
Accounts receivable, net		309,079	173,168
Inventories, net	5	316,929	282,346
Prepaid expenses and other current assets	9	241,661	216,553
Total current assets		4,053,542	5,207,078
Property, plant and equipment, net	6	1,178,038	845,946
Operating lease right-of-use assets		98,742	109,960
Intangible assets, net	7	53,657	40,616
Other non-current assets	9	140,900	175,690
Total non-current assets		1,471,337	1,172,212
Total assets		5,524,879	6,379,290
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		341,857	294,781
Accrued expenses and other payables	9	505,824	467,352
Deferred revenue, current portion	3	—	213,861
Tax payable	8	20,158	25,189
Operating lease liabilities, current portion		23,246	24,041
Research and development cost share liability, current portion	3	63,652	114,335
Short-term debt	10	328,560	328,969
Total current liabilities		1,283,297	1,468,528
Non-current liabilities:			
Long-term bank loans	10	202,491	209,148
Deferred revenue, non-current portion	3	300	42,026
Operating lease liabilities, non-current portion		25,474	34,517
Deferred tax liabilities	8	16,358	15,996
Research and development cost share liability, non-current portion	3	191,739	179,625
Other long-term liabilities	9	41,986	46,095
Total non-current liabilities		478,348	527,407
Total liabilities		1,761,645	1,995,935
Commitments and contingencies	17		
Shareholders' equity:			
Ordinary shares, US$0.0001 par value per share; 9,500,000,000 shares authorized; 1,352,997,624 and 1,356,140,180 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively		135	135
Additional paid-in capital		11,502,527	11,540,979
Accumulated other comprehensive loss	14	(144,931)	(77,417)
Accumulated deficit		(7,594,497)	(7,080,342)
Total shareholders' equity		3,763,234	4,383,355
Total liabilities and shareholders' equity		5,524,879	6,379,290

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

BEIGENE, LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)
(Unaudited)

	Note	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		$	$	$	$
Revenues					
Product revenue, net	11	595,290	349,506	1,559,326	915,590
Collaboration revenue	3	186,018	38,122	265,044	120,236
Total revenues		781,308	387,628	1,824,370	1,035,826
Expenses					
Cost of sales - product		96,309	76,543	274,088	212,953
Research and development		453,259	426,363	1,284,607	1,194,485
Selling, general and administrative		364,421	322,892	1,087,954	948,868
Amortization of intangible assets		1,287	187	1,662	563
Total expenses		915,276	825,985	2,648,311	2,356,869
Loss from operations		(133,968)	(438,357)	(823,941)	(1,321,043)
Interest income, net		26,649	12,759	57,735	34,261
Other income (expense), net		336,657	(125,640)	291,142	(243,290)
Income (loss) before income taxes		229,338	(551,238)	(475,064)	(1,530,072)
Income tax expense	8	13,925	6,318	39,091	28,408
Net income (loss)		215,413	(557,556)	(514,155)	(1,558,480)
Earnings (loss) per share					
Basic	12	0.16	(0.41)	(0.38)	(1.16)
Diluted	12	0.15	(0.41)	(0.38)	(1.16)
Weighted-average shares outstanding—basic		1,360,716,279	1,345,303,747	1,358,392,470	1,337,976,853
Weighted-average shares outstanding—diluted		1,390,331,833	1,345,303,747	1,358,392,470	1,337,976,853
Earnings (loss) per American Depositary Share ("ADS")					
Basic	12	2.06	(5.39)	(4.92)	(15.14)
Diluted	12	2.01	(5.39)	(4.92)	(15.14)
Weighted-average ADSs outstanding—basic		104,670,483	103,484,904	104,491,728	102,921,296
Weighted-average ADSs outstanding—diluted		106,948,603	103,484,904	104,491,728	102,921,296

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

BEIGENE, LTD.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Amounts in thousands of U.S. Dollars ("$"))
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Net income (loss)	215,413	(557,556)	(514,155)	(1,558,480)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	(2,559)	(80,326)	(75,732)	(168,411)
Unrealized holding income (loss), net	1,315	1,253	8,218	(11,062)
Comprehensive income (loss)	214,169	(636,629)	(581,669)	(1,737,953)

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 ("$"))
(Unaudited)

	Note	Nine Months Ended September 30, 2023	2022
		$	$
Operating activities:			
Net loss		(514,155)	(1,558,480)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		63,856	48,262
Share-based compensation expenses	13	274,697	225,036
Unrealized losses on equity investments	4	12,273	16,413
Acquired in-process research and development		15,000	20,000
Amortization of research and development cost share liability	3	(38,569)	(70,389)
Deferred income tax benefits		735	380
Gain on BMS termination settlement	15	(362,917)	—
Other items, net		822	7,762
Changes in operating assets and liabilities:			
Accounts receivable		(143,511)	284,717
Inventories		(52,371)	(75,632)
Other assets		(17,598)	30,325
Accounts payable		31,366	4,203
Accrued expenses and other payables		50,089	1,628
Deferred revenue		(255,587)	(112,820)
Other liabilities		55	167
Net cash used in operating activities		(935,815)	(1,178,428)
Investing activities:			
Purchases of property, plant and equipment		(404,937)	(204,076)
Purchase of intangible asset		(9,413)	—
Purchases of investments		(15,581)	(14,735)
Proceeds from sale or maturity of investments		567,519	1,352,398
Purchase of in-process research and development		(15,000)	(95,000)
Net cash provided by investing activities		122,588	1,038,587
Financing activities:			
Proceeds from long-term loan	10	22,502	37,372
Repayment of long-term loan	10	(8,462)	—
Proceeds from short-term loans	10	162,614	163,774
Repayment of short-term loans	10	(159,576)	(145,428)
Proceeds from option exercises and employee share purchase plan		52,352	35,677
Net cash provided by financing activities		69,430	91,395
Effect of foreign exchange rate changes, net		(50,348)	(133,929)
Net decrease in cash, cash equivalents, and restricted cash		(794,145)	(182,375)
Cash, cash equivalents, and restricted cash at beginning of period		3,875,037	4,382,887
Cash, cash equivalents, and restricted cash at end of period		3,080,892	4,200,512
Supplemental cash flow information:			
Cash and cash equivalents		3,067,336	4,197,132
Short-term restricted cash		11,548	191
Long-term restricted cash		2,008	3,189
Income taxes paid		42,516	25,006
Interest expense paid		15,893	19,865
Supplemental non-cash information:			
Capital expenditures included in accounts payable and accrued expenses		107,611	47,310
Acquired intangible asset included in accounts payable		9,384	—

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

BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

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

(Unaudited)

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
		$	$	$	$	$
Balance at December 31, 2022	1,356,140,180	135	11,540,979	(77,417)	(7,080,342)	4,383,355
Use of shares reserved for share option exercises	(98,774)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	6,610,695	1	28,656	—	—	28,657
Share-based compensation	—	—	75,322	—	—	75,322
Other comprehensive income	—	—	—	18,403	—	18,403
Net loss	—	—	—	—	(348,431)	(348,431)
Balance at March 31, 2023	1,362,652,101	136	11,644,957	(59,014)	(7,428,773)	4,157,306
Use of shares reserved for share option exercises	220,116	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	13,379,119	1	3,691	—	—	3,692
Share-based compensation	—	—	103,371	—	—	103,371
Other comprehensive loss	—	—	—	(84,673)	—	(84,673)
Net loss	—	—	—	—	(381,137)	(381,137)
Balance at June 30, 2023	1,376,251,336	137	11,752,019	(143,687)	(7,809,910)	3,798,559
Use of shares reserved for share option exercises	(4,689,438)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	4,708,834	—	17,419	—	—	17,419
Cancellation of ordinary shares	(23,273,108)	(2)	(362,915)	—	—	(362,917)
Share-based compensation	—	—	96,004	—	—	96,004
Other comprehensive loss	—	—	—	(1,244)	—	(1,244)
Net income	—	—	—	—	215,413	215,413
Balance at September 30, 2023	1,352,997,624	135	11,502,527	(144,931)	(7,594,497)	3,763,234
Balance at December 31, 2021	1,334,804,281	133	11,191,007	17,950	(5,076,527)	6,132,563
Cost from issuance of ordinary shares	—	—	(152)	—	—	(152)
Use of shares reserved for share option exercises	(2,850,328)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	2,851,316	—	11,880	—	—	11,880
Share-based compensation	—	—	65,555	—	—	65,555
Other comprehensive loss	—	—	—	(496)	—	(496)
Net loss	—	—	—	—	(435,198)	(435,198)
Balance at March 31, 2022	1,334,805,269	133	11,268,290	17,454	(5,511,725)	5,774,152
Use of shares reserved for share option exercises	5,016,518	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	9,817,938	1	7,091	—	—	7,092
Share-based compensation	—	—	81,305	—	—	81,305
Other comprehensive loss	—	—	—	(99,904)	—	(99,904)
Net loss	—	—	—	—	(565,726)	(565,726)
Balance at June 30, 2022	1,349,639,725	134	11,356,686	(82,450)	(6,077,451)	5,196,919
Use of shares reserved for share option exercises	(3,971,942)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	3,972,397	1	16,704	—	—	16,705
Share-based compensation	—	—	78,176	—	—	78,176
Other comprehensive loss	—	—	—	(79,073)	—	(79,073)
Net loss	—	—	—	—	(557,556)	(557,556)
Balance at September 30, 2022	1,349,640,180	135	11,451,566	(161,523)	(6,635,007)	4,655,171

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", "BeiGene", "it", "its") is a global biotechnology company that is discovering and developing innovative oncology treatments that are more accessible and affordable to cancer patients worldwide.

The Company currently has three approved medicines that were internally discovered and developed, including BRUKINSA®, a small molecule inhibitor of Bruton's Tyrosine Kinase for the treatment of various blood cancers; TEVIMBRA® (tislelizumab), an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers; and pamiparib, a selective small molecule inhibitor of PARP1 and PARP2. The Company has obtained approvals to market BRUKINSA in the United States, the People's Republic of China ("China" or the "PRC"), the European Union, the United Kingdom, Canada, Australia and additional international markets; tislelizumab in the European Union and China; and pamiparib in China. By leveraging its strong commercial capabilities, the Company has in-licensed the rights to distribute an additional 14 approved medicines for the China market. Supported by its global clinical development and commercial capabilities, the Company has entered into collaborations with world-leading biopharmaceutical companies such as Amgen Inc. ("Amgen") and Novartis Pharma AG ("Novartis") to develop and commercialize innovative medicines.

The Company is committed to advancing best- and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. The Company has conducted more than 120 clinical trials in-house, with over 21,000 subjects enrolled in approximately 45 regions. This includes more than 36 pivotal or potentially registration-enabling trials across its portfolio, including three internally discovered, approved medicines.

The Company has built, and is expanding, its internal manufacturing capabilities. The Company is building a commercial-stage biologics manufacturing and clinical R&D center in Hopewell, New Jersey (the "Hopewell facility"), in addition to its existing state-of-the-art biologic and small molecule manufacturing facilities in China to support current and potential future demand of its medicines. The Company also works with high quality global contract manufacturing organizations ("CMOs") to manufacture its internally developed clinical and commercial products.

Since its inception in 2010, the Company has become a fully integrated global organization of over 10,000 employees worldwide, primarily in the United States, China and Europe.

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of September 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022, and the condensed consolidated statements of shareholders' equity for the three and nine months ended September 30, 2023 and 2022, and the related footnote disclosures are unaudited. The accompanying unaudited interim condensed 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, 2022 (the "Annual Report").

The unaudited interim 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 operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results expected for the full fiscal year or for any future annual or interim period.

The unaudited interim 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.

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating variable consideration in product sales and collaboration revenue arrangements, identifying separate accounting units and determining the standalone selling price of each performance obligation in the Company's revenue arrangements, assessing the impairment of long-lived assets, valuation and recognition of share-based compensation expenses, realizability of deferred tax assets, estimating uncertain tax positions, valuation of inventory, estimating the allowance for credit losses, determining defined benefit pension plan obligations, 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 and reported amounts of revenues and expenses. Actual results could differ from these estimates.

Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the unaudited interim 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, 2022.

There have been no material changes to the Company's significant accounting policies as of and for the nine months ended September 30, 2023, 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 markets 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 September 30, 2023 and December 31, 2022:

As of September 30, 2023	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Cash equivalents			
Money market funds	616,845	—	—
Time deposits	42,348	—	—
Short-term investments (Note 4):			
U.S. Treasury securities	106,989	—	—
Prepaid expenses and other current assets:			
Convertible debt instrument	—	—	4,668
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	1,014	72	—
Convertible debt instrument	—	—	3,239
Total	767,196	72	7,907

As of December 31, 2022	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Cash equivalents			
Money market funds	758,114	—	—
Short-term investments (Note 4):			
U.S. Treasury securities	665,251	—	—
Prepaid expenses and other current assets:			
Convertible debt instrument	—	—	5,190
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	3,307	706	—
Convertible debt instrument	—	—	3,000
Total	1,426,672	706	8,190

The Company's cash equivalents are highly liquid investments with original maturities of 3 months or less. Short-term investments represent the Company's investments in available-for-sale debt securities. The Company determines the fair value of cash equivalents and available-for-sale debt securities using a market approach based on quoted prices in active markets.

The Company's equity securities carried at fair value 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 collaboration and license agreement entered into in January 2020 and in Leap's underwritten public offering in September 2021. 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. Refer to Note 4, Restricted Cash and Investments for details of the determination of the carrying amount of private equity investments without readily determinable fair values and equity method investments.

The Company holds convertible notes issued by two private biotech companies. The Company has elected the fair value option method of accounting for the convertible notes. Accordingly, the convertible notes are remeasured at fair value on a recurring basis using Level 3 inputs, with any changes in the fair value option recorded in other income (expense), net. The Company recorded a loss on fair value adjustment of $283 for the three and nine months ended September 30, 2023, respectively, related to the convertible debt instrument to other income (expense), net in the consolidated statements of operations.

As of September 30, 2023 and December 31, 2022, the fair values of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and short-term debt approximated their carrying values due to their short-term nature. Long-term bank loans approximate their fair value due to the fact that the related interest rates approximate the rates currently offered by financial institutions for similar debt instrument of comparable maturities.

3. Collaborative and Licensing Arrangements

The Company has entered into collaborative arrangements for the research and development, manufacture and/or commercialization of medicines and drug candidates. To date, these collaborative arrangements have included out-licenses of and options to out-license internally developed products and drug candidates to other parties, in-licenses of products and drug candidates from other parties, and profit- and cost-sharing arrangements. These arrangements may include non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost-sharing and reimbursement arrangements, royalty payments, and profit sharing.

Out-Licensing Arrangements

For the three and nine months ended September 30, 2023 and 2022, the Company's collaboration revenue primarily consisted of the recognition of previously deferred revenue from its former collaboration agreements with Novartis for tislelizumab and ociperlimab.

The following table summarizes total collaboration revenue recognized for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue from Collaborators	$	$	$	$
Research and development service revenue	59,052	9,834	79,432	34,074
Right to access intellectual property revenue	51,978	26,249	104,475	78,746
Material rights revenue	71,980	—	71,980	—
Other	3,008	2,039	9,157	7,416
Total	186,018	38,122	265,044	120,236

Novartis

Tislelizumab Collaboration and License

In January 2021, the Company entered into a collaboration and license agreement with Novartis, granting Novartis rights to develop, manufacture and commercialize tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia and Japan ("Novartis Territory"). The Company and Novartis agreed to jointly develop tislelizumab in the Novartis Territory, with Novartis responsible for regulatory submissions and Novartis had the right to commercialization upon regulatory approvals. In addition, both companies had the ability to conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and the Company was provided with an option to co-detail the product in North America, funded in part by Novartis.

Under the agreement the Company received an upfront cash payment of $650,000 from Novartis. The Company was eligible to receive up to $1,300,000 upon the achievement of regulatory milestones, $250,000 upon the achievement of sales milestones, and royalties on future sales of tislelizumab in the licensed territory. Under the terms of the agreement, the Company was responsible for funding ongoing clinical trials of tislelizumab, Novartis agreed to fund new registrational, bridging, or post-marketing studies in its territory, and each party was responsible for funding clinical trials evaluating tislelizumab in combination with its own or third party products. Each party retained the worldwide right to commercialize its propriety products in combination with tislelizumab.

The Company evaluated the Novartis agreement under ASC 606 as all the material units of account within the agreement represented transactions with a customer. The Company identified the following material components under the agreement: (1) exclusive license for Novartis to develop, manufacture, and commercialize tislelizumab in the Novartis Territory, transfer of know-how and use of the tislelizumab trademark; (2) conducting and completing ongoing trials of tislelizumab ("tislelizumab R&D services"); and (3) supplying Novartis with required quantities of the tislelizumab drug product, or drug substance, upon receipt of an order from Novartis.

The Company determined that the license, transfer of know-how and use of trademarks were not distinct from each other and represented a single performance obligation. The tislelizumab R&D services represented a material promise and were determined to be a separate performance obligation at the outset of the agreement as the promise is distinct and had standalone value to Novartis. The Company evaluated the supply component of the contract and noted the supply would not be provided at a significant incremental discount to Novartis. The Company concluded that, for the purpose of ASC 606, the provision related to providing clinical and commercial supply of tislelizumab in the Novartis Territory was an option but not a performance obligation of the Company at the outset of the agreement. A performance obligation for the clinical and commercial supply would be established as quantities of drug product or drug substance were ordered by Novartis.

The Company determined that the transaction price as of the outset of the arrangement was the upfront payment of $650,000. The potential milestone payments that the Company was eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained due to uncertainty of achievement. The transaction price was allocated to the two identified performance obligations based on a relative fair value basis. The standalone selling price of the license, transfer of know-how and use of trademarks performance obligation was determined using the adjusted market assessment approach. Based on the valuation performed by the Company, the standalone selling price of the license, transfer of know-how and use of trademarks was valued at $1,231,000. The standalone selling price of the tislelizumab R&D services was valued at $420,000 using a cost plus margin valuation approach. Based on the relative standalone selling prices of the two performance obligations, $484,646 of the total transaction price was allocated to the license and $165,354 was allocated to the tislelizumab R&D services.

The Company satisfied the license performance obligation at a point in time when the license was delivered and the transfer of know-how completed which occurred during the nine months ended September 30, 2021. As such, the Company recognized the entire amount of the transaction price allocated to the license as collaboration revenue during the nine months ended September 30, 2021. The portion of the transaction price allocated to the tislelizumab R&D services was deferred and was being recognized as collaboration revenue as the tislelizumab R&D services were performed using a percentage-of-completion method. Estimated costs to complete were reassessed on a periodic basis and any updates to the revenue earned were recognized on a prospective basis.

In September 2023, the Company and Novartis agreed to mutually terminate the collaboration and license agreement, effective immediately. Pursuant to the termination agreement, the Company regained full, global rights to develop, manufacture and commercialize tislelizumab with no royalty payments due to Novartis. Novartis may continue its ongoing clinical trials and has the ability to conduct future combination trials with tislelizumab subject to BeiGene’s approval. BeiGene agreed to provide Novartis with ongoing clinical supply of tislelizumab to support its clinical trials. Pursuant to the termination agreement, Novartis agreed to provide transition services to the Company to enable key aspects of the tislelizumab development and commercialization plan to proceed without disruption, including manufacturing, regulatory, safety and clinical support.

Upon termination of the agreement in September 2023, there were no further performance obligations, and the remaining deferred revenue balance associated with the tislelizumab R&D services was recognized in full. The Company recognized R&D service revenue of $55,483 and $72,279 during the three and nine months ended September 30, 2023, respectively, and $8,043 and $28,699 during the three and nine months ended September 30, 2022, respectively. The Company also recognized other collaboration revenue of $54 and $5,067 during the three and nine months ended September 30, 2023, respectively, and $2,039 and $7,416 during the three and nine ended September 30, 2022, respectively, related to the sale of tislelizumab clinical supply to Novartis in conjunction with the collaboration.

Ociperlimab Option, Collaboration and License Agreement and China Broad Market Development Agreement

In December 2021, the Company expanded its collaboration with Novartis by entering into an option, collaboration and license agreement with Novartis to develop, manufacture and commercialize the Company's investigational TIGIT inhibitor ociperlimab in the Novartis Territory. In addition, the Company and Novartis entered into an agreement granting the Company rights to market, promote and detail five approved Novartis oncology products, TAFINLAR® (dabrafenib), MEKINIST® (trametinib), VOTRIENT® (pazopanib), AFINITOR® (everolimus), and ZYKADIA® (ceritinib), across designated regions of China referred to as “broad markets.” In the first quarter of 2022, the Company initiated marketing and promotion of these five products.

Under the terms of the option, collaboration and license agreement, the Company received an upfront cash payment of $300,000 in January 2022 from Novartis and would have received an additional payment of $600,000 or $700,000 in the event Novartis exercised its exclusive time-based option prior to mid-2023 or between then and late-2023, respectively. Following option exercise, the Company was eligible to receive up to $745,000 upon the achievement of regulatory approval milestones, $1,150,000 upon the achievement of sales milestones, and royalties on future sales of ociperlimab in the Novartis Territory. Subject to the terms of the option, collaboration and license agreement, during the option period, Novartis agreed to initiate and

fund additional global clinical trials with ociperlimab and the Company agreed to expand enrollment in two ongoing trials. Following the option exercise, Novartis agreed to share development costs of global trials. Following approval, the Company agreed to provide 50 percent of the co-detailing and co-field medical efforts in the United States, and had an option to co-detail up to 25 percent in Canada and Mexico, funded in part by Novartis. Each party retained the worldwide right to commercialize its propriety products in combination with ociperlimab. The prior tislelizumab collaboration and license agreement was not modified as a result of the ociperlimab option, collaboration and license agreement.

The Company evaluated the Novartis agreements under ASC 606 as the units of account within the agreement represented transactions with a customer. The Company identified the following material promises under the agreement: (1) exclusive option for Novartis to license the rights to develop, manufacture, and commercialize ociperlimab in the Novartis Territory; (2) Novartis' right to access ociperlimab in its own clinical trials during the option period; (3) initial transfer of BeiGene know-how; and (4) conducting and completing ongoing trials of ociperlimab during the option period (“ociperlimab R&D Services”, together with “tislelizumab R&D services”, “R&D services”). The market development activities are considered immaterial in the context of the contracts.

The Company concluded that, at the inception of the agreement, the option for the exclusive product license constituted a material right as it represents a significant and incremental discount to the fair value of the exclusive product license that Novartis would not have received without entering into the agreement and was therefore considered a distinct performance obligation. The Company determined that Novartis' right to access ociperlimab in its own trials over the option period and the initial transfer of know-how were not distinct from each other, as the right to access ociperlimab has limited value without the corresponding know-how transfer, and therefore should be combined into one distinct performance obligation. The ociperlimab R&D Services represent a material promise and were determined to be a separate performance obligation at the outset of the agreement as the promise is distinct and has standalone value to Novartis.

The Company determined the transaction price at the outset of the arrangement as the upfront payment of $300,000. The option exercise fee was contingent upon Novartis exercising its right and was considered fully constrained until the option was exercised. Additionally, the milestone and royalty payments were not applicable until after the option is exercised, at which point the likelihood of meeting milestones, regulatory approval and meeting certain sales thresholds would be assessed. The transaction price was allocated to the three identified performance obligations based on a relative fair value basis. The standalone selling price of the material right for the option to the exclusive product license was calculated as the incremental discount between (i) the value of the license determined using a discounted cash flow method adjusted for probability of the option being exercised and (ii) the expected option exercise fee using the most-likely-amount method at option exercise. The standalone selling price of the combined performance obligation for Novartis' right to access ociperlimab for its own clinical trials during the option period and the initial transfer of BeiGene know-how was determined using a discounted cash flow method. The standalone selling price of the ociperlimab R&D Services was determined using an expected cost plus margin approach. Based on the relative standalone selling prices of the three performance obligations, $71,980 of the total transaction price was allocated to the material right, $213,450 was allocated to Novartis' right to use ociperlimab in its own clinical trials during the option period and the transfer of BeiGene know-how, and $14,570 was allocated to the ociperlimab R&D Services.

The Company would have satisfied the material right performance obligation at a point in time at the earlier of when Novartis exercised the option and the license was delivered or the expiration of the option period. As such, the entire amount of the transaction price allocated to the material right was deferred. The portion of the transaction price allocated to Novartis' right to access ociperlimab in its own clinical trials during the option period and the initial transfer of BeiGene know-how was deferred and was recognized over the expected option period. The portion of the transaction price allocated to the ociperlimab R&D Services was deferred and was recognized as collaboration revenue as the ociperlimab R&D Services were performed over the expected option period.

In July 2023, the Company and Novartis mutually agreed to terminate the ociperlimab option, collaboration and license agreement, effective immediately. Pursuant to the termination agreement, the Company regained full, global rights to develop, manufacture and commercialize ociperlimab. Upon termination the Company had no further performance obligations under the collaboration, and all remaining deferred revenue balances were recognized in full. The China broad markets agreement remains in place.

The Company recognized collaboration revenue of $51,978 and $104,475 related to Novartis’ right to access ociperlimab in clinical trials and the transfer of know how performance obligation during the three and nine months ended September 30, 2023, respectively, and $26,249 and $78,746 during the three and nine months ended September 30, 2022, respectively. The Company recognized R&D service revenue of $3,569 and $7,153 during the three and nine months ended September 30, 2023 and $1,791 and $5,375 during the three and nine months ended September 30, 2022, respectively. The Company recognized the $71,980 allocated to the material right as collaboration revenue upon termination during the quarter ended September 30, 2023. The Company also recognized other collaboration revenue of $2,954 and $5,590 related to revenue generated under the broad

markets marketing and promotion agreement in conjunction with the collaboration during the three and nine months ended September 30, 2023, respectively.

In-Licensing Arrangements - Commercial

Amgen

In October 2019, the Company entered into a global strategic oncology collaboration with Amgen ("Amgen Collaboration Agreement") for the commercialization and development in China, excluding Hong Kong, Taiwan and Macau, 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. The agreement became effective on January 2, 2020, following approval by the Company's shareholders and satisfaction of other closing conditions.

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 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 in November 2020 for the prevention of skeletal-related events in cancer patients with bone metastases. In July 2020, the Company began commercializing XGEVA in China. In December 2020, BLINCYTO was approved in China for injection for the treatment of adult patients with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL). In July 2021, KYPROLIS was conditionally approved in China for injection in combination with dexamethasone for the treatment of adult patients with R/R multiple myeloma. In April 2022, BLINCYTO was conditionally approved for injection for the treatment of pediatric patients with R/R CD19-positive B-cell precursor ALL.

Amgen and the Company are also jointly developing a portfolio of Amgen oncology pipeline assets under the collaboration. 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 LUMAKRAS® (sotorasib), Amgen's KRAS G12C inhibitor, 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 LUMAKRAS).

On April 20, 2022, the parties entered into the First Amendment to Amgen Collaboration Agreement, which amends certain terms and conditions relating to the financial responsibilities of the parties in connections with the development and commercialization of certain Amgen proprietary products for the treatment of oncology-related diseases and conditions. In connection with the Company's ongoing assessment of the Amgen Collaboration Agreement cost-share contributions, the Company determined that further investment in the development of LUMAKRAS was no longer commercially viable for BeiGene. As a result, in February 2023, the Company and Amgen entered into the Second Amendment to the Amgen Collaboration Agreement to (i) stop sharing costs with Amgen for the further development of LUMAKRAS during the period starting January 1, 2023 and ending August 31, 2023; and (ii) cooperate in good faith to prepare a transition plan with the anticipated termination of LUMAKRAS from the Amgen Collaboration Agreement.

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 recognizes 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 Amgen Collaboration Agreement, a Share Purchase Agreement ("SPA") was entered into by the parties in October 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, and Anthony

Hooper joined the Company's board of directors as the Amgen designee in January 2020. Amgen relinquished its right to appoint a designated director to the Company's board of directors in January 2023.

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 Company's portion of the co-development funding on the pipeline assets for the three and nine months ended September 30, 2023 and 2022 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Research and development expense	16,321	25,462	39,595	72,251
Amortization of research and development cost share liability	15,900	24,806	38,569	70,389
Total amount due to Amgen for BeiGene's portion of the development funding	32,221	50,268	78,164	142,640

	As of September 30, 2023
Remaining portion of development funding cap	517,544

As of September 30, 2023 and December 31, 2022, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Research and development cost share liability, current portion	63,652	114,335
Research and development cost share liability, non-current portion	191,739	179,625
Total research and development cost share liability	255,391	293,960

The total reimbursement due to (from) Amgen under the commercial profit-sharing agreement for product sales is classified in the income statement for the three and nine months ended September 30, 2023 and 2022 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Cost of sales - product	3,159	319	4,343	3,797
Research and development	431	(1,125)	1,743	(227)
Selling, general and administrative	(14,679)	(13,854)	(44,067)	(40,496)
Total	(11,089)	(14,660)	(37,981)	(36,926)

The Company purchases commercial inventory from Amgen to distribute in China. Inventory purchases amounted to $18,746 and $58,023 during the three and nine months ended September 30, 2023, respectively, and $29,269 and $59,330 during the three and nine months ended September 30, 2022, respectively. Net amounts payable to Amgen was $45,918 and $54,064 as of September 30, 2023 and December 31, 2022, respectively.

In-Licensing Arrangements - Development

The Company has in-licensed the rights to develop, manufacture and, if approved, commercialize multiple development stage drug candidates 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 milestone payments made under these arrangements for the three and nine months ended September 30, 2023 and 2022 are set forth below. All upfront and development milestones were expensed to research and development expense. All regulatory and commercial milestones were capitalized as intangible assets and are being amortized over the remainder of the respective product patent or the term of the commercialization agreements.

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
Payments due to collaboration partners	**Classification**	**$**	**$**	**$**	**$**
Upfront payments	Research and development expense	15,000	20,000	15,000	20,000
Regulatory and commercial milestone payments	Intangible asset	9,379	—	18,612	—
Total		24,379	20,000	33,612	20,000

4. Restricted Cash and Investments

Restricted Cash

The Company's restricted cash 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. Restricted cash as of September 30, 2023 and December 31, 2022 was as follows:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Short-term restricted cash	11,548	196
Long-term restricted cash	2,008	5,277
Total	13,556	5,473

In addition to the restricted cash balances above, the Company is required by the PRC securities law to use the proceeds from the STAR Offering in strict compliance with the planned uses as disclosed in the PRC prospectus as well as those disclosed in the Company's proceeds management policy approved by the board of directors. As of September 30, 2023, the Company had cash remaining related to the STAR Offering proceeds of $1,349,492.

Short-Term Investments

Short-term investments as of September 30, 2023 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	107,783	—	794	106,989
Total	107,783	—	794	106,989

Short-term investments as of December 31, 2022 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	674,262	—	9,011	665,251
Total	674,262	—	9,011	665,251

As of September 30, 2023, 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 September 30, 2023.

Equity Securities with Readily Determinable Fair Values

Leap Therapeutics, Inc. (Leap)

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. In September 2021, the Company purchased $7,250 of common stock in Leap's underwritten public offering. As of September 30, 2023, the Company's ownership interest in the outstanding common stock of Leap was 2.9% based on information from Leap. Inclusive of the shares of common stock issuable upon the exercise of the currently exercisable warrants, the Company's interest is approximately 4.7%. The Company measures the investment in the common stock and warrants at fair value, with changes in fair value recorded to other income (expense), net.

Losses recognized on the Company's investment in Leap were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Other income (expense), net	(2,291)	(2,950)	(2,927)	(25,611)

As of September 30, 2023 and December 31, 2022, the fair value of the common stock and warrants were as follows:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Fair value of Leap common stock	1,014	3,307
Fair value of Leap warrants	72	706

Private Equity Securities without Readily Determinable Fair Values

The Company invests in equity securities of certain companies whose securities are not publicly traded and fair value is not readily determinable and where the Company has concluded it does not have significant influence based on its ownership percentage and other factors. These investments are recorded at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The Company held investments of $57,631 and $57,054 in equity securities without readily determinable fair values as of September 30, 2023 and December 31, 2022, respectively.

Gains/losses recognized on the Company's investments in equity securities without readily determinable fair values were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Other income (expense), net	(5,522)	4,699	(4,441)	5,065

Equity-Method Investments

The Company records equity-method investments at cost and subsequently adjusts the basis based on the Company's ownership percentage in the investee's income and expenses, as well as dividends, if any. The Company holds equity-method investments totaling $27,325 and $27,710 as of September 30, 2023 and December 31, 2022, respectively, that it does not consider to be individually significant to its financial statements.

Losses recognized on the Company's equity-method investments were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Other income (expense), net	(2,675)	(1,357)	(5,299)	(2,591)

5. Inventories, Net

The Company's inventories, net consisted of the following:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Raw materials	94,031	88,957
Work in process	40,023	20,886
Finished goods	182,875	172,503
Total inventories, net	316,929	282,346

6. Property, Plant and Equipment, Net

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

	As of	
	September 30, 2023	December 31, 2022
	$	$
Land	65,485	65,485
Building	215,182	222,448
Manufacturing equipment	172,692	175,679
Laboratory equipment	186,545	158,908
Leasehold improvement	53,135	53,786
Software, electronics and office equipment	74,766	47,483
Property, plant and equipment, at cost	767,805	723,789
Less: accumulated depreciation	(220,835)	(171,470)
Construction in progress	631,068	293,627
Property, plant and equipment, net	1,178,038	845,946

As of September 30, 2023, the Company has construction in process of $419,498 related to the Hopewell facility construction.

Depreciation expense was $19,242 and $59,574 for the three and nine months ended September 30, 2023, respectively, and $15,214 and $45,255 for the three and nine months ended September 30, 2022, respectively.

7. Intangible Assets

Intangible assets as of September 30, 2023 and December 31, 2022 are summarized as follows:

	As of					
	September 30, 2023			December 31, 2022		
	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	(5,663)	1,837	7,500	(4,000)	3,500
Developed products	58,396	(6,576)	51,820	41,235	(4,119)	37,116
Trading license	816	(816)	—	816	(816)	—
Total finite-lived intangible assets	66,712	(13,055)	53,657	49,551	(8,935)	40,616

Product distribution rights consist of distribution rights on the approved cancer therapies licensed from Bristol-Myers Squibb Company ("BMS") as part of the BMS collaboration. The Company is amortizing the product distribution rights, as a single identified asset, through December 31, 2023, when the rights revert back to BMS under the terms of the Settlement Agreement. Developed products represent the post-approval milestone payments under license and commercialization agreements. The Company is amortizing the developed products over the remainder of the respective product patent or the term of the commercialization agreements. Trading license represents the Guangzhou drug distribution license acquired in September 2018. The Company amortized the drug distribution trading license over the remainder of the initial license term through February 2020. The trading license has been renewed through February 2024.

Amortization expense for developed products is included in cost of sales - product in the accompanying consolidated statements of operations. Amortization expense for product distribution rights and the trading licenses is included in operating expenses in the accompanying consolidated statements of operations.

The weighted-average life for each finite-lived intangible assets is approximately 9 years. Amortization expense was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Amortization expense - Cost of sales - product	981	800	2,620	2,444
Amortization expense - Operating expense	1,287	187	1,662	563
Total	2,268	987	4,282	3,007

Estimated amortization expense for each of the five succeeding years and thereafter, as of September 30, 2023 is as follows:

Year Ending December 31,	Cost of Sales - Product	Operating Expenses	Total
	$	$	$
2023 (remainder of year)	1,561	1,837	3,398
2024	6,240	—	6,240
2025	6,240	—	6,240
2026	6,240	—	6,240
2027	6,240	—	6,240
2028 and thereafter	25,299	—	25,299
Total	51,820	1,837	53,657

8. Income Taxes

Income tax expense was $13,925 and $39,091 for the three and nine months ended September 30, 2023, respectively. Income tax expense was $6,318 and $28,408 for the three and nine months ended September 30, 2022. The income tax expense for the three and nine months ended September 30, 2023 and 2022 was primarily attributable to current China tax expense due to certain non-deductible expenses and current U.S. tax expense determined after other special tax deductions and research and development tax credits.

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, as of September 30, 2023, the Company will maintain a full valuation allowance against its net deferred tax assets.

As of September 30, 2023, the Company had gross unrecognized tax benefits of $13,910. 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 $1,386 and $2,355 in the three and nine months ended September 30, 2023 primarily due to U.S. federal and state tax credits and incentives.

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 September 30, 2023, Australia tax matters are open to examination for the years 2013 through 2023, China tax matters are open to examination for the years 2013 through 2023, Switzerland tax matters are open to examination for the years 2018 through 2023, and U.S. federal tax matters are open to examination for years 2015 through 2023. Various U.S. states and other non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2012 through 2023.

9. Supplemental Balance Sheet Information

Prepaid expenses and other current assets consist of the following:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Prepaid research and development costs	73,036	71,488
Prepaid manufacturing cost	71,993	58,950
Prepaid taxes	19,568	20,478
Other receivables	43,911	22,777
Prepaid commercial	1,089	1,461
Interest receivable	1,628	3,039
Prepaid insurance	6,492	3,664
Other current assets	23,944	34,696
Total	241,661	216,553

Other non-current assets consist of the following:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Prepayment of property and equipment	12,343	22,025
Prepaid supply cost (1)	28,290	48,642
Prepaid VAT	2,034	804
Rental deposits and other	6,944	7,054
Long-term restricted cash	2,008	5,277
Long-term investments	89,281	91,779
Other	—	109
Total	140,900	175,690

(1) Represents payments for future supply purchases under the license agreement with Luye Pharma Group and facility expansion under commercial supply agreements. The payments are providing future benefit to the Company through credits on commercial supply purchases.

Accrued expenses and other payables consist of the following:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Compensation related	173,980	184,775
External research and development activities related	92,710	139,168
Commercial activities	60,692	51,806
Individual income tax and other taxes	23,191	18,815
Sales rebates and returns related	112,256	41,817
Other	42,995	30,971
Total	505,824	467,352

Other long-term liabilities consist of the following:

	As of	
	September 30, 2023	December 31, 2022
	$	$
Deferred government grant income	33,909	38,176
Pension liability	7,830	7,760
Other	247	159
Total	41,986	46,095

10. Debt

The following table summarizes the Company's short-term and long-term debt obligations as of September 30, 2023 and December 31, 2022:

Lender	Agreement Date	Line of Credit	Term	Maturity Date	Interest Rate	As of			
						September 30, 2023		December 31, 2022	
						$	RMB	$	RMB
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	10,273	75,000	7,250	50,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	6,800	49,643	1,450	10,000
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(3)	5,479	40,000	5,437	37,500
China Minsheng Bank (the "Senior Loan")	September 24, 2020	$200,000		(4)	4.3%	150,000	1,095,130	150,000	1,034,554
Shanghai Pudong Development Bank	February 25, 2022	$50,000	1-year	February 25, 2023	2.2%	—	—	50,000	344,851
China Merchants Bank	June 5, 2023	RMB 400,000	1-year	June 4, 2024	3.2%	54,788	400,000	—	—
HSBC Bank	May 4, 2023	RMB 340,000	1-year	May 3, 2024	4.7%	46,570	340,000	—	—
China Industrial Bank	May 30, 2023	RMB 200,000	1-year	May 29, 2024	2.8%	27,394	200,000	—	—
Other short-term debt (5)						27,257	199,000	114,832	792,000
Total short-term debt						328,560	2,398,773	328,969	2,268,905
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	64,376	470,000	75,395	520,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	38,743	282,857	47,847	330,000
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(3)	42,529	310,500	49,369	340,500
China CITIC Bank	July 29, 2022	RMB480,000	10-year	July 28, 2032	(6)	56,842	415,000	36,537	252,000
Total long-term bank loans						202,491	1,478,357	209,148	1,442,500

1. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.5% as of September 30, 2023. The loan is secured by BeiGene Guangzhou Factory's land use right and certain Guangzhou Factory fixed assets in the first phase of the Guangzhou manufacturing facility's build out. The Company repaid $3,483 (RMB25,000) during the nine months ended September 30, 2023.

2. On January 22, 2020, BeiGene Guangzhou Biologics Manufacturing Co., Ltd.("BeiGene Guangzhou Factory") entered into a nine-year bank loan with China Merchants Bank to borrow up to RMB1,100,000 at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan is secured by Guangzhou Factory's second land use right and fixed assets placed into service upon completion of the second phase of the Guangzhou manufacturing facility's build out. In connection with the Company's short-term loan agreements with China Merchants Bank entered into during the year ended December 31, 2020, the borrowing capacity was reduced from RMB1,100,000 to RMB350,000. The loan interest rate was 4.1% as of September 30, 2023. The Company repaid $1,081 (RMB7,500) during the nine months ended September 30, 2023.

3. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.9% as of September 30, 2023. The loan is secured by fixed assets placed into service upon completion of the third phase of the Guangzhou manufacturing facility's build out. The Company repaid $3,898 (RMB27,500) during the nine months ended September 30, 2023.

4. In September 2020, the Company entered into a loan agreement with China Minsheng Bank for a total loan facility of up to $200,000 ("Senior Loan"), of which $120,000 was designated to fund the purchase of noncontrolling equity interest in BeiGene Biologics Co., Ltd. ("BeiGene Biologics") from Guangzhou GET Technology Development Co., Ltd. (now Guangzhou High-tech Zone Technology Holding Group Co., Ltd.) ("GET") and repayment of the loan provided by GET ("Shareholder Loan") and $80,000 was designated for general working capital purposes. The Senior Loan had an original maturity date of October 8, 2021, which was the first anniversary of the first date of utilization of the loan. The Company may extend the original maturity date for up to two additional 12 month periods. On October 8, 2021, the Company extended the maturity date for twelve months to October 8, 2022 and repurposed the Senior Loan for general working capital purposes. On September 30, 2022, the Company entered into an amendment and restatement agreement with China Minsheng Bank to extend the maturity date to October 9, 2023. In October 2023, the Company repaid the outstanding principal of the Senior Loan in the amount of $150,000.

5. During the years ended December 31, 2022 and 2021, the Company entered into short-term working capital loans with China Industrial Bank and China Merchants Bank to borrow up to RMB875,000 in aggregate, with maturity dates ranging from December 15, 2022 to May 24, 2023. The Company repaid $109,576 (RMB792,000) and drew down $28,174 (RMB199,000) during the nine months ended September 30, 2023.The weighted average interest rate for the short-term working capital loans was approximately 3.2% as of September 30, 2023. The outstanding principal balance is due in May 2024.

6. In July 2022, the Company entered into a 10-year bank loan agreement with China CITIC Bank to borrow up to RMB480,000 at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The Company drew down $22,502 (RMB163,000) during the nine months ended September 30, 2023. The weighted average loan interest rate was 3.9% as of September 30, 2023. The loan is secured by BeiGene Suzhou Co., Ltd.'s land use right and construction in process.

Line of Credit

On July 28, 2023 (the "Signing Date"), a credit facility agreement (the "Credit Agreement") was entered into by and between the Company, as the borrower, and China Merchants Bank Co., Ltd., as the lender (the "Lender"). The Credit Agreement provides for a $400 million uncommitted and unsecured credit facility (the "Credit Facility"), pursuant to which each loan issued has a term up to one year, provided that all loans must be repaid within eighteen months of the Signing Date. Loans under the Credit Facility have a floating interest rate based on the secured overnight financing rate plus an applicable margin and are calculated daily from the date the loan is utilized and settled on a quarterly basis. As of September 30, 2023, no borrowings were outstanding under the Credit Agreement.

Interest Expense

Interest expense recognized for the three and nine months ended September 30, 2023 was $6,630 and $16,095, respectively, among which, $11,632 and $12,404 was capitalized, respectively. Interest expense recognized for the three and nine months ended September 30, 2022 was $5,596 and $16,580, respectively, among which, $527 and $2,462 was capitalized, respectively.

11. Product Revenue

The Company's product revenue is primarily derived from the sale of its internally developed products BRUKINSA in the United States China, and other regions, and tislelizumab and pamiparib in China; XGEVA, BLINCYTO and KYPROLIS in China under a license from Amgen; REVLIMID® and VIDAZA® in China under a license from BMS; and POBEVCY® in China under a license from Bio-Thera.

The table below presents the Company's net product sales for the three and nine months ended September 30, 2023 and 2022.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Product revenue – gross	731,515	398,379	1,908,448	1,036,652
Less: Rebates and sales returns	(136,225)	(48,873)	(349,122)	(121,062)
Product revenue – net	595,290	349,506	1,559,326	915,590

The following table disaggregates net product sales by product for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
BRUKINSA®	357,695	155,495	877,353	388,567
Tislelizumab	144,352	128,206	408,666	320,728
REVLIMID®	14,960	19,046	59,965	60,622
XGEVA®	24,456	18,148	68,621	47,156
POBEVCY®	14,130	9,873	41,894	29,671
BLINCYTO®	14,870	6,214	40,394	27,610
KYPROLIS®	11,101	2,820	27,096	11,225
VIDAZA®	4,320	3,314	11,439	12,260
Pamiparib	1,887	1,266	5,612	5,843
Other	7,519	5,124	18,286	11,908
Total product revenue – net	595,290	349,506	1,559,326	915,590

The following table presents the roll-forward of accrued sales rebates and returns for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
	$	$
Balance at beginning of the period	41,817	59,639
Accrual	349,122	121,062
Payments	(278,683)	(130,811)
Balance at end of the period	112,256	49,890

12. Earnings (Loss) Per Share

The following table reconciles the numerator and denominator in the computations of basic and diluted earnings (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Numerator:				
Net income (loss)	215,413	(557,556)	(514,155)	(1,558,480)
Denominator:				
Weighted average shares outstanding—basic	1,360,716,279	1,345,303,747	1,358,392,470	1,337,976,853
Effect of dilutive securities:				
Stock options, restricted stock units and ESPP shares	29,615,554	—	—	—
Weighted average shares outstanding—diluted	1,390,331,833	1,345,303,747	1,358,392,470	1,337,976,853

Basic earnings per share was computed using the weighted-average number of ordinary shares outstanding during the period. For the three months ended September 30, 2023, diluted earnings per share was computed using the weighted-average number of ordinary shares and the effect of potentially dilutive shares outstanding during the periods. Potentially dilutive shares consist of stock options, restricted stock units and ESPP shares. The dilutive effect of outstanding stock options, restricted stock units and ESPP shares is reflected in diluted net earnings per share by application of the treasury stock method.

For the nine months ended September 30, 2023 and the three and nine months ended September 30, 2022, the computation of basic loss per share using the two-class method was not applicable as the Company was in a net loss position, and the effects of all share options, restricted shares, restricted share units and ESPP shares were excluded from the calculation of diluted loss per share, as their effect would have been anti-dilutive.

13. Share-Based Compensation Expense

2016 Share Option and Incentive Plan

In January 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 in February 2016. The Company initially reserved 65,029,595 ordinary shares for the issuance of awards under the 2016 Plan, plus any shares available under the 2011 Option Plan (the “2011 Plan”), and not subject to any outstanding options as of the effective date of the 2016 Plan, along with underlying share awards under the 2011 Plan that are cancelled or forfeited without issuance of ordinary shares. As of September 30, 2023, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,166,822. In December 2018, the shareholders approved an 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. In June 2020, the shareholders approved an Amendment No. 1 to the 2016 Plan to increase the number of shares authorized for issuance by 57,200,000 ordinary shares and to extend the term of the plan through April 13, 2030. The number of shares available for issuance under the 2016 Plan is subject to adjustment in the event of a share split, share dividend or other change in the Company’s capitalization.

During the nine months ended September 30, 2023, the Company granted options for 9,710,389 ordinary shares and restricted share units for 32,773,429 ordinary shares under the 2016 Plan. As of September 30, 2023, options and restricted share units for ordinary shares outstanding under the 2016 Plan totaled 62,526,923 and 67,329,574, respectively. As of September 30, 2023, share-based awards to acquire 37,482,015 ordinary shares were available for future grant under the 2016 Plan.

In order to continue to provide incentive opportunities under the 2016 Plan, the Board of Directors and shareholders of the Company approved an amendment to the 2016 Plan (the "Amendment No. 2"), which became effective as of June 22, 2022, to increase the number of authorized shares available for issuance under the 2016 Plan by 66,300,000 ordinary shares, or 5% of the Company's outstanding shares as of March 31, 2022.

2018 Inducement Equity Plan

In June 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 listing rules of the Stock Exchange of Hong Kong Limited ("HKEX").

As of September 30, 2023, there were no options or restricted share units for ordinary shares outstanding under the 2018 Plan.

Upon the effectiveness of Amendment No. 2 to the 2016 Plan, on June 22, 2022, the 2018 Plan was terminated to the effect that no new equity awards shall be granted under the plan but the outstanding equity awards under the plan shall continue to vest and/or be exercisable in accordance with their terms.

2018 Employee Share Purchase Plan

In June 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 December 2018, the board of directors of the Company approved an 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. In June 2021, the board of directors of the Company adopted the third amended and restated ESPP to include certain technical amendments under U.S. tax rules and to consolidate the changes in the prior amendment, effective on September 1, 2021. 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.

As of September 30, 2023, 1,941,075 ordinary shares were available for future issuance under the ESPP.

The following tables summarizes the shares issued under the ESPP:

		Market Price[1]		Purchase Price[2]		
Issuance Date	Number of Ordinary Shares Issued	ADS	Ordinary	ADS	Ordinary	Proceeds
August 31, 2023	794,144	$ 207.55	$ 15.97	$ 176.42	$ 13.57	$ 10,777
February 28, 2023	930,582	$ 171.10	$ 13.16	$ 145.44	$ 11.19	$ 10,414
August 31, 2022	861,315	$ 171.66	$ 13.20	$ 145.91	$ 11.22	$ 9,667
February 28, 2022	667,160	$ 210.52	$ 16.19	$ 178.94	$ 13.76	$ 9,183

[1] The market price is the lower of the closing price on the Nasdaq Stock Market on the issuance date or the offering date, in accordance with the terms of the ESPP.

[2] The purchase price is the price which was discounted from the applicable market price, in accordance with the terms of the ESPP.

The following table summarizes total share-based compensation expense recognized for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
Research and development	44,150	36,417	124,126	104,382
Selling, general and administrative	51,969	41,759	150,710	120,654
Total	96,119	78,176	274,836	225,036

14. Accumulated Other Comprehensive Loss

The movement of accumulated other comprehensive loss was as follows:

	Foreign Currency Translation Adjustments	Unrealized Gains/(Losses) on Available-for-Sale Securities	Pension Liability Adjustments	Total
	$	$	$	$
Balance as of December 31, 2022	(62,523)	(9,011)	(5,883)	(77,417)
Other comprehensive (loss) income before reclassifications	(75,732)	8,218	—	(67,514)
Net-current period other comprehensive (loss) income	(75,732)	8,218	—	(67,514)
Balance as of September 30, 2023	(138,255)	(793)	(5,883)	(144,931)

15. Shareholders' Equity

BMS Settlement

On August 1, 2023, the Company entered into a Settlement and Termination Agreement (the "Settlement Agreement") with BMS-Celgene and certain of its affiliates relating to the termination of the parties' ongoing contractual relationships, the previously-disclosed ongoing arbitration proceeding concerning ABRAXANE® (the "Arbitration"), the License and Supply Agreement ("LSA"), the Amended and Restated Quality Agreement (the "QA"), and the Share Subscription Agreement (the "SSA"), entered into by the parties in 2017 and 2018. Pursuant to the Settlement Agreement, the parties agreed to mutually dismiss the Arbitration and BMS-Celgene and its affiliates agreed to transfer 23,273,108 ordinary shares of the Company originally purchased in 2017, in each case subject to and in accordance with the terms and conditions of the Settlement Agreement. In consideration for the shares being returned, the Company agreed to drop its claims pursuant to the Settlement Agreement. Furthermore, the parties agreed to terminate the LSA and QA on December 31, 2023, subject to the Company's right to continue selling all inventory of REVLIMID and VIDAZA until sold out or December 31, 2024, whichever is earlier. The Settlement Agreement provides for a settlement and release by each party of claims arising from or relating to the Arbitration, the LSA, the QA and the SSA, as well as other disputes and potential disputes between the parties, in each case subject to and in accordance with the terms and conditions of the Agreement. The receipt of the shares occurred on August 15, 2023. The Company recorded a noncash gain upon receipt of $362,917, which represents the fair value on the day the shares were received. The gain was recorded within other income (expense), net in the consolidated statements of operations. The shares were constructively retired as of September 30, 2023. The Company recorded the amount of the cancelled shares in excess of par to additional paid-in capital.

16. 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.

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 September 30, 2023 and December 31, 2022, the net assets of the Company's PRC subsidiaries amounted to $3,825,964 and $3,548,881, respectively.

17. Commitments and Contingencies

Purchase Commitments

As of September 30, 2023, the Company had non-cancellable purchase commitments amounting to $131,693, of which $41,186 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $90,507 related to binding purchase obligations of inventory from BMS and Amgen. The Company does not have any minimum purchase requirements for inventory from BMS or Amgen.

Capital Commitments

The Company had capital commitments amounting to $442,562 for the acquisition of property, plant and equipment as of September 30, 2023, which were mainly for the Company's Hopewell facility, additional capacity at the Guangzhou and Suzhou manufacturing facilities, and new building for Beijing Innerway Bio-tech Co., Ltd.

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 September 30, 2023, the Company's remaining co-development funding commitment was $517,544.

Research and Development Commitment

The Company entered into a long-term research and development agreement in June 2021, which includes obligations to make an upfront payment and fixed quarterly payments over the next three years. As of September 30, 2023, the total research and development commitment amounted to $16,498.

Funding Commitment

The Company had committed capital related to two equity method investments in the amount of $15,053. As of September 30, 2023, the remaining capital commitment was $10,553 and is expected to be paid from time to time over the investment period.

18. 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 primarily located in the PRC and the U.S.

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 revenues by geographic area are presented as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
United States- total revenue	**398,229**	**133,431**	**815,059**	**347,180**
Product revenue	270,084	108,104	632,391	264,373
Collaboration revenue	128,145	25,327	182,668	82,807
China- total revenue	**287,935**	**233,077**	**831,399**	**636,241**
Product revenue	284,981	233,077	825,809	636,241
Collaboration revenue	2,954	—	5,590	—
Europe- total revenue	**85,583**	**17,995**	**153,273**	**46,634**
Product revenue	30,664	5,200	76,487	9,205
Collaboration revenue	54,919	12,795	76,786	37,429
Rest of world- product revenue	**9,561**	**3,125**	**24,639**	**5,771**
Total Revenue	**781,308**	**387,628**	**1,824,370**	**1,035,826**

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

Cautionary Note Regarding Forward-Looking Statements

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 "Part I – Item 1 – Financial Statements." This Quarterly Report contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are based on management's current expectations and projections about future events and trends that may affect the business, financial condition, and operating results. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. Forward-looking statements often include words such as "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. These forward-looking statements, include, but are not limited to, statements regarding: our ability to successfully commercialize our approved medicines and to obtain approvals in additional indications and territories for our medicines; our ability to successfully develop and commercialize our in-licensed medicines and drug candidates and any other medicines and drug candidates we may in-license; our ability to further develop sales and marketing capabilities and launch and commercialize new medicines, if approved; our ability to maintain and expand regulatory approvals for our medicines and drug candidates, if approved; the pricing and reimbursement of our medicines 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 and obtain regulatory approvals; 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, medicines, drug candidates and technology; the scope of protection we (or our licensors) are able to establish and maintain for intellectual property rights covering our medicines, 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; the regulatory environment and regulatory developments in the United States, China, the United Kingdom ("UK"), Switzerland, the European Union ("EU") and other jurisdictions in which we operate; 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 plans and expectations to build significant technical operations and independent production capabilities for small molecule medicines and large molecule biologics to support the global demand for both commercial and clinical supply; 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 medicines for commercial sale; the rate and degree of market access and acceptance of our medicines and drug candidates, if approved; developments relating to our competitors and our industry, including competing therapies; the size of the potential markets for our medicines 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, key milestones, expenses, capital expenditures, capital requirements and share performance; and the future trading price of our ADSs, ordinary shares and RMB Shares, and impact of securities analysts' reports on these prices. These statements involve risks and uncertainties, including those that are described in "Part II – Item 1A – Risk Factors" of this Quarterly Report, that may cause actual future events or results to differ materially from those expected. Given these uncertainties, you should not place undue reliance on these forward-looking statements. 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. This Quarterly Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, you are cautioned not to give undue weight to this information. Unless the context requires otherwise, in this Quarterly Report, the terms "BeiGene," the "Company," "we," "us" and "our" refer to BeiGene, Ltd., a Cayman Islands holding company with operations conducted by its subsidiaries, and its subsidiaries, on a consolidated basis.

Overview

We delivered another strong quarter across our global portfolio, driven by the ongoing successful launch of BRUKINSA® , where we continue to see rapid uptake across all approved indications, including chronic lymphocytic leukemia (CLL).

We have regained the rights to TEVIMBRA® worldwide, which is now approved in the EU and under regulatory review in 10 additional markets. We are now better positioned than ever before to execute on our global growth strategy while steadily improving operating leverage with moderate expense growth.

Key highlights for the third quarter of 2023 are as follows:

- Generated global sales of BRUKINSA of $357.7 million, an increase of 130.0% compared with the prior-year period, as global launch momentum continues across multiple indications, including CLL;
- Received a positive opinion from the European Committee for Health and Medicinal Products (CHMP) of the European Medicines Agency for BRUKINSA for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least two prior systematic treatments;
- Received positive guidance from the National Institute for Health and Care Excellence for reimbursement of BRUKINSA on the National Health Service in England and Wales for the treatment of adult patients with R/R CLL;
- Regained global rights to the development, manufacture and commercialization of TEVIMBRA, strengthening the Company's global portfolio in solid tumors;
- Announced European Commission (EC) approval of TEVIMBRA as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic ESCC after prior platinum-based chemotherapy; and
- Announced U.S. Food and Drug Administration (FDA) acceptance for review of a Biologics License Application (BLA) for tislelizumab as a first-line treatment for patients with unresectable, recurrent, locally advanced, or metastatic ESCC with a target action date in July 2024, under the Prescription Drug User Fee Act (PDUFA).

Recent Developments

Recent Business Developments

On October 20, 2023, we announced that the National Institute for Health and Care Excellence of the UK issued a final draft guidance recommending BRUKINSA (zanubrutinib) for the treatment of eligible adult patients with: untreated CLL if there is a 17p deletion or TP53 mutation (high risk) or untreated CLL without a 17p deletion or TP53 mutation, and fludarabine-cyclophosphamide-rituximab or bendamustine plus rituximab is unsuitable and relapsed or refractory CLL.

On October 17, 2023, we announced results from the final analysis of the Phase 3 RATIONALE 305 trial showing tislelizumab plus chemotherapy significantly improved overall survival in the intent-to-treat population as a first-line treatment for patients with advanced gastric or gastroesophageal junction adenocarcinoma.

On October 17, 2023, we announced that the Phase 3 RATIONALE 315 trial met primary endpoints of major pathological response rate and event-free survival for tislelizumab plus chemotherapy in patients with resectable non-small cell lung cancer ("NSCLC").

On October 13, 2023, we announced that the Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion recommending approval of BRUKINSA (zanubrutinib), in combination with obinutuzumab for the treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least two prior lines of systemic therapy.

On September 19, 2023, we announced that the European Commission approved TEVIMBRA (tislelizumab) as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic ESCC after prior platinum-based chemotherapy. Additionally, the U.S. Food and Drug Administration accepted for review a Biologics License Application for tislelizumab as a first-line treatment for patients with unresectable, recurrent, locally advanced, or metastatic ESCC.

On September 19, 2023, we announced that we entered into a Mutual Termination and Release Agreement with Novartis to regain worldwide rights to develop, manufacture, and commercialize TEVIMBRA.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	$	%	2023	2022	$	%
	(dollars in thousands)							
Revenues								
Product revenue, net	$ 595,290	$ 349,506	$245,784	70.3 %	$1,559,326	$ 915,590	$643,736	70.3 %
Collaboration revenue	186,018	38,122	147,896	388.0 %	265,044	120,236	144,808	120.4 %
Total revenues	781,308	387,628	393,680	101.6 %	1,824,370	1,035,826	788,544	76.1 %
Expenses								
Cost of sales - product	96,309	76,543	19,766	25.8 %	274,088	212,953	61,135	28.7 %
Research and development	453,259	426,363	26,896	6.3 %	1,284,607	1,194,485	90,122	7.5 %
Selling, general and administrative	364,421	322,892	41,529	12.9 %	1,087,954	948,868	139,086	14.7 %
Amortization of intangible assets	1,287	187	1,100	588.2 %	1,662	563	1,099	195.2 %
Total expenses	915,276	825,985	89,291	10.8 %	2,648,311	2,356,869	291,442	12.4 %
Loss from operations	(133,968)	(438,357)	304,389	(69.4)%	(823,941)	(1,321,043)	497,102	(37.6)%
Interest income, net	26,649	12,759	13,890	108.9 %	57,735	34,261	23,474	68.5 %
Other income (expense), net	336,657	(125,640)	462,297	(368.0)%	291,142	(243,290)	534,432	(219.7)%
Income (loss) before income taxes	229,338	(551,238)	780,576	(141.6)%	(475,064)	(1,530,072)	1,055,008	(69.0)%
Income tax expense	13,925	6,318	7,607	120.4 %	39,091	28,408	10,683	37.6 %
Net income (loss)	$ 215,413	$(557,556)	$772,969	(138.6)%	$(514,155)	$(1,558,480)	$1,044,32	(67.0)%

Comparison of the Three Months Ended September 30, 2023 and 2022

Revenue

Total revenue increased to $781.3 million for the three months ended September 30, 2023, from $387.6 million for the three months ended September 30, 2022, due to an increase in sales of BRUKINSA and tislelizumab, as well as increased sales of our in-licensed products from Amgen. Additionally, collaboration revenue increased due to the recognition of the remaining deferred revenue associated with the Novartis collaborations upon termination of the agreements.

The following table summarizes the components of revenue for the three months ended September 30, 2023 and 2022, respectively:

	Three Months Ended September 30,		Changes	
	2023	2022	$	%
	(dollars in thousands)			
Product revenue	$ 595,290	$ 349,506	$ 245,784	70.3 %
Collaboration revenue:				
Material rights revenue	71,980	—	71,980	NM
Research and development service revenue	59,052	9,834	49,218	500.5 %
Right to access intellectual property revenue	51,978	26,249	25,729	98.0 %
Other	3,008	2,039	969	47.5 %
Total collaboration revenue	186,018	38,122	147,896	388.0 %
Total Revenue	$ 781,308	$ 387,628	$ 393,680	101.6 %

Net product revenues consisted of the following:

	Three Months Ended September 30,		Changes	
	2023	2022	$	%
	(dollars in thousands)			
BRUKINSA®	$ 357,695	$ 155,495	$ 202,200	130.0 %
Tislelizumab	144,352	128,206	16,146	12.6 %
REVLIMID®	14,960	19,046	(4,086)	(21.5)%
XGEVA®	24,456	18,148	6,308	34.8 %
POBEVCY®	14,130	9,873	4,257	43.1 %
BLINCYTO®	14,870	6,214	8,656	139.3 %
KYPROLIS®	11,101	2,820	8,281	293.7 %
VIDAZA®	4,320	3,314	1,006	30.4 %
Pamiparib	1,887	1,266	621	49.1 %
Other	7,519	5,124	2,395	46.7 %
Total product revenue	$ 595,290	$ 349,506	$ 245,784	70.3 %

Net product revenue increased 70.3% to $595.3 million for the three months ended September 30, 2023, compared to $349.5 million in the prior-year period, primarily due to continued increases in sales of BRUKINSA globally and tislelizumab in China. In addition, product revenues in the third quarter of 2023 were positively impacted by sales of in-licensed products from Amgen in China. During the quarter ended September 30, 2023, we continued to see increased patient demand in China for tislelizumab and BRUKINSA due to broader reimbursement and increase in market share, and this demand more than offset the effect of the related price reductions.

Global sales of BRUKINSA totaled $357.7 million in the third quarter, representing a 130.0% increase compared to the prior-year period; U.S. sales of BRUKINSA totaled $270.1 million in the third quarter, compared to $108.1 million in the prior-year period, representing growth of 149.8%. U.S. sales continued to accelerate after the approval and launch of BRUKINSA in the first quarter of 2023 for adult patients with CLL and small lymphocytic lymphoma (SLL). BRUKINSA sales in China totaled $47.4 million, representing growth of 20.8% over the prior-year period, driven by increases in all approved indications. BRUKINSA rest of world sales totaled $40.2 million in the third quarter, representing growth of 410.2% compared to the prior-year period, primarily driven by an increase in all approved indications, including CLL and SLL in Europe.

Sales of tislelizumab in China totaled $144.4 million in the third quarter, compared to $128.2 million in the prior-year period, representing a 12.6% increase. In the third quarter, new patient demand from broader reimbursement and hospital listings continued to drive increased market penetration and market share for tislelizumab. We believe that our strategy of expanding our salesforce and hospital listings and continuing to seek expanded labels in broad indications will allow us to continue to increase our market share.

Collaboration revenue totaled $186.0 million for the three months ended September 30, 2023, of which $183.0 million related to the recognition of the remaining deferred revenue associated with the Novartis collaborations upon termination of the agreements, consisting of $59.1 million recognized from deferred R&D service revenue under both the tislelizumab and ociperlimab collaborations, $52.0 million recognized from deferred revenue for Novartis' right to access ociperlimab over the option period prior to termination and $72.0 million recognized from deferred material right revenue associated with the ociperlimab collaboration upon termination. Additionally, $3.0 million was recognized primarily related to the sale of tislelizumab and ociperlimab clinical supply to Novartis and revenue generated under the broad markets marketing and promotion agreement. Collaboration revenue totaled $38.1 million for the three months ended September 30, 2022, of which $9.8 million was recognized from deferred revenue for R&D services performed during the three months ended September 30, 2022 under both the tislelizumab and ociperlimab collaborations and $26.2 million was recognized from deferred revenue for Novartis' right to access ociperlimab over the option period (see Note 3 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q).

Cost of Sales

Cost of sales increased to $96.3 million for the three months ended September 30, 2023 from $76.5 million for the three months ended September 30, 2022, primarily due to increased product sales of BRUKINSA and tislelizumab, as well as sales of in-licensed products from Amgen in China.

Gross Margin

Gross margin on global product sales increased to $499.0 million for the three months ended September 30, 2023, compared to $273.0 million in the prior-year period, primarily due to increased product sales in the current year period. Gross margin as a percentage of product sales increased to 83.8% for the three months ended September 30, 2023, from 78.1% in the comparable period of the prior year. The increase is primarily due to proportionally higher sales mix of global BRUKINSA compared to lower margin sales of in-licensed products, as well as lower costs per unit for tislelizumab in China.

Research and Development Expense

Research and development expense increased by $26.9 million, or 6.3%, to $453.3 million for the three months ended September 30, 2023 from $426.4 million for the three months ended September 30, 2022. The following table summarizes external clinical, external non-clinical and internal research and development expense for the three months ended September 30, 2023 and 2022, respectively:

	Three Months Ended September 30,		Changes	
	2023	2022	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 126,301	$ 128,635	$ (2,334)	(1.8)%
Upfront license fees	15,000	20,000	(5,000)	(25.0)%
Amgen co-development expense[1]	15,832	25,463	(9,631)	(37.8)%
Total external research and development expenses	157,133	174,098	(16,965)	(9.7)%
Internal research and development expenses	296,126	252,265	43,861	17.4 %
Total research and development expenses	$ 453,259	$ 426,363	$ 26,896	6.3 %

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended September 30, 2023 totaled $31.7 million, of which $15.8 million was recorded as R&D expense. The remaining $15.9 million was recorded as a reduction of the R&D cost share liability.

The decrease in external research and development expenses in the third quarter was primarily attributable to a decrease in Amgen co-development expense, external clinical trial costs for TEVIMBRA (tislelizumab) and ZW25 (zanidatamab) and preclinical trial costs for certain assets in our portfolio, partially offset by higher external clinical trial costs for BRUKINSA.

Internal research and development expense increased $43.9 million, or 17.4%, to $296.1 million, and was primarily attributable to the expansion of our global discovery and development organization, as well as our continued efforts to internalize research and clinical trial activities, and included the following:

- $22.8 million increase of employee salary and benefits, primarily attributable to hiring more research and development personnel to support our expanding research and development activities;
- $7.7 million increase of share-based compensation expense, primarily attributable to our increased headcount of research and development employees, resulting in more awards being expensed;
- $6.4 million net increase in depreciation, market access, and other expenses;
- $6.0 million increase of consulting fees, which was mainly attributable to activities in the United States and Europe; and
- $1.0 million increase of travel and meeting expenses, which was mainly due to travel normalizing and key conferences in connection with the advancement of our drug candidates.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $41.5 million, or 12.9%, to $364.4 million for the three months ended September 30, 2023, from $322.9 million for the three months ended September 30, 2022. The increase was primarily attributable to the following:

- $39.2 million increase of external commercial-related expenses, including grants and sponsorships, meetings, conferences and seminars, travel expenses, marketing and promotional activities, and market access studies and analytics, related to commercial expansion in the United States and Europe driven by the launch of BRUKINSA in CLL;
- $20.0 million decrease in consulting expenses due primarily to lower external commercial expenses in China;
- $11.5 million increase of employee salary and benefits, primarily attributable to hiring more commercial and medical affairs personnel to support our commercial expansion activities;
- $10.1 million increase of share-based compensation expense, primarily attributable to our increased headcount of sales and administrative employees, resulting in more awards being expensed; and
- $0.7 million increase of professional fees and other administrative expenses.

Interest Income, Net

Interest income, net increased by $13.9 million, or 108.9%, to $26.6 million of net interest income for the three months ended September 30, 2023, from $12.8 million of net interest income for three months ended September 30, 2022. The increase in interest income, net, was primarily attributable to increased interest income resulting from higher interest rates on our cash and short-term investment balances and a decrease in interest expense as a result of higher interest capitalized related to Hopewell construction in process.

Other Income (Expense), Net

Other income, net was $336.7 million for the three months ended September 30, 2023, primarily due to the noncash gain recorded for the receipt of ordinary shares resulting from the BMS settlement and government subsidy income, partially offset by foreign exchange losses resulting from the strengthening of the U.S. dollar compared to the RMB in the period and the revaluation impact of foreign currencies held in U.S. functional currency subsidiaries and unrealized losses on our equity investments.

For the three months ended September 30, 2022, other expense, net, was $125.6 million, which was primarily due to foreign exchange losses resulting from the strengthening of the U.S. dollar compared to the RMB in the period and the revaluation impact of foreign currencies held in U.S. functional currency subsidiaries and unrealized losses on our equity investments.

Income Tax Expense

Income tax expense was $13.9 million for the three months ended September 30, 2023 as compared to $6.3 million for the three months ended September 30, 2022. The income tax expense for the three months ended September 30, 2023 and 2022 was primarily attributable to current China tax expense due to certain non-deductible expenses and current U.S. tax expense determined after other special tax deductions and research and development tax credits.

Comparison of the Nine Months Ended September 30, 2023 and 2022

Revenue

Total revenue increased to $1.8 billion, or 76.1%, for the nine months ended September 30, 2023, from $1.0 billion for the nine months ended September 30, 2022, primarily due to increased sales of our internally developed products, BRUKINSA and tislelizumab, as well as increased sales of in-licensed products, most notably from the Amgen products. Additionally, collaboration revenue increased due to the recognition of the remaining deferred revenue associated with the Novartis collaborations upon termination of the agreements.

The following table summarizes the components of revenue for the nine months ended September 30, 2023 and 2022, respectively:

	Nine Months Ended September 30,		Changes	
	2023	2022	$	%
	(dollars in thousands)			
Product revenue	$ 1,559,326	$ 915,590	$ 643,736	70.3 %
Collaboration revenue:				
Material rights revenue	71,980	—	71,980	NM
Research and development service revenue	79,432	34,074	45,358	133.1 %
Right to access intellectual property revenue	104,475	78,746	25,729	32.7 %
Other	9,157	7,416	1,741	23.5 %
Total collaboration revenue	265,044	120,236	144,808	120.4 %
Total Revenue	$ 1,824,370	$ 1,035,826	$ 788,544	76.1 %

Net product revenues consisted of the following:

	Nine Months Ended September 30,		Changes	
	2023	2022	$	%
	(dollars in thousands)			
BRUKINSA®	877,353	388,567	$ 488,786	125.8 %
Tislelizumab	408,666	320,728	87,938	27.4 %
REVLIMID®	59,965	60,622	(657)	(1.1)%
XGEVA®	68,621	47,156	21,465	45.5 %
POBEVCY®	41,894	29,671	12,223	41.2 %
BLINCYTO®	40,394	27,610	12,784	46.3 %
KYPROLIS®	27,096	11,225	15,871	141.4 %
VIDAZA®	11,439	12,260	(821)	(6.7)%
Pamiparib	5,612	5,843	(231)	(4.0)%
Other	18,286	11,908	6,378	53.6 %
Total product revenue	$ 1,559,326	$ 915,590	$ 643,736	70.3 %

Net product revenue increased 70.3% to $1,559.3 million for the nine months ended September 30, 2023, compared to $915.6 million in the prior year period, primarily due to increased sales of BRUKINSA in the United States and China and increased sales of tislelizumab in China. In addition, there were increased sales of our in-licensed products from Amgen.

Global sales of BRUKINSA totaled $877.4 million in the nine months ended September 30, 2023, representing a 125.8% increase compared to the prior year period; U.S. sales of BRUKINSA totaled $632.4 million in the nine months ended September 30, 2023, compared to $264.4 million in the prior year period, representing growth of 139.2%. U.S. sales continued to accelerate in the period, driven by the approval and launch of BRUKINSA for adult patients with CLL and SLL. BRUKINSA sales in China totaled $144.0 million in the nine months ended September 30, 2023, representing growth of 31.6% compared to the prior year period, driven by an increase in all approved indications. BRUKINSA rest of world sales totaled $101.0 million in the nine months ended September 30, 2023, representing growth of 602.5% compared to the prior-year period, driven by a significant increase in all approved indications, including CLL and SLL in Europe.

Sales of tislelizumab in China totaled $408.7 million in the nine months ended September 30, 2023, representing a 27.4% increase compared to $320.7 million in the prior year period. In the nine months ended September 30, 2023, new patient demand from broader reimbursement and further expansion of our salesforce and hospital listings continued to drive increased market penetration and market share for tislelizumab.

Collaboration revenue totaled $265.0 million for the nine months ended September 30, 2023, primarily related to the recognition of the remaining deferred revenue associated with the Novartis collaborations upon termination of the agreements

during the third quarter of 2023. Collaboration revenue for the nine months ended September 30, 2023 consisted of $79.4 million recognized from deferred revenue for R&D services performed during the nine months ended September 30, 2023 under both the tislelizumab and ociperlimab collaborations, $104.5 million recognized from deferred revenue for Novartis' right to access ociperlimab over the option period, $72.0 million recognized from deferred material right revenue associated with the ociperlimab collaboration upon termination and $9.2 million recognized primarily related to the sale of tislelizumab clinical supply to Novartis and revenue generated under the broad markets marketing and promotion agreement. Collaboration revenue totaled $120.2 million for the nine months ended September 30, 2022, of which $34.1 million was recognized from deferred revenue for R&D services performed during the nine months ended September 30, 2022, $78.7 million was recognized from deferred revenue for Novartis' right to access ociperlimab over the option period, and $7.4 million was recognized related to the sale of tislelizumab clinical supply to Novartis (see Note 3 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q).

Cost of Sales

Cost of sales increased to $274.1 million for the nine months ended September 30, 2023 from $213.0 million for the nine months ended September 30, 2022, primarily due to increased product sales of BRUKINSA and tislelizumab as well as sales of in-licensed products from Amgen in China.

Gross Margin

Gross margin on product sales increased to $1.3 billion for the nine months ended September 30, 2023, compared to $702.6 million in the prior year period, primarily due to increased product revenue in the current year period. Gross margin as a percentage of product sales increased to 82.4% for the nine months ended September 30, 2023, from 76.7% in the comparable period of the prior year. The increase is primarily due to a proportionally higher sales mix of global BRUKINSA compared to lower margin sales of in-licensed products and lower per unit costs for BRUKINSA and tislelizumab, partially offset by the impact of lower selling prices in China from the listing of tislelizumab and BRUKINSA on the updated NRDL.

Research and Development Expense

Research and development expense increased by $90.1 million, or 7.5%, to $1.3 billion for the nine months ended September 30, 2023 from $1.2 billion for the nine months ended September 30, 2022. The following table summarizes external clinical, external non-clinical and internal research and development expense for the nine months ended September 30, 2023 and 2022, respectively:

	Nine Months Ended September 30,		Changes	
	2023	2022	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 384,520	$ 360,644	$ 23,876	6.6 %
Upfront license fees	15,000	20,000	(5,000)	(25.0)%
Amgen co-development expense[1]	39,106	72,252	(33,146)	(45.9)%
Total external research and development expenses	438,626	452,896	(14,270)	(3.2)%
Internal research and development expenses	845,981	741,589	104,392	14.1 %
Total research and development expenses	$ 1,284,607	$ 1,194,485	$ 90,122	7.5 %

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the nine months ended September 30, 2023 totaled $77.7 million, of which $39.1 million was recorded as R&D expense. The remaining $38.6 million was recorded as a reduction of the R&D cost share liability.

The decrease in external research and development expenses in the nine months ended September 30, 2023 was primarily attributable to decrease in Amgen co-development expense and lower external clinical trial costs for TEVIMBRA (tislelizumab) and ZW25 (zanidatamab), partially offset by increases in external clinical trial costs for BRUKINSA and sonrotoclax (BGB-11417) and preclinical trial costs for certain assets in our portfolio.

Internal research and development expense increased $104.4 million, or 14.1%, to $846.0 million and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, as well as our continued efforts to internalize research and clinical trial activities, and included the following:

- $62.3 million increase of employee salary and benefits, primarily attributable to hiring more research and development personnel to support our expanding research and development activities;
- $19.7 million increase of share-based compensation expense, primarily attributable to our increased headcount of research and development employees, resulting in more awards being expensed related to the growing research and development employee population;
- $21.8 million increase of facilities, depreciation, consulting, regulatory, office expense, rental fees, lab consumables and other expenses to support the growth of our organization, partially offset by a $6.3 million decrease in clinical inventory; and
- $6.9 million increase in meetings, seminars and travel expenses mainly attributable to increased meetings and conferences travel normalizing.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $139.1 million, or 14.7%, to $1.1 billion, for the nine months ended September 30, 2023, from $948.9 million for the nine months ended September 30, 2022. The increase was primarily attributable to the following:

- $73.0 million increase in external commercial-related expenses, including market research, sales and marketing, conference, meeting and seminar and travel related expenses related to the growth of our global commercial organization, including commercial expansion of BRUKINSA in CLL in the United States and Europe, as we continue to build our worldwide footprint and capabilities;
- $35.4 million increase in grants and donations;
- $30.4 million increase of employee salary and benefits, which was primarily attributable to the expansion of our commercial organizations in the United States, Europe, Canada, China and emerging markets, and the hiring of personnel to support our growing business;
- $30.0 million increase of share-based compensation expense, primarily attributable to our increased headcount of sales and administrative employees, resulting in more awards being expensed related to the growing sales and administrative employee population;
- $21.5 million decrease in consulting expenses due primarily to lower external commercial expenses in China; and
- $8.2 million decrease in general and administrative and other expenses primarily attributable to increased legal fees related to increased arbitration activities for the prior nine months period ended September 30, 2022.

Interest Income (Expense), Net

Interest income (expense), net increased by $23.5 million, or 68.5%, to $57.7 million of net interest income for the nine months ended September 30, 2023, from $34.3 million of net interest income for nine months ended September 30, 2022. The increase in interest income was primarily attributable to higher interest rates earned on our cash, cash equivalents and short-term investments and lower interest expense due to an increase in interest capitalization related to Hopewell construction.

Other Income (Expense), Net

Other income, net was $291.1 million for the nine months ended September 30, 2023, primarily due to the noncash gain recorded for the receipt of ordinary shares as a result of the BMS settlement and government subsidy income, partially offset by foreign exchange losses resulting from the strengthening of the U.S. dollar compared to the RMB and the revaluation impact of RMB-denominated deposits held in U.S. functional currency subsidiaries and unrealized losses on equity investments.

For the nine months ended September 30, 2022, other expense, net was $243.3 million, which was primarily due to foreign exchanges losses resulting from the strengthening of the U.S. dollar compared to the RMB and the revaluation impact of RMB-denominated deposits held in U.S. functional currency subsidiaries being greater in the prior-year period. Also contributing to the decrease in expense was decrease in the unrealized loss on our equity investment in Leap Therapeutics.

Income Tax Expense

Income tax expense increased to $39.1 million for the nine months ended September 30, 2023, from $28.4 million for the nine months ended September 30, 2022. The income tax expense for the nine months ended September 30, 2023 and September

30, 2022 was primarily attributable to current China tax expense due to certain non-deductible expenses and current U.S. tax expense determined after other special deductions and research and development tax credits.

Liquidity and Capital Resources

The following table represents our cash, short-term investments, and debt balances as of September 30, 2023 and December 31, 2022:

	As of	
	September 30, 2023	December 31, 2022
	(dollars in thousands)	
Cash, cash equivalents and restricted cash	$ 3,080,892	$ 3,875,037
Short-term investments	$ 106,989	$ 665,251
Total debt	$ 531,051	$ 538,117

With the exception of the periods in which we received upfront payments from out-licensing rights to tislelizumab to Novartis, and prior to that BMS, and the current quarter where we recorded a large noncash gain from the BMS settlement and accelerated deferred revenue recognition from the Novartis terminations, we have incurred net losses and negative cash flows from operations since inception, resulting from the funding of our research and development programs and selling, general and administrative expenses to support the commercialization of our products and our global operations. We recognized net income of $215.4 million and net loss of $514.2 million for the three and nine months ended September 30, 2023, respectively, and net losses of $557.6 million and $1.6 billion for the three and nine months ended September 30, 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $7.6 billion.

To date, we have financed our operations principally through proceeds from public and private offerings of our securities and proceeds from our collaborations. Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of September 30, 2023 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months after the date that the financial statements included in this report are issued.

The following table provides information regarding our cash flows for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
	(dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 3,875,037	$ 4,382,887
Net cash used in operating activities	(935,815)	(1,178,428)
Net cash provided by investing activities	122,588	1,038,587
Net cash provided by financing activities	69,430	91,395
Net effect of foreign exchange rate changes	(50,348)	(133,929)
Net decrease in cash, cash equivalents, and restricted cash	(794,145)	(182,375)
Cash, cash equivalents and restricted cash at end of period	$ 3,080,892	$ 4,200,512

Operating Activities

Cash flows from operating activities is net loss adjusted for certain non-cash items and changes in assets and liabilities.

Operating activities used $935.8 million of cash in the nine months ended September 30, 2023, principally from our net loss of $514.2 million, an increase in our net operating assets and liabilities of $387.6 million, and non-cash charges of $34.1 million.

The increase in net operating assets and liabilities was primarily driven by increased working capital associated with our growth in product sales. The non-cash charges were primarily the result of the BMS termination settlement and amortization of the research and development cost share liability, offset by share-based compensation expense, depreciation and amortization expense.

Operating activities used $1.2 billion of cash in the nine months ended September 30, 2022, which resulted principally from our net loss of $1.6 billion, partially offset by a decrease in our net operating assets and liabilities of $132.6 million and by non-cash charges of $247.5 million. Net loss for the three months ended September 30, 2022 includes $125.6 million of other losses due primarily to the strengthening of the U.S. dollar and the related revaluation of RMB-denominated deposits held by U.S. functional currency subsidiaries.

The decrease in working capital was driven largely by decreases in accounts receivable (due to the receipt of the upfront from Novartis related to the ociperlimab collaboration), decreases in prepaid assets and other non-current assets, and an increase in taxes payable, partially offset by increases in inventories and decreases in accounts payable, accrued expenses, deferred revenue and other long-term liabilities. The non-cash charges were primarily driven by share-based compensation expense, depreciation and amortization expense, and unrealized loss on our Leap investment, offset by amortization of the research and development cost share liability and deferred income tax benefits.

Investing Activities

Cash flows from investing activities consist primarily of capital expenditures, investment purchases, sales, maturities, and disposals, and upfront payments related to our collaboration agreements.

Investing activities provided $122.6 million of cash in the nine months ended September 30, 2023, consisting of sales and maturities of investment securities of $567.5 million, partially offset by capital expenditures of $404.9 million, purchase of IPR&D assets of $15.0 million, purchase of intangible assets of $9.4 million and $15.6 million in purchases of investment securities.

Investing activities provided $1.0 billion of cash in the nine months ended September 30, 2022, consisting of sales and maturities of investment securities of $1.4 billion, offset by $14.7 million in purchases of investment securities, capital expenditures of $204.1 million, and $95.0 million of acquired in-process research and development.

Financing Activities

Cash flows from financing activities consist primarily of sale of ordinary shares, RMB Shares and ADSs through equity offerings, issuance and repayment of short-term and long-term debt, and proceeds from the sale of ordinary shares and ADSs through employee equity compensation plans.

Financing activities provided $69.4 million of cash in the nine months ended September 30, 2023, consisting primarily of $22.5 million of net proceeds from long-term bank loans, $162.6 million of proceeds from short-term bank loans and $52.4 million from the exercise of employee share options and proceeds from the issuance of shares through our employee share purchase plan, which were partially offset by $159.6 million in repayments of short-term bank loans and $8.5 million in repayments of long-term bank loans.

Financing activities provided $91.4 million of cash in the nine months ended September 30, 2022, consisting primarily of $163.8 million of proceeds from short-term bank loans, $37.4 million of proceeds from a long-term bank loan and $35.7 million from the exercise of employee share options and proceeds from the issuance of shares through our employee share purchase plan, which were partially offset by $145.4 million in repayment of short-term bank loans.

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. We hold a significant amount of RMB-denominated deposits at our China subsidiaries. Since the reporting currency of the Company is the U.S. dollar, periods of volatility in exchange rates may have a significant impact on our consolidated cash balances as they are translated into U.S. dollars. The impact of foreign currency deposits being translated into the U.S. dollar negatively impacted ending cash by $50.3 million in the nine months ended September 30, 2023, compared to a negative impact of $133.9 million in the prior-year period.

Future Liquidity and Material Cash Requirements

Until such time, if ever, as we can generate substantial product revenue sufficient to cover our costs and capital investments, 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 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. In May 2023, 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 may 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, ordinary shares, or RMB 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 our investors' 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 medicines or drug candidates, future revenue streams or research programs, or to grant licenses on terms that may not be favorable to us.

Furthermore, our ability to raise additional capital may be adversely impacted by worsening global economic conditions, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, recent and potential future bank failures and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. 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.

Our material cash requirements in the short- and long-term consist of the following operational, capital, and manufacturing expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources together with our anticipated receipts of accounts receivable, product sales and royalty revenues.

Contractual and Other Obligations

The following table summarizes our significant contractual obligations as of the payment due date by period as of September 30, 2023:

	Payments Due by Period		
	Total	Short Term	Long Term
	(dollars in thousands)		
Contractual obligations			
Operating lease commitments	$ 55,049	$ 6,981	$ 48,068
Purchase commitments	131,693	92,654	39,039
Debt obligations	531,052	328,561	202,491
Interest on debt	35,244	11,756	23,488
Co-development funding commitment	517,544	128,989	388,555
Funding commitment	10,553	2,625	7,928
Research and development commitment	16,498	6,004	10,494
Capital commitments	442,562	442,562	—
Total	$ 1,740,195	$ 1,020,132	$ 720,063

Operating Lease Commitments

We lease office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou in China; office facilities in California, Massachusetts, Maryland, and New Jersey in the United States; and office facilities in Basel, Switzerland under non-cancelable operating leases expiring on various dates. Payments under operating leases are expensed on a straight-line basis over the respective lease terms. The aggregate future minimum payments under these non-cancelable operating leases are summarized in the table above.

Purchase Commitments

As of September 30, 2023, non-cancellable purchase commitments amounted to $131.7 million, of which $41.2 million related to minimum purchase requirements for supply purchased from contract manufacturers and $90.5 million related to

binding purchase obligations of inventory from BMS and Amgen. We do not have any minimum purchase requirements for inventory from BMS or Amgen.

Debt Obligations and Interest

Total debt obligations coming due in the next twelve months is $328.6 million. Total long-term debt obligations are $202.5 million. See Note 10 in the Notes to the Financial Statements for further detail of our debt obligations.

Interest on bank loans is paid quarterly until the respective loans are fully settled. For the purpose of contractual obligations calculation, current interest rates on floating rate obligations were used for the remainder contractual life of the outstanding borrowings.

Co-Development Funding Commitment

Under the Amgen collaboration, we are responsible for co-funding global development costs for the licensed Amgen oncology pipeline assets up to a total cap of $1.25 billion. We are funding our portion of the co-development costs by contributing cash and development services. As of September 30, 2023, our remaining co-development funding commitment was $517.5 million.

Funding Commitment

Funding commitment represents our committed capital related to two equity method investments. As of September 30, 2023, our remaining capital commitment was $10.6 million and is expected to be paid from time to time over the investment period.

Research and Development Commitment

We entered into a long-term research and development agreement in June 2021, which includes obligations to make fixed quarterly payments over the next three years. As of September 30, 2023, the total research and development commitment amounted to $16.5 million.

Capital Commitments

We had capital commitments amounting to $442.6 million for the acquisition of property, plant and equipment as of September 30, 2023, which were mainly for our Hopewell facility, and additional capacity at the Guangzhou and Suzhou manufacturing facilities.

We are making a significant investment in our future manufacturing and clinical R&D center in the United States, a 42-acre site that is being constructed in Hopewell, NJ. We purchased this site for $75.2 million, announced its groundbreaking on April 29, 2022 and have $419.5 million of construction in process related to the project. We expect continued significant capital expenditures as we build out the Hopewell facility over the next several years.

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 U.S. generally accepted accounting principles (“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, valuation and recognition of 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 and nine months ended September 30, 2023, 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, 2022.

For new accounting policies adopted during the three and nine months ended September 30, 2023 , 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.

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 $3.1 billion and $3.9 billion, restricted cash of $13.6 million and $5.5 million, and short-term investments of $0.1 billion and $0.7 billion as of September 30, 2023 and December 31, 2022, respectively. Our cash and cash equivalent are deposited with various major reputable financial institutions located within or 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 unable 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. On September 30, 2023, 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 increase or decrease in market interest rates would result in a decrease of $0.2 million or an increase of $0.2 million, respectively, as of September 30, 2023.

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

We had accounts receivable, net of $309.1 million and $173.2 million as of September 30, 2023 and December 31, 2022, respectively. Accounts receivable, net represent amounts arising from product sales and amounts due from our collaboration partners. We monitor economic conditions to identify facts or circumstances that may indicate receivables are at risk of collection. To date, we have not experienced any significant losses with respect to the collection of our accounts receivable.

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, Euro, and Australian dollar. While we hold significant amounts of RMB, and are subject to foreign currency exchange risk upon revaluation or translation into our reporting currency, we expect to utilize our existing RMB cash deposits in the operation of our China business over the next several years, and as a result, have not used 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. Since 2005, the RMB has been permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. The RMB compared to the U.S. dollar depreciated approximately 5.5% in the nine months ended September 30, 2023 and depreciated approximately 8.2% in the year ended December 31, 2022, 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, 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 foreign cash balances and trade receivables. Further, volatility in exchange rate fluctuations may have a significant impact on the foreign currency translation adjustments recorded in other comprehensive income (loss). We have not used derivative financial instruments to hedge exposure to foreign exchange risk.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2023.

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 September 30, 2023, 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 September 30, 2023 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 of a nature considered ordinary course in our business, including the intellectual property litigation described herein. Most of the issues raised by such claims are highly complex and subject to substantial uncertainties. For a description of risks relating to these legal proceedings, see "Part II – Item 1A – Risk Factors" of this Quarterly Report, including the discussion under the headings entitled "Risks Related to Our Intellectual Property." The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. 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.

ABRAXANE®

On June 26, 2020, following the suspension and recall of ABRAXANE in China supplied to us by Celgene Logistics Sàrl, a Bristol-Myers Squibb Company (referred to elsewhere in this report as BMS, but for this paragraph only, "BMS-Celgene"), we initiated an arbitration proceeding at the International Chamber of Commerce against BMS-Celgene (the "Arbitration") asserting that it had breached and continued to breach the terms and conditions of the License and Supply Agreement entered into by BeiGene and BMS-Celgene in July 2017 (the "LSA") and the Amended and Restated Quality Agreement (the "QA" and collectively with the LSA, the "BMS-Celgene License"). Under the BMS-Celgene License, we alleged that BMS-Celgene was obligated, among other things, to ensure the continuity and adequacy of its supply of ABRAXANE to us. In the Arbitration, we sought (i) a declaration that BMS-Celgene was and continued to be in breach of the BMS-Celgene License, (ii) a declaration that BMS-Celgene acted with gross negligence and/or willful misconduct, (iii) an award of damages, and (iv) such other relief as the arbitrators deemed appropriate. BMS-Celgene responded in part by submitting a counterclaim against us seeking to recover approximately $30 million in costs that it contends it incurred as part of the ABRAXANE recall. In October 2021, BMS-Celgene delivered a notice to us purporting to terminate the BMS-Celgene License with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE from the range of products for sale or distribution in China pursuant to Section 2.6 of the BMS-Celgene License. Thereafter, we amended our claims to add a claim for wrongful termination of the BMS-Celgene License with respect to ABRAXANE. A hearing was held in the Arbitration in June 2022.

Prior to a decision being issued in the Arbitration, on August 1, 2023, we entered into a Settlement and Termination Agreement (the "Settlement Agreement") with BMS-Celgene and certain of its affiliates relating to the termination of the parties' ongoing contractual relationship, the Arbitration, the LSA, the QA, and the Share Subscription Agreement (the "SSA"), entered into by the parties in 2017 and 2018. Pursuant to the Settlement Agreement, the parties agreed to mutually dismiss the Arbitration and BMS-Celgene and its affiliates agreed to transfer 23,273,108 of our ordinary shares originally purchased in 2017, in each case subject to and in accordance with the terms and conditions of the Settlement Agreement. We have no payment obligation in exchange for the transferred shares pursuant to the Settlement Agreement. Furthermore, the parties agreed to terminate the LSA and QA on December 31, 2023, subject to our right to continue selling all inventory of REVLIMID® and VIDAZA® until sold out or December 31, 2024, whichever is earlier. The Settlement Agreement provides for a settlement and release by each party of claims arising from or relating to the Arbitration, the LSA, the QA and the SSA, as well as other disputes and potential disputes between the parties, in each case subject to and in accordance with the terms and conditions of the Agreement. The settlement closed on August 15, 2023, and the matter is concluded.

BRUKINSA®

On June 13, 2023, Pharmacyclics LLC ("Pharmacyclics") filed a complaint in the U.S. District Court for the District of Delaware (the "Court") against the Company and its subsidiary, BeiGene USA, Inc., alleging that BRUKINSA infringes Pharmacyclics' U.S Patent No. 11,672,803 issued on June 13, 2023 (the "'803 patent"). Pharmacyclics seeks a declaration of infringement, unspecified monetary damages and other relief. The Company intends to vigorously defend against the claims.

On October 12, 2023, the Court entered a joint stipulation filed by the parties to stay the infringement suit pending resolution of a petition for post-grant review ("PGR") of the '803 Patent with the U.S. Patent and Trademark Office ("USPTO") to be filed by the Company by November 3, 2023. On November 1, 2023, the Company filed a PGR petition against the '803 Patent with the USPTO.

Item 1A. Risk Factors.

The following section includes material 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, ordinary shares or RMB 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, ordinary shares or RMB 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. Please refer to the explanation of the qualifications and limitation on forward-looking statements set forth at the outset of "Part I – Item 2 – Management's Discussion and Analysis of Financial Condition and Results of 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, 2022 (the "Annual Report").*

Summary of Risk Factors

Below is a summary of the material factors that make an investment in our American Depositary Shares ("ADSs") listed on Nasdaq, our ordinary shares listed on The Stock Exchange of Hong Kong Limited, and our ordinary shares issued to permitted investors in China and listed and traded on the Science and Technology Innovation Board of the Shanghai Stock Exchange in Renminbi ("RMB Shares") speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, are set forth herein and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the U.S. Securities and Exchange Commission ("SEC"), before making an investment decision regarding our ADSs, ordinary shares or RMB Shares.

- Our medicines may fail to achieve and maintain the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.
- We have limited experience in launching and marketing our internally developed and in-licensed medicines. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our medicines, 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 medicines before or more successfully than we do.
- The market opportunities for our medicines may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate levels of reimbursement, our commercial success and business operations could be adversely affected.
- We depend substantially on the success of the clinical development of our medicines and drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals and commercialize our medicines and drug candidates, or experience significant delays in doing so, our business will be materially harmed.
- Clinical 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.
- 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.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, and we may face difficulties in complying with or be unable to comply with such regulations, which could have a material adverse effect on our business.
- The approval processes of regulatory authorities in the United States, China, Europe and other comparable regulatory authorities are lengthy, time consuming, costly, and inherently unpredictable. If we experience delays or are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

- Our medicines 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 medicines and drug candidates.
- Even if we are able to commercialize our medicines and any approved drug candidates, the medicines may become subject to unfavorable pricing regulations or third-party reimbursement practices or healthcare reform initiatives, which could harm our business.
- 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 not become profitable.
- 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 of our drug candidates or achieve profitability.
- If we are unable to obtain and maintain patent protection for our medicines and drug candidates through intellectual property rights, or if the scope of such intellectual property rights is not sufficiently broad, third parties may compete against us.
- We rely on third parties to manufacture some 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.
- We have entered into licensing and collaboration arrangements and may enter into additional collaborations, licensing arrangements, or strategic alliances in the future, and we may not realize the benefits of such arrangements.
- If we fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.
- If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.
- If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize.
- We have significantly increased and expect to continue to increase our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our business is subject to complex and evolving industry-specific laws and regulations regarding the collection and transfer of personal data. These laws and regulations can be complex and stringent, and many are subject to change and uncertain interpretation, which could result in claims, changes to our data and other business practices, significant penalties, increased cost of operations, or otherwise adversely impact our business.
- We manufacture some of our medicines and intend to manufacture some of our drug candidates, if approved. Failure to comply with regulatory requirements could result in sanctions being imposed against us and 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.
- Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments, and the significant oversight and discretion the PRC government has over the conduct of the business operations of our PRC subsidiaries 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.
- The audit reports included in our previous annual reports on Form 10-K filed with the SEC have historically been prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, and as such, investors have previously been deprived of the benefits of such inspection.
- The trading prices of our ordinary shares, ADSs, and/or RMB Shares can be volatile, which could result in substantial losses to you.

Risks Related to Clinical Development and Commercialization of Our Medicines and Drug Candidates

Our medicines may fail to achieve and maintain the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

Our medicines may fail to achieve and maintain 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 medicines. If our medicines do not achieve and maintain an adequate level of market acceptance, the sales of our medicines may be limited and we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our medicines will depend on a number of factors, including: the clinical indications for which our medicines are approved; physicians, hospitals, cancer treatment centers, and patients considering our medicines safe and effective; government agencies, professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations, and organizations recommending our medicines and reimbursement; the perceived advantages and relative cost of alternative treatments; the prevalence and severity of any side effects; product labeling, including limitations or warnings, or product insert requirements of regulatory authorities; the timing of market introduction of our medicines as well as competitive medicines; the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities; and the effectiveness of our sales and marketing efforts.

Even if our medicines 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 medicines, are more cost effective or render our medicines obsolete.

We have limited experience in launching and marketing our internally developed and in-licensed medicines. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our medicines, we may not be able to generate substantial product sales revenue.

We became a commercial-stage company in 2017, when we entered into a license and supply agreement with Celgene Logistics Sàrl, now a Bristol-Myers Squibb Company ("BMS"), to commercialize three of BMS's approved cancer therapies, in the People's Republic of China ("PRC" or "China"). In October 2019, we entered into a collaboration with Amgen for its commercial-stage oncology products and a portfolio of clinical- and late-preclinical-stage oncology pipeline products. We received the first approvals for our internally developed drug candidates in late 2019 in the United States, in 2020 in China, and in 2021 in Europe. Given this, we have limited experience in commercializing our internally developed and in-licensed medicines, including building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, and managing distributors and a sales force for our medicines. As a result, our ability to successfully commercialize our medicines may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in launching medicines.

If we are unable to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for any or all of our medicines in any country or region, we will likely pursue collaborative arrangements regarding the sales and marketing of our medicines. 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. 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 medicines ourselves.

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 medicine, 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 medicines before or more successfully than we do.

The development and commercialization of new medicines 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 medicines or are pursuing the development of medicines for the treatment of cancer for which we are commercializing our medicines or developing our drug candidates. For example, BRUKINSA, tislelizumab, and pamiparib 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 medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our medicines. Our competitors also may obtain approval from regulatory authorities for their medicines 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 medicines 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, management and marketing 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 medicines 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 medicines 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 medicines 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 diseases we are targeting, as well as the subset of people with these diseases in a position to receive later stage therapy and who have the potential to benefit from treatment with our medicines and drug candidates, 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 medicines and drug candidates may be limited or may not be amenable to treatment with our medicines and drug candidates. Even if we obtain significant market share for our medicines 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 or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate levels of reimbursement, our commercial success and business operations could be adversely affected.***

Our ability or the ability of any third parties with which we collaborate to commercialize our medicines successfully will depend in part on the extent to which reimbursement for these medicines is 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 medicines will depend substantially, both domestically and abroad, on the extent to which the costs of our medicines 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. Without third-party payor reimbursement, patients may not be able to obtain or afford prescribed medications. Third-party payors also are seeking to encourage the use of generic or biosimilar products or entering into sole source contracts with healthcare providers, which could effectively limit the coverage and level of reimbursement for our medicines and have an adverse impact on the market access or acceptance of our medicines. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products. For additional information, please see the section of our Annual Report titled "Part I —Item 1 — Business — Government Regulation — Pharmaceutical Coverage, Pricing, and Reimbursement."

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 medicines 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 the

Centers for Medicare and Medicaid Services (the "CMS"). They decide 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 United States Food and Drug Administration ("FDA") or comparable regulatory authorities in other countries. Even if we obtain coverage for a given medicine, 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 medicines. Patients are unlikely to use our medicines unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the medicine. Because some of our medicines 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. Furthermore, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

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 and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

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. Government authorities regularly review the inclusion or removal of medicines 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, and the tier under which a medicine will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those medicines. There can be no assurance that our medicines 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 typically been generic and essential drugs. Innovative drugs similar to our medicines and drug candidates have historically been more limited on their inclusion in the NRDL due to the affordability of the Chinese government's Basic Medical Insurance, although this has been changing in recent years. For example, BRUKINSA, tislelizumab, pamiparib, XGEVA and KYPROLIS have been included in the NRDL. While the demand for these medicines has generally increased after inclusion in the NRDL, there can be no assurance that demand will continue to increase and such increases will be sufficient to offset the reduction in the prices and our margins, which could have a material adverse effect on our business, financial condition and results of operations. We prepare for the NRDL negotiations in China for our eligible medicines/indications annually. If any of these medicines/indications are not included in the NRDL or included at a significantly lower price, the revenues for such medicines could be limited, 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 medicine 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 medicine which we commercialize. Obtaining or maintaining reimbursement for our medicines may be particularly difficult because of the higher prices often associated with medicines 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 medicine and drug candidate that we in-license or successfully develop.

There may be significant delays in obtaining reimbursement for approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by regulatory authorities. Moreover, eligibility for reimbursement does not imply that any medicine 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 medicines, 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 medicine and the clinical setting in which it is used, may be based on payments allowed for lower cost medicines that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for medicines 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 medicines 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 medicines and

any new medicines 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 medicines and drug candidates in the United States, China, Europe and in other jurisdictions. In some countries, such as those in Europe, 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 medicines will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our medicines and may be affected by existing and future health care reform measures.

We have operations in the United States, China, Europe, and other markets and plan to expand in these and new markets on our own or with collaborators, which exposes us to risks of conducting business in international markets.

We are currently developing and commercializing or plan to commercialize our medicines in international markets, including China, Europe and other markets outside of the United States, either on our own or with third party collaborators or distributors. Our 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 or actions taken by U.S. or China governmental authorities on companies with significant operations in the U.S. and China, such as us;
- 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;
- business interruptions resulting from geo-political actions, including trade disputes, war and terrorism, public health crises, such as the COVID-19 pandemic, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires; and
- international military conflicts and related sanctions.

These and other risks, including the risks described in "Risks Related to Our Doing Business in the PRC", may materially adversely affect our ability to attain or sustain revenue in international markets.

The illegal distribution and sale by third parties of counterfeit versions of our medicines 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 medicines, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit medicine 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 medicines 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.

We depend substantially on the success of the clinical development of our medicines and drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals and commercialize our medicines 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 medicines and other drug candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development of our medicines and drug candidates. The success of our medicines 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;
- 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 that we do not infringe, misappropriate or otherwise violate the valid patent, trade secret or other intellectual property rights of third parties;
- successfully launching our medicines and drug candidates, if and when approved;
- obtaining favorable reimbursement from third-party payors for our medicines 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 medicines, drug candidates and any competing drug products that may be necessary for use in clinical trials for evaluation of our drug candidates and commercialization of our medicines.

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 medicines 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 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 development 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 involved in such trials. A number of companies in our industry 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 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 CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; manufacturing issues, including problems with manufacturing, supply quality, compliance with good manufacturing practice ("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 medicines and drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates or commercialization of our medicines 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, or 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 or obtain reimbursement at a commercially viable level for use of the drug.

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

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 have and may continue to 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.

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 Regulatory Approval and Extensive Government Regulation

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, and we may face difficulties in complying with or be unable to comply with such regulations, which could have a material adverse effect on our business.

All jurisdictions in which we conduct or intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We are currently focusing our activities in the major markets of the United States, China, Europe, and other select countries and regions. 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. Additionally, the China National Medical Products Administration's ("NMPA") reform of the medicine and approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our medicines and drug candidates in a timely manner.

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 us 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, and the drug was subsequently recalled by BMS and is not currently available for sale in China. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. We have not had any sales of ABRAXANE since the suspension and do not expect future revenue from ABRAXANE. For additional information, please see the section of this Quarterly Report titled "Legal Proceedings". Additionally, although we have obtained regulatory approvals of our medicines, regulatory authorities could suspend or withdraw these approvals. In any event, the receipt of regulatory approval does not assure the success of our commercialization efforts for our medicines.

****We may be subject to 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 sales.***

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 ("FCA"), 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. For additional information, please see the section of our Annual Report, titled "Part I —Item 1 — Business — Government Regulation — Other U.S. Healthcare Laws and Compliance Requirements."

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. In addition, the approval, commercialization, and other activities for our medicines and drug candidates outside the United States subjects 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 and subject to the discretion of non-U.S. law enforcement authorities, including the Chinese authorities who has recently increased its anti-bribery efforts to reduce improper payments and other benefits received by physicians, staff and hospital administrators in relation to sales, marketing and purchase of pharmaceuticals. 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.

In the past, we have made grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations and we may make such grants in the future. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Furthermore, there has been increased scrutiny of company-sponsored patient assistance programs, including co-pay assistance programs, and donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments of reimbursement support offerings, clinical education programs and promotional speaker programs. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

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 FCA 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. Furthermore, 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 adversely affect our business.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule ("FSS") pricing program, and the Tricare Retail Pharmacy program, which require us to disclose average manufacturer pricing, and, in the future may require us to report the average sales price for certain of our drugs to the Medicare program. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. Furthermore, regulatory and legislative changes, and judicial rulings relating to these programs and policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation. For example, in the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements increase our costs and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. Additionally, our agreement to participate in the 340B program or our Medicaid drug rebate agreement could be terminated, in which case federal payments may not be available under Medicaid or Medicare Part D for our covered outpatient drugs. Additionally, if we overcharge the government in connection with our arrangements with FSS or Tricare Retail Pharmacy, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations.

Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B program. The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain.

The approval processes of regulatory authorities in the United States, China, Europe and other comparable regulatory authorities are lengthy, time consuming, costly, and inherently unpredictable. If we experience delays or are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

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 comprehensive 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.

Regulatory authorities outside of the United States, such as the NMPA and European Medicines Agency ("EMA"), also have requirements for approval of medicines for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements, approval processes and review periods can vary 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. Seeking regulatory approvals outside of the United States could require additional nonclinical studies or clinical trials, which could be costly and time consuming. For all of these reasons, we may not obtain regulatory approvals on a timely basis, if at all.

The processes required to obtain approval by the FDA, the NMPA, the EMA, and other comparable regulatory authorities is complex, costly, 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. Regulatory approval is never guaranteed. Furthermore, we have limited experience in obtaining regulatory approvals for our drug candidates, including preparing the required materials for regulatory submission and navigating the regulatory approval process. As a result, our ability to successfully 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.

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;
- a delay in or the inability of health authorities to complete regulatory inspections of our development activities, regulatory filings or manufacturing operations, whether as a result of a global pandemic or other reasons, or our failure to satisfactorily complete such inspections;
- 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.

For example, in June 2022, the FDA extended the Prescription Drug User Fee Act goal date for the supplemental new drug application ("sNDA") for BRUKINSA as a treatment for adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma by three months to January 2023, to allow time to review additional clinical data submitted by us, which was deemed a major amendment to the sNDA. Additionally, in July 2022, the FDA deferred action on the BLA for tislelizumab as a second-line treatment for patients with unresectable or metastatic ESCC. In the FDA's general advice letter communicating the deferral of action, the FDA cited only the inability to complete inspections due to COVID-19 related restrictions on travel as the reason for the deferral. As of the date hereof, the FDA has not provided a new anticipated action date.

Delays in the completion of a clinical trial of any of our drug candidates will increase our costs, slow down our drug development and approval process, and jeopardize our ability to commence product sales and generate 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, regulatory filings and manufacturing operations also could be harmed or delayed by a shutdown of the U.S. government, including the FDA, or governments and regulatory authorities in other jurisdictions. If the FDA or other health authorities are delayed or unable to complete required regulatory inspections of our development activities, regulatory filings or manufacturing operations due to government shutdowns, public health crises, or other reasons, or we do not satisfactorily complete such inspections, our business could be materially harmed.

We are currently conducting and may in the future conduct clinical trials for our drug candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting and may in the future conduct clinical trials for our drug candidates outside the U.S., including in China. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with good clinical practice ("GCP") requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected, and (ii) the FDA is able to validate the data from the trial through an onsite inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in drug candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Our medicines 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 medicines and drug candidates.

Our medicines 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-marketing information, including both federal and state requirements in the United States and requirements of comparable regulatory authorities in China, Europe and other regions. As such, we and our collaborators 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 medicines, 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, BLA or 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, and the drug was subsequently recalled by BMS and is not currently available for sale in China. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. We have not had any sales of ABRAXANE since the suspension and do not expect future revenue from ABRAXANE. For additional information, please see the section of this Quarterly Report titled "Legal Proceedings".

The regulatory approvals for our medicines 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 medicine may be marketed or to the conditions of approval, which could adversely affect the medicine's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the medicine or drug candidate. The FDA, NMPA, EMA or comparable regulatory authorities may also require a Risk Evaluation Mitigation Strategy ("REMS") program or comparable program as a condition of approval of our drug candidates or following approval. 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 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 medicines 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 medicines, 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 medicines 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 obtain accelerated approval or conditional approval of any of our drug candidates, as we have done with the accelerated approval of BRUKINSA in the United States and China and certain approvals of tislelizumab, pamiparib, XGEVA, BLINCYTO, KYPROLIS and QARZIBA in China, we will be required to conduct a confirmatory study to verify the predicted clinical benefit and may also be required to conduct post-marketing safety studies. The Food and Drug Omnibus Reform Act of 2022 ("FDORA") granted the FDA the authority to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to granting accelerated approval or within a specified time period after the date accelerated approval is granted. FDORA also gave the FDA increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner or such studies fail to verify clinical benefit. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval. For example, the FDA generally requires that all advertising and promotional materials be submitted to the FDA for review prior to dissemination or publication for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Historically, products launched in Europe do not follow price structures of the U.S. and generally prices tend to be significantly lower. Countries in Europe provide options 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. Countries 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 our medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available on adequate terms, or at all, from government health administration authorities, private health insurers and other organizations. For additional information, please see the section of this Quarterly Report titled "Part II — Item 1A — Risk Factors Risks Related to Clinical Development and Commercialization of Our Medicines and Drug Candidates — If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate level of reimbursement, our commercial success and business operations could be adversely affected."

In China, the 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. Under the program, one of the key determining factors for a successful bid is the price. The Chinese 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 had been charging. On March 25, 2020, the NHSA removed ABRAXANE from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE, which has adversely impacted our business and results of operations. In August 2020, VIDAZA and its generic forms were included for bidding in the program. We did not win the bid for VIDAZA, which resulted in the drug being

restricted from use in public hospitals, which account for a large portion of the market, and a decline in sales revenue. 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, which could have a material adverse effect on our business, financial condition and results of operations.

Although China adopted changes to its patent law to include patent term extension and an early resolution mechanism for pharmaceutical patent disputes, key provisions of the law remain unclear and/or subject to implementing regulations. The absence of effective regulatory exclusivity for pharmaceutical products in China could further increase the risk of early generic or biosimilar competition with our medicines in China.

In the United States, a law commonly referred to as "Hatch-Waxman Act" 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 Act also provides for patent linkage, pursuant to which FDA will stay approval of certain follow-on new drug applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, for a period of up to 30 months. Finally, the Hatch-Waxman Act provides for regulatory exclusivity that can prevent submission or approval of certain follow-on marketing applications. For example, U.S. law provides a five-year period of exclusivity to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical trials to obtain approval for the modification. Similarly, the Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases. These provisions, which are designed to promote innovation, can prevent competing products from entering the market for a certain period of time after marketing approval for the innovative product.

In China, however, laws on data exclusivity (referred to as regulatory data protection) are still developing. The PRC Patent Law (as amended in 2020, the "Amended PRC Patent Law") contains both patent term extension and a mechanism for early resolution of patent disputes. Accordingly, NMPA and the National Intellectual Property Administration ("NIPA") jointly issued the Implementation Measures for the Early Settlement Mechanism of Drug Patent Disputes (for Trial Implementation). However, the provisions for patent term extension are unclear and/or remain subject to the approval of implementing regulations that are still in draft form or have not yet been proposed, leading to uncertainty about their scope and implementation. Until the relevant implementing regulations for patent term extension in the Amended PRC Patent Law are implemented, and until data exclusivity is adopted and implemented, we may be subject to earlier generic or biosimilar competition in China than in the United States and other jurisdictions with stronger regulatory data protection for pharmaceutical products.

Undesirable adverse events caused by our medicines 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 medicines 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, 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 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.

As is typical in the development of pharmaceutical products, drug-related AEs and serious AEs ("SAEs") have been reported in our clinical trials. Some of these events have led to patient deaths. 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 medicines and drug candidates, or caused by our medicines 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 medicine;
- regulatory authorities may withdraw approvals or revoke licenses of the medicine, 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 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-marketing 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, financial condition, and prospects.

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

We plan to develop certain of our medicines and drug candidates for use as a combination therapy. If a regulatory authority revokes its approval of the other therapeutic that we use in combination with our medicines or drug candidates, we will not be able to market our medicines or 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 medicines and 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 medicines or 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 medicines. 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. For additional information, please see the section of this Quarterly Report titled “Part II — Item 1A — Risk Factors — Risks Related to Our Reliance on Third Parties — We rely on third parties to manufacture some 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.”

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

In the United States, China, Europe 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 medicines 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 medicine. For additional information, please see the section of our Annual Report titled “Part I — Item 1 — Business – Government Regulation – Healthcare Reform.”

For example, the Inflation Reduction Act of 2022 (“IRA”) contains several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the U.S. Department of Health and Human Services (“HHS”) rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the

IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS issued a proposal in response to an executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through the FDA's accelerated approval pathway. Although a number of these proposed measures may require additional legislation to become effective, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if we obtain regulatory approval; our ability to set a price that we believe is fair for our approved products; our ability to generate revenue and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital.

Risks Related to Our Financial Position and Need for Additional Capital

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 not become profitable.

Investment in pharmaceutical drug development is highly capital-intensive and 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 most periods since our inception, other than periods when we were profitable due to revenue recognized from up-front license fees from collaboration agreements or the settlement of legal proceedings. As of September 30, 2023 and December 31, 2022, we had an accumulated deficit of $7.6 billion and $7.1 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, although we expect these losses to decrease in the near term as product sales growth exceeds expense growth. We expect expenses to continue to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and our manufacturing facilities, commercialize our medicines and launch new medicines, if approved, maintain and expand regulatory approvals, contribute up to $1.25 billion to the global development of a portfolio of Amgen pipeline assets under our collaboration agreement, and commercialize the medicines that we have in-licensed and any other medicines 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. We will also incur costs in support of our growth as a 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 we fail to achieve market acceptance for our medicines or if promising 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 of our drug candidates or achieve profitability.

Our portfolio of 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. Additionally, we are investing in the manufacturing and commercialization of our approved medicines. Our operations have consumed substantial amounts of cash since inception. Our operating activities used $1.5 billion, $1.3 billion and $1.3 billion of net cash during the years ended December 31, 2022, 2021 and 2020, respectively, and used $935.8 million and $1,178.4 million of net cash during the nine months ended September 30, 2023 and 2022, respectively. We recorded negative net cash flows from operating activities in 2022, 2021 and 2020 primarily due to our net losses of $2.0

billion, $1.5 billion and $1.6 billion, respectively. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future.

Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise 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' medicines 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 medicines in China licensed from BMS, and since the fourth quarter of 2019, we have generated revenues from our internally developed medicines. 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 launch all of our current medicines 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.

With uncertainty in the capital markets, 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 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 shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our 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. Fluctuations in the value of the U.S. dollar against currencies in countries in which we operate could have a negative impact on our results of operations. 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 governments. It is difficult to predict how market forces or PRC, Australia, other governments outside the U.S. and U.S. government policies may impact the exchange rate of the RMB and the U.S. dollar or any other currencies in the future. There

remains significant international pressure on China 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, 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. 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 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 approval from or registration with appropriate government authorities or designated banks 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 any dividends payable on, our shares 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 or by actual events or concerns involving the liquidity, default, or non-performance of financial institutions, including the U.S. government, 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, 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.

Furthermore, actual events involving reduced liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any such events, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silvergate Bank, La Jolla, California, announced its decision to voluntarily liquidate its assets and wind down operations, Silicon Valley Bank, Santa Clara, California ("SVB"), was closed by the California Department of Financial Protection and Innovation, and Signature Bank, New York, New York, was closed by the New York State Department of Financial Services, and, in each case the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. These events lead to volatility and declines in the market for bank stock and questions regarding confidence in depository institutions. At the time of closure, we maintained limited cash deposits at SVB. While the FDIC has since stated that all depositors of SVB will be made whole and we have received access to our funds held at SVB, there is no guarantee that the federal government would similarly guarantee depositors in the event of a future bank closure. Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could adversely impact our ability to meet our operating expenses or result in breaches of our financial or contractual obligations which could have material adverse impact on our liquidity and our projected business operations, financial condition and results of operations.

As a result of uncertain political, credit and financial market conditions, including the potential of the U.S. government to default on the payment of its obligations for a period of time due to federal debt ceiling limitations or other unresolved political issues, investments in financial instruments issued or guaranteed by the U.S. government pose credit default and liquidity risks. A payment default or delay by the U.S. government, or continued uncertainty surrounding the U.S. debt ceiling, could result in a variety of adverse effects for financial markets, market participants and U.S. and global economic conditions. In addition, U.S. debt ceiling and budget deficit concerns have increased the possibility a downgrade in the credit rating of the U.S. government and could result in economic slowdowns or a recession in the U.S. No assurance can be made that losses or significant deterioration in the fair value of our U.S. government issued or guaranteed investments will not occur. At September 30, 2023, we had approximately $616.8 million invested in government money market funds, $107.0 million invested directly in U.S. Treasury securities, and $42.3 million invested in time deposits. Downgrades to the U.S. credit rating could affect the stability of securities issued or guaranteed by the U.S. government and the valuation or liquidity of our portfolio of such investment securities.

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 $3.1 billion, $3.9 billion and $4.4 billion, restricted cash of $13.6 million, $5.5 million and $7.2 million and short-term investments of $107.0 million, $665.3 million and $2.2 billion as

of September 30, 2023, December 31, 2022 and 2021, respectively, most of which are deposited in financial institutions outside of China. As required by the PRC securities laws, the net proceeds from the STAR Offering must be used in strict compliance with the planned uses as disclosed in the PRC prospectus for the STAR Offering as well as our proceeds management policy for the STAR Offering approved by our board of directors. 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 unable to claim our deposits back in full.

As of September 30, 2023 and December 31, 2022, our short-term investments consisted of U.S. Treasury securities. Although we 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 medicines and drug candidates through intellectual property rights, or if the scope of such intellectual property rights is not sufficiently broad, third parties may compete against us.

Our success depends in large part on our ability to protect our medicines, drug candidates and proprietary technology from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the medicines, drug candidates and technology that we consider commercially important by filing patent applications in the United States, the PRC, Europe and other territories, 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, 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 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, an organization or individual that wishes to apply for a patent in a foreign country for an invention or utility model conceived in China is required to report to the NIPA for security examination of such invention or utility model before applying for the patent in the foreign jurisdiction. Otherwise, the organization or individual may lose the patent right to the invention or utility model in China.

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, the 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 medicines or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize medicines 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, medicines, 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 medicines 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, we may face competition from generic medications for our approved medicines even if we successfully obtain patent protection. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents, 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 medicines and drug candidates are expected to expire on various dates as described in “Part I-Item 1-Business-Intellectual Property” of our Annual Report. 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. If we fail to adequately protect our intellectual property rights, our competitive position could be impaired and our business could be materially harmed.

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 countries can have a different scope and strength than in the United States. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as U.S. laws do, particularly those relating to biopharmaceutical products. 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 other 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 medicines 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.

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 medicines and drug candidates could be found invalid or unenforceable if challenged in court or before government patent authorities.

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 challenging the validity or enforceability of our patents or alleging that we infringe their intellectual property rights.

In addition, generic drug companies may in the future file an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market a generic version of our products, or our competitors' products, before the expiration of the patents covering such products, which may trigger ANDA litigation over the associated patent. Settlements and related licensing agreements resulting from ANDA litigation can be challenged and have the potential to generate additional litigation which can be costly. The success of such litigation depends on the strength of the patents covering the branded product and the manufacturer's ability to prove infringement. The outcome of such litigation is inherently uncertain and may result in potential loss of market exclusivity for the product which may have a significant financial impact on product revenue. Furthermore, the Federal Trade Commission ("FTC") has brought lawsuits to challenge ANDA litigation settlements as anti-competitive. If we engage in ANDA litigation, we may also face an FTC challenge with respect to the related settlement which may result in additional expense or penalty.

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 patents, 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 medicines 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 medicines 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 medicines 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 bear the risk that our products may be found to infringe patents owned or licensed by third parties, including research-based and generic pharmaceutical companies and individuals. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields of our medicines 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 be issued 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 medicines 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. For example, on June 13, 2023, Pharmacyclics LLC ("Pharmacyclics") filed a complaint in the U.S. District Court for the District of Delaware against us and one of our subsidiaries, alleging that BRUKINSA infringes a Pharmacyclics' patent issued on June 13, 2023. For additional information on this litigation, please see the section of this Quarterly Report titled "Legal Proceedings". 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 medicines and drug candidates. 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 medicines 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 medicines 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 medicines 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 patents in the U.S. and some other jurisdictions 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; 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; and the use of TIGIT antagonist in combination with PD-1 binding antagonist to treat cancers that are relevant to the use of ociperlimab in combination with tislelizumab for which patents are expected to expire in 2034. 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 medicine was approved for sale in the United States before the expiration of the relevant patents, we would need a license to commercialize the medicine 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 medicine before the expiration of corresponding patents covering that medicine. 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 our shares. 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 other 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 our medicines, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our medicines and drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. 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, although the Amended PRC Patent Law includes patent term extension, the patent term extension provision of the law is unclear and/or remains subject to the approval of implementing regulations that are still in draft form and soliciting comments, leading to uncertainty about its scope and implementation. 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 medicines or drug candidates.

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 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 medicines 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 members of our senior management, executed proprietary rights, non-disclosure and in some cases non-competition agreements in connection with their 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.

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 medicine 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.

Risks Related to Our Reliance on Third Parties

We rely on third parties to manufacture some 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 manufacture commercial supply of tislelizumab, zanubrutinib, and pamiparib at our manufacturing facilities in China, and are constructing a commercial-stage biologics manufacturing and clinical R&D center in New Jersey and a new small molecule manufacturing campus in Suzhou, China, we continue to rely on outside vendors to manufacture supplies and process some of our medicines 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 generally rely on our collaboration partners and their third-party manufacturers for supply of in-licensed medicines in China. We have limited experience in manufacturing or processing our medicines and drug candidates on a commercial scale. 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 use 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 medicines 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 regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our medicines and drug candidates. This evaluation would require new testing and GMP-compliance inspections by regulatory authorities;

- our manufacturers may have little or no experience with manufacturing our medicines 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 medicines and drug candidates;

- our third-party manufacturers might be unable to timely manufacture our medicines and drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any. This may, in the future, require us to transfer manufacturing technology to a different manufacturer or use a different process, each of which would be both time consuming and costly and potentially require us to conduct comparative studies to determine bioequivalence of the new and prior manufacturers' products or the new and old processes;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with GMP requirements and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. Manufacturers may be unable to comply with these GMPs which may result in fines and civil penalties, suspension of production, suspension, delay or withdrawal of product approval, or product seizure or recall. We do not have control over third-party manufacturers’ compliance with these regulations and requirements;

- we may not own, or may have to share, the intellectual property rights to some of the technology used and improvements made by our third-party manufacturers in the manufacturing process for our medicines 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;
- our contract manufacturers and 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 or pandemics; and
- manufacturing partners may require us to fund capital improvements to support scale-up of manufacturing and related activities to the extent our drug candidates or medicines become approved for commercial sale.

For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS, and the drug was subsequently recalled by BMS and is not currently available for sale in China. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. We have not had any sales of ABRAXANE since the suspension and do not expect future revenue from ABRAXANE. For additional information, please see the section of this Quarterly Report titled "Legal Proceedings".

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 of our drug candidates or commercialization of our medicines. In addition, we will rely on third parties to perform certain specification tests on our medicines and drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

Currently, the raw materials for our manufacturing activities are supplied by multiple source suppliers, 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.

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 medicines 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 medicines 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 medicines 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.

We have entered into licensing and collaboration arrangements and may enter into additional collaborations, licensing arrangements, or strategic alliances in the future, and we may not realize the benefits of such arrangements.

We have entered into licensing and collaboration agreements and may enter into additional collaboration, licensing arrangements, or strategic alliances with third parties that we believe will complement or augment our research, development and commercialization efforts. 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's commercial operations in China and an exclusive license to Celgene's (now BMS's) commercial cancer portfolio in China, REVLIMID, VIDAZA and ABRAXANE. On March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS, and the drug was subsequently recalled by BMS and is not currently available for sale in China. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. We have not had any sales of ABRAXANE since the suspension and do not expect future revenue from ABRAXANE. For additional information, please see the section of this Quarterly Report titled "Legal Proceedings".

In 2019, we entered into a strategic collaboration with Amgen with respect to its commercial-stage oncology products XGEVA, BLINCYTO and KYPROLIS and a portfolio of clinical- and late-preclinical-stage oncology pipeline products. In January 2021, we entered into a collaboration and license agreement with Novartis Pharma AG ("Novartis"), granting Novartis

rights to develop, manufacture and commercialize our anti-PD-1 antibody tislelizumab in North America, Japan, the EU, and six other European countries, but that agreement was terminated in September 2023, pursuant to a mutual termination and release agreement, whereby we regained full, global rights to develop, manufacture and commercialize tislelizumab. In December 2021, we entered into an option, collaboration and license agreement with Novartis to develop, manufacture and commercialize our investigational TIGIT inhibitor, ociperlimab, in North America, Europe, and Japan, but that agreement was terminated in July 2023, pursuant to a mutual termination and release agreement, whereby we regained full, global rights to develop, manufacture and commercialize ociperlimab.

Our strategic collaborations involve numerous risks. We cannot be certain that we will achieve the financial and other benefits that led us to enter into the collaborations. Moreover, we may not achieve the revenue and cost synergies expected from our collaborations 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 license agreement in 2017, was terminated in June 2019 in advance of the acquisition of Celgene by BMS, and we received a termination notice in October 2021 to terminate our license agreement for ABRAXANE in China. Similarly, we recently mutually terminated our agreement with Novartis regarding rights to develop, manufacture and commercialize both tislelizumab and ociperlimab.

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 collaboration or other alternative arrangements for our medicines 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 medicines 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 medicine or drug candidate, we can expect to relinquish some or all of the control over the future success of that medicine or drug candidate to the third party. For any medicines 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 not result in the anticipated benefits.

Collaborations involving our medicines and drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates and medicines 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 medicines or drug candidates;
- a collaborator with marketing and distribution rights to one or more medicines may not commit sufficient resources to their marketing and distribution or may set prices that reduce the profitability of the medicines;
- 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 medicines 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 medicines and drug candidates; and
- collaborators may own or co-own intellectual property covering our medicines 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, licensing arrangements or strategic alliances for our medicines 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 fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.

We rely on third-party distributors to distribute our approved medicines. For example, we rely on sole third-party distributors to distribute some of our in-licensed approved medicines in China and multiple third-party distributors for the distribution of our internally developed medicines. We also expect to rely on third-party distributors to distribute our other internally developed and in-licensed medicines, if approved. 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 medicines. However, we have relatively limited control over our distributors, who may fail to distribute our medicines 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 either party upon six months' written notice. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our medicines 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 medicines is interrupted, our sales volumes and business prospects could be adversely affected.

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

Before a third party can begin commercial manufacture of our medicines, they 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, any potential third-party manufacturer may be unable to initially pass regulatory inspections in a timely or cost-effective manner in order for us to obtain regulatory approval. If 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 or our collaborators' 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 or our collaborators' 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. On March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China supplied to us by BMS, and the drug was subsequently recalled by BMS and is not currently available for sale in China. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. We have not had any sales of ABRAXANE since the suspension and do not expect future revenue from ABRAXANE. For additional information, please see the section of this Quarterly Report titled "Legal Proceedings".

If we are not able to successfully develop and/or commercialize Amgen's oncology products, 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 the commercialization of Amgen's oncology products XGEVA, BLINCYTO and KYPROLIS in China, and the global development and commercialization in China of a portfolio of Amgen's clinical- and late-preclinical-stage pipeline products. Amgen has paused or stopped development of some of the pipeline assets due to portfolio prioritization, and the parties expect that the development plan for the pipeline assets will continue to evolve over time. In connection with our ongoing assessment of the collaboration agreement cost-share contributions, we determined that our further investment in the development of LUMAKRAS (sotorasib) ("AMG 510"), a first-in-class KRAS G12C inhibitor, was no longer commercially viable for BeiGene. As a result, in February 2023, we entered into an amendment to the collaboration agreement to (i) stop sharing costs with Amgen for the further development of AMG 510 during the period starting January 1, 2023 and ending August 31, 2023; and (ii) cooperate in good faith to prepare a transition plan with the anticipated termination of AMG 510 from the Collaboration Agreement. Additionally, for the period between 2020 and 2022, we were advised by Amgen that its applications to the Human Genetic Resources Administration of China ("HGRAC") to obtain approval to conduct clinical studies in China for the pipeline assets were delayed. Approval from the HGRAC is required for the initiation of clinical trials involving the collection of human genetic materials in China. We do not expect the previous HGRAC delay to affect the conduct of the clinical trials in China for our drug candidates, other than assets that are part of the Amgen collaboration. The Amgen collaboration 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.

We may rely on third parties to conduct our preclinical studies and clinical trials. 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 medicines and drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely to some extent upon third-party CROs to monitor and manage data and provide other services for our ongoing preclinical and clinical programs. We may 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 regulatory authorities for all of our drug candidates 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 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 drug 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 investigations 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.

Risks Related to Our Industry, Business and Operations

We have significantly increased and expect to continue to increase our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.

At the beginning of 2022, we had approximately 8,000 employees, and we ended the year with approximately 9,000 employees, an increase of 15%. As of the date of this Quarterly Report, we had over 10,000 employees. We expect to continue

our growth. 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, drug development, clinical, regulatory affairs, manufacturing, sales, marketing, financial and other personnel in the United States, China, Europe and other regions. Our recent growth and any anticipated future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing the growth in our research, clinical operations, commercial, and supporting functions;
- managing our internal development efforts effectively, including the clinical and regulatory review process for our drug candidates, while complying with our contractual obligations to 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 medicines 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 medicines and drug candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals.

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

Xiaodong Wang, Ph.D., our Co-Founder, Chairman of our scientific advisory board, and director; John V. Oyler, our Co-Founder, Chief Executive Officer and Chairman of the board of directors; Xiaobin Wu, Ph.D., our President, Chief Operating Officer and General Manager of China; Julia Wang, our Chief Financial Officer; and the other principal members of our management and scientific teams play a critical role in the Company's operation and development. Although we have 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 or based on performance conditions. The value to employees of these equity grants that may be significantly affected by movements in our share price that are beyond our control and may 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 executives, 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.

Our business is subject to complex and evolving industry-specific laws and regulations regarding the collection and transfer of personal data. These laws and regulations can be complex and stringent, and many are subject to change and uncertain interpretation, which could result in claims, changes to our data and other business practices, significant penalties, increased cost of operations, or otherwise adversely impact our business.

Regulatory authorities around the world have implemented industry-specific laws and regulations that affect the collection and transfer of personal data. For example, in China, the Regulation on the Administration of Human Genetic Resources ("HGR" and, such regulation, the "HGR Regulation") promulgated by the State Council applies to activities that involve sampling, biobanking, use of HGR materials and associated data, in China, and provision of such materials 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 HGR material is required, and transfer of China HGR data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data to the HGR administration for record. The HGR Regulation also requires that foreign parties ensure the full participation of Chinese parties in international collaborations and all records and data must be shared with the Chinese parties. The Implementing Rules for the HGR Regulation (the "HGR Implementing Rules") and additional issued guidance has clarified many areas of the HGR Regulation, including: data covered excludes gene-irrelevant clinical data, image data, protein data, and metabolic data; "actual control" by foreign parties includes not only being controlled through equity interests but also investment or contractual arrangements; companies incorporated in Hong Kong Special Administration Region ("SAR") and Macau SAR but essentially controlled by Chinese domestic entities are not foreign parties; foreign entities operating the electronic data capture system for an in-China trial are not foreign parties; if foreign entities do not substantively participate in gene-related scientific studies, nor obtain any study data, then such studies are not subject to HGR Regulation; and human urine, feces, blood plasma, and blood serum are not regarded as HGR materials. For information about applications under the HGR Regulation for clinical studies in China that are part of the Amgen - BeiGene Collaboration, see the risk factor entitled "If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize."

Further to the draft HGR implementing rules, the Cyberspace Administration of China ("CAC") released the final Measures of Cross-Border Data Transfer Security Assessment on July 7, 2022 (effective as of September 1, 2022), under which any transfer of certain "important data" out of China shall trigger a security assessment to be conducted by the Chinese government. The term "important data" is a broadly defined term under the Cybersecurity Law and Data Security Law, and further clarifications need to be put in place by the Chinese government before international companies could find a practical way to comply. However, under the latest draft Important Data Identification Rules, HGR data is classified as "important data," and if the guidance is finalized as is, it can be expected that this new cross-border data transfer rule may create considerable additional regulatory burdens on international companies' human gene-involved R&D activities in China (*i.e.*, adding a third layer of CAC's regulatory approval in addition to HGRAC's and NMPA's).

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 or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or the initiation of new trials, confiscation of HGR samples and associated data and administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further HGR projects and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in China. So far, the HGR administration has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain HGR materials to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGR administration to take rectification measures and at the same time banned from submitting any HGR applications until the HGR administration was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, a public hospital was found to have illegally transferred certain HGR data to a university in Europe, and that hospital was eventually subject to the same ban.

To further tighten the control of China HGR, the Chinese government adopted amendments to the Criminal Code, effective as of March 1, 2021, which criminalize the illegal collection of China HGR, the illegal transfer of China HGR materials outside

of China, and the transfer of China HGR data to foreign parties or entities established or actually controlled by them without going through security review and assessment. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to 7 years, and/or a criminal fine. On April 15, 2021, the Biosecurity Law became effective. The Biosecurity Law establishes an integrated system to regulate biosecurity-related activities in China, including the security regulation of HGR and biological resources. The Biosecurity Law for the first time expressly declared that China has sovereignty over its HGR and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese HGR by foreign entities in China. Although the Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulatory authority of HGR, i.e., the Ministry of Science and Technology, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for Chinese HGR will evolve and become even more rigorous. 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 and continued attention and scrutiny from regulators and the public going forward, which could increase our compliance costs and subject us to heightened risks and challenges associated with data security and protection. If we are unable to manage these risks, we could become subject to significant penalties, including fines, suspension of business and revocation of required licenses, and our reputation and results of operations could be materially and adversely affected.

We manufacture some of our medicines and intend to manufacture some of our drug candidates, if approved. Failure to comply with regulatory requirements could result in sanctions being imposed against us and 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. We are also constructing a commercial-stage biologics manufacturing and clinical R&D center in New Jersey, United States, and a new small molecule manufacturing campus in 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 medicines 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. For example, we may not be able to complete the construction and validation of and obtain regulatory approval for the new manufacturing and clinical R&D center in New Jersey, the new manufacturing campus in Suzhou and manufacturing facility expansion in Guangzhou in a timely or economic manner.

In addition to the similar manufacturing risks described in "Risks Related to Our Reliance on Third Parties," our manufacturing facilities are 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. Historically, some manufacturing facilities in China have had difficulty meeting the FDA's, NMPA's or EMA's standards. 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 medicines. 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 medicines, 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 medicines 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 medicines in a sufficient quantity to meet future demand.

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 medicines manufactured at that facility. 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 medicines 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 medicines if there were a catastrophic event or interruption or failure of our manufacturing facilities or processes.

We incur significant costs as a result of operating as a public company, 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 listed in the United States, Hong Kong and Shanghai, 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), The Stock Exchange of Hong Kong Limited (the "HKEx") and the STAR Market of the Shanghai Stock Exchange (the "SSE"), and incur significant legal, accounting and other expenses to comply with applicable requirements. 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 of 2002 (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. 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 shares 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, China Securities Regulatory Commission (the "CSRC"), SSE or other applicable regulatory authorities, and our business could be harmed.

If we engage in acquisitions or strategic collaborations, 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 collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic collaboration 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 or strategic collaborations, 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 our transaction with Amgen, we issued to Amgen a total of 206,635,013 ordinary shares in the form of ADSs in January 2020, representing 20.5% of the then 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 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, which was amended in June 2022 and became effective as of August 1, 2022, and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings 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 for 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 Measures for Security Review of Foreign Investment jointly issued by the National Development and Reform Commission and MOFCOM and 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"), which became effective in February 2020.

Furthermore, according to the Overseas Listing Trial Measures, if a Chinese overseas listed company issues overseas listed securities to acquire assets, such issuance would be subject to filing requirements with the CSRC.

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 or filing processes, including obtaining approval from or filing with CFIUS, the SAMR, the MOFCOM, the CSRC or other agencies 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, SAMR, MOFCOM, CSRC or other government agencies may publish explanations in the future determining that certain 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 U.S. 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. 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. 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.

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 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 waste. 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 waste. 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 such liability could exceed our 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, manufacturing or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

****Our information technology systems, or those used by our contractors or collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization efforts.***

Despite the implementation of security measures, our information technology systems and those of our contractors and collaborators, 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 can 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, regulatory 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 systems and data and leave us unable to utilize key business systems or access important data needed to operate our business. Our contractors and collaborators have faced, and in the future 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 and our third-party vendors have on occasion experienced, and will continue to experience, threats to our or their data and systems, including malicious codes and viruses, phishing, email compromise attacks, ransomware, or other cyber-attacks. For example, one of our third-party vendors experienced a business email compromise which results in us sending payment to a fraudulent bank account. Funds were successfully recovered in this case, but it is possible that to the extent a similar future event occurs, funds will not be recoverable. 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, 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 processes 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. It is possible that the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our remote working environment, which may be less secure and more susceptible to hacking attacks. 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 contractors and collaborators, as well as our and their efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruptions, 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, ransomware, industrial espionage attack or insider threat attack 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.

****The increasing use of artificial intelligence-based software (including machine learning) and social media platforms may result in reputation harm or liability or could otherwise adversely affect our business.***

The use of artificial intelligence-based software is increasingly being used in the biopharmaceutical and global healthcare industries. As with many developing technologies, artificial intelligence-based software presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. For example, algorithms may be flawed; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end-users could impair results. If the analyses that artificial intelligence applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability, and brand or reputational harm. Furthermore, use of artificial intelligence-based software may lead to the release of confidential information which may impact our ability to realize the benefit of our intellectual property.

Relatedly, social media platforms are increasingly being used to communicate about our products and the diseases our medicines and drug candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of

a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we may fail to monitor and comply with applicable adverse event reporting obligations. There is also a risk of negative or inaccurate posts about us on social media, including criticism regarding our medicines or drug candidates. The immediacy of social media precludes us from having real-time control over postings made regarding our company, medicines or drug candidates. Our reputation could be damaged by negative publicity posted on social media platforms which we may not be able to timely reverse. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

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.

In the United States, Europe, China, and many other jurisdictions where we operate, 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, without limitation, privacy laws (such as the European Union's General Data Protection Regulation ("GDPR") or similar laws), security breach notification laws (such as Australia's amendment to the Privacy Act), health information privacy laws (such as the United States' Health Insurance Portability and Accountability Act ("HIPAA") and the Human Genetic Resources Administration of China's rules), and consumer protection laws (such as the United States' Federal Trade Commission's unfair or deceptive practices rules or California's Consumer Privacy Act and California's Privacy Rights Act), govern the collection, use, disclosure and protection of health-related and other personal information. A subset of these laws also have strict requirements governing the cross-border transmission of personal information (see the risk factor entitled "*Compliance with the Data Security Law of the People's Republic of China (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the People's Republic of China (the "PIPL"), regulations and guidelines relating to the multi-level protection scheme (the "MLPS") and any other future laws and regulations may entail significant expenses and could materially affect our business*.").

The legal and regulatory landscape around data privacy is rapidly changing with countries, states and other localities passing new laws and regulations every year. Tracking and complying with these laws and regulations requires significant time and expenses and could materially affect our business. By way of example and without limitation, these laws may require updating of contracts, informed consent forms, clinical trial protocols and privacy notices; changes to company procedures; limiting what personal information we collect, who has access to it and how/where we use it; performing internal assessments; changes to the security and hosting solution of our systems; specific reporting and remediation efforts in the event of a data breach; and even opening our business up for external assessments by government bodies.

Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may face challenges in implementing all measures required by regulators or courts in their interpretation. Additionally, we may experience a reportable data breach (see the risk factor entitled "*Our information technology systems, or those used by our contractors or collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization efforts*"). Any failure or perceived failure by us to comply with applicable laws and regulations could subject us to significant administrative, civil or criminal fines or other penalties and negatively impact our reputation. For severe violations, in some countries these laws even allow courts and government agencies to delay or halt transfer of personal information, require deletion of personal information, or even order we stop collection, use or other processing of personal information in that country. All of these could materially harm our business, prospects, and financial condition or even disrupt our operations.

These laws apply not just to us, but also to those vendors working on our behalf, as well as our business partners. Any actual or perceived failure of them to comply with these laws and regulations could impact the services they provide to us, our collaborations with them and our reputation; additionally, there is a risk of liability flowing to us under certain contractual and/or legal conditions.

Compliance with the Data Security Law of the People's Republic of China (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the People's Republic of China (the "PIPL"), regulations and guidelines relating to the multi-level protection scheme (the "MLPS") and any other future laws and regulations may entail significant expenses and could materially affect our business.

China has implemented extensive data protection, privacy and information security rules and is considering a number of additional proposals relating to these subject areas. We face significant uncertainties and risks related to these laws, regulations and policies, some of which were only recently enacted, and the interpretation of these legal requirements by government regulators as applied to biotechnology companies like us. For example, we do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or pseudonymized health data for clinical trials in compliance with local regulations. This data could be deemed "personal data" or

"important data" by government regulators. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or pseudonymized health data for clinical trials may be subject to the new national security legal regime, including the Data Security Law, the Cyber Security Law of the People's Republic of China (the "Cyber Security Law"), the PIPL, and various implementing regulations and standards.

China's Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the relevant PRC authority. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or the legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used.

The Cyber Security Law requires companies to take certain measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt an MLPS, under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. The CAC released draft amendments to the Cyber Security Law in September 2022, which propose to impose more stringent legal liabilities for violations. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network systems belong, from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cybersecurity. The grading result will determine the set of security protection obligations that entities must comply with and when relevant government authority examination and approval is required.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We are obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents. Establishing and maintaining such systems takes substantial time, effort and cost, and we may not be able to establish and maintain such systems as fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not adequately protect us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we may face.

Furthermore, under the Data Security Law, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, is to be processed and handled with a higher level of protection. The notion of important data is not clearly defined by the Cyber Security Law or the Data Security Law. In order to comply with the statutory requirements, we will need to determine whether we possess important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments and ensure we are complying with reporting obligations to applicable regulators. We may also be required to disclose to regulators business sensitive or network security-sensitive details regarding our processing of important data and may need to pass the government security review or obtain government approval in order to share important data with offshore recipients, which can include foreign licensors, or share data stored in mainland China with judicial and law enforcement authorities outside of mainland China. If judicial and law enforcement authorities outside mainland China require us to provide data stored in mainland China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the foreign authorities' requirements and may be unable to share information outside of China which may disrupt the operation of our business. The potential conflicts in legal obligations could have adverse impacts on our operations in and outside of mainland China. PRC regulatory authorities have also enhanced the supervision and regulation of cross-border data transmission. The Data Security Law prohibits entities and individuals in China from providing any foreign judicial or law enforcement authority with any data stored in China without approval from competent PRC authority, and sets forth the legal liabilities of entities and individuals found to be in violation of their data protection obligations, including rectification order, warning, fines, suspension of relevant business, and revocation of business permits or licenses. Moreover, the CAC promulgated the Measures for the Security Assessment of Cross-border Data Transmission, which became effective as of September 1, 2022. According to these measures, personal data processors are subject to security assessment prior to any cross-border transfer of data if the transfer involves (i) important data; (ii) personal information transferred overseas by operators of critical information infrastructure or a data processor that has processed personal data of more than one million persons; (iii) personal information transferred overseas by a data processor who has already provided personal data of 100,000 persons or sensitive personal data of 10,000 persons overseas since January 1 of last year; or (iv) other circumstances as requested by the CAC. Any cross-border data transfer activities conducted in violation of the Measures for the Security Assessment of Cross-border Data Transmission before the effectiveness of these measures were required to be rectified by March 2023. Though these measures have already taken effect, substantial uncertainties still exist with respect to the interpretation and implementation of these measures in practice and how they will affect our business operation.

The CAC has taken action against several Chinese internet companies listed on U.S. securities exchanges for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law of the People's Republic of China (the "National Security Law"), the Cyber Security Law and the Cybersecurity Review Measures. Effective February 15, 2022, the CAC, together with 12 other PRC governmental authorities, promulgated the Revised Cybersecurity Review Measures, pursuant to which critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, shall conduct a cybersecurity review. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. The relevant competent governmental authorities may also initiate a cybersecurity review against the relevant operators if the authorities believe that the network product or service or data processing activities of such operators affect or may affect national security. There are still uncertainties as to the exact scope of network product or service or data processing activities that will or may affect national security, and the PRC government authorities may have discretion in the interpretation and enforcement of these measures.

Additionally, the CAC published the draft Administrative Regulations on Cyber Data Security ("Draft Cyber Data Security Regulations"), pursuant to which data processors shall apply for cybersecurity review if they engage in (i) merger, reorganization or division of internet platform operators with significant data resources related to national security, economic development or public interests that affects or may affect national security; (ii) overseas listing while processing over one million users' personal information; (iii) Hong Kong listing that affects or may affect national security; or (iv) other data processing activities that affect or may affect national security. The Draft Cyber Data Security Regulations further require data processors processing important data or going public overseas to conduct annual data security self-assessment and submit an assessment report to the CAC before January 31 each year. As the Draft Cyber Data Security Regulations were released only for public comment, the final version and the effective date thereof may be subject to change with substantial uncertainty.

It is unclear how widespread the cybersecurity review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. China's regulators may impose penalties for non-compliance ranging from fines or suspension of operations, and the imposition of any such penalties on our business could cause a material adverse effect on our business, financial condition, results of operations, prospects and the trading price of our ordinary shares, ADSs and RMB Shares, and could lead to our delisting from the Nasdaq. As of the date of this report, we have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "data processor," or requiring us to go through the cybersecurity review procedures pursuant to the Revised Cybersecurity Review Measures and the Draft Cyber Data Security Regulations. However, there remains uncertainty as to how the regulations if enacted as currently proposed, will be interpreted or implemented and whether the Chinese regulatory authorities will adopt additional regulations. We intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised Cybersecurity Review Measures, the Draft Cyber Data Security Regulations or other laws and regulations related to privacy, data protection and information security.

Additionally, the Standing Committee of the National People's Congress of the PRC promulgated the PIPL, which expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The PIPL also provides that critical information infrastructure operators and personal information processing entities that process personal information meeting a volume threshold are also required to store in China personal information generated or collected in China, and to pass a security assessment for any export of such personal information. Lastly, the PIPL contains proposals for significant fines for serious violations of up to RMB50 million, or 5% of annual revenues from the prior year, and penalties, including that companies found to have violated the PIPL may be ordered to suspend any related activity.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with the Cyber Security Law, the Data Security Law and the PIPL could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulation, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our

business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law and the recent Chinese government actions could materially adversely affect our ability, on favorable terms, to raise capital in the U.S. and other markets in the future.

If we or parties on whom we rely fail to maintain the necessary licenses for the development, manufacture, sale 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, manufacture, promote and sell our products. Third parties, such as distributors, third-party promoters and third-party manufacturers, on whom we may rely to develop, manufacture, 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.

****Our financial and operating performance may be adversely affected by government shutdowns, public health crises, natural catastrophes, or other business interruptions outside of our control.***

Our global operations and those of our third-party contractors and collaborators expose us to natural or man-made disasters, such as earthquakes, hurricanes, floods, fires, explosions, public health crises, such as epidemics or pandemics, terrorist activity, wars, or other business interruptions outside of our control. Furthermore, we do not maintain any insurance other than property insurance for some of our buildings, vehicles and equipment. Accordingly, unexpected business interruptions resulting from disasters could disrupt our operations and thereby result in substantial costs and diversion of resources. For example, our Guangzhou manufacturing facility was hit by a typhoon in 2019 and although the typhoon did not cause material damage to the facility, the boundary area and the adjacent land were flooded, causing a power outage for a few days. Afterwards, we built a gutter along the boundary and installed waterproof electricity cables to fortify the facility and to help prevent future interruptions. A significant disruption at either our Guangzhou or Suzhou manufacturing facilities, even on a short-term basis, could impair our ability to timely produce products, which could have a material adverse effect on our business, financial position and results of operations.

Our production process requires a continuous supply of electricity. We have encountered power shortages historically in China due to restricted power supply to industrial users during summers when the usage of electricity is high and supply is limited or as a result of damage to the electricity supply network. Because the duration of those power shortages was brief, they had no material impact on our operations. Longer interruptions of electricity supply could result in lengthy production shutdowns, increased costs associated with restarting production and the loss of production in progress. Any major suspension or termination of electricity or other unexpected business interruptions could have a material adverse impact on our business, financial condition and results of operations.

We also rely in part on third-party manufacturers to produce and process our medicines and drug candidates. Our ability to obtain supplies of our medicines and drug candidates could be disrupted if the operations of these suppliers are affected by man-made or natural disasters, public health epidemics or other business interruptions which could cause us to delay or cease development or commercialization of some or all of our medicines and drug candidates. 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. For example, the ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the

FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

In particular, the COVID-19 pandemic negatively impacted our business and our financial performance, and future global pandemics or other public health crises could have similar negative impacts, including causing a delay in or the inability of health authorities to complete regulatory inspections of our development activities, regulatory filings, manufacturing operations, or clinical trial recruitment. Additionally, the commercial or clinical supply of our medicines 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.

The COVID-19 pandemic also resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. To the extent similar measure are enacted in the future, such measures may negatively affect our business by inducing absenteeism or employee turnover, disrupting our operations, or increasing the risk of a cybersecurity incident.

Climate change manifesting as physical or transition risks, included related environmental regulation, could have a material adverse impact on our business operations, clients and customers.

The long-term effects of climate change are difficult to assess and predict. Our business and the activities of our clients and customers could be impacted by climate change. Climate change could manifest as a financial risk either through changes in the physical climate or from the process of transitioning to a low-carbon economy, including related environmental regulation of companies with respect to risks posed by climate change.

The physical impacts of climate change may include physical risks (such as rising sea levels or frequency and severity of extreme weather conditions), social and human effects (such as population dislocations or harm to health and well-being), compliance costs and transition risks (such as regulatory or technology changes) and other adverse effects. The effects could impair, for example, the availability and cost of certain products, commodities and energy (including utilities), which in turn may impact our ability to procure goods or services required for the operation of our business at the quantities and levels we require. Furthermore, related environmental regulation as a response to climate change could result in additional costs in the form of taxes and investments of capital to maintain complacent with such laws. We bear losses incurred as a result of, for example, physical damage to or destruction of our facilities, loss or spoilage of inventory, and business interruption due to weather events that may be attributable to climate change and could materially adversely affect our business operations, financial position or results of operation.

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 medicines in the United States, China, Europe and other markets, and for the clinical testing and any future commercialization of our drug candidates globally. For example, we may be sued if our medicines 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 medicine, 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 medicines 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 medicines; 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 our management's time and 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 medicine or drug candidate; and a decline in our 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 medicines 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 and challenges of doing business globally, which may adversely affect our business operations.

Our business is subject to risks and challenges 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; challenges in replicating or adapting our company policies and procedures to operating environments different from that of the United States; 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, 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; 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; restrictions on international travel and commerce; and significant adverse changes in local currency exchange rates. In addition, in 2017 the United Kingdom Financial Conduct Authority ("UKFCA"), which regulates the London Interbank Offered Rate ("LIBOR"), announced that it would no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator. Following June 30, 2023, the UKFCA ceased to publish one month, three month and six month USD LIBOR settings. In the United States, the Alternative Reference Rate Committee ("ARRC"), a steering committee assembled by the Federal Reserve Board and the Federal Reserve Bank of New York, was tasked with identifying alternative reference rates to replace LIBOR. The AARC selected, and the Federal Reserve Bank of New York has recommended, the Secured Overnight Finance Rate ("SOFR") as an alternative to LIBOR. SOFR is a broad measure of the cost of borrowing cash in the overnight United States treasury market. LIBOR and SOFR have significant differences: LIBOR was an unsecured lending rate and SOFR is a secured lending rate, and SOFR is an overnight rate while LIBOR is a forward-looking rate that reflected term rates at different maturities. At this time, it is not possible to predict how markets will respond to SOFR or other alternative reference rates, and as such, the replacement of LIBOR could have an adverse effect on the market for, or value of, LIBOR-linked financial instruments. Failure to manage these risks and challenges could negatively affect our ability to expand our businesses and operations as well as materially and adversely affect our business, financial condition and results of operations.

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 intended to address concerns over base erosion and profit shifting (BEPS) and other perceived international tax avoidance techniques as a result of both coordinated actions by governments, such as the OECD/G20 Inclusive Framework on BEPS, and unilateral measures designed by individual countries. 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 must comply with the requirements from the date they commence the relevant activity. Although we believe that we currently are not obliged to meet 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 obliged to meet certain 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 consistent with accepted tax ruling practices, the ultimate resolution of such activities cannot be predicted and could also have an adverse impact on future operating results.

Risks Related to Our Doing Business in the PRC

Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments and the oversight and discretion the PRC government has over the conduct of the business operations of our PRC subsidiaries 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 operations in China, our business, results of operations, financial condition and prospects may be influenced by economic, legal and social conditions in the PRC or changes in government relations between China and the United States or other governments. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. China's economy differs from the economies of other countries in many respects, including with respect to the level of development, growth rate, amount of government involvement and oversight upon foreign exchange. While China's economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government oversight of capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to manage the pace of economic growth and prevent the economy from overheating. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations.

The PRC government has the ability to exert oversight over any offering of securities conducted overseas and/or foreign investment in China-based issuers, and, as a result, may limit or completely hinder our ability to offer or continue to offer securities to investors, and may cause the value of such securities to significantly decline or be worthless.

The PRC government has indicated its intent to exert more oversight over securities offerings and other capital markets activities that are conducted overseas and foreign investment in China-based companies. If the PRC authorities attempt to exercise such oversight or administration through regulation over our PRC subsidiaries, we could be required to restructure our operations to comply with such regulations or potentially cease operations in the PRC entirely, which could adversely affect our business, results of operations and financial condition. Any such action, once taken by the PRC government, could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless.

For example, the PRC government initiated a series of regulatory actions and statements to regulate business operations in China, including cracking down on illegal activities in the securities market, enhancing supervision over China-based companies listed overseas using the variable interest entity structure, adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement. For example, in July 2021, the relevant PRC government authorities made public the Opinions on Intensifying Crack Down on Illegal Securities Activities (the "Securities Opinions"), which emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas listed companies.

Furthermore, in July 2021, the PRC government provided guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities ("VIEs"). In light of such developments, the SEC has imposed enhanced disclosure requirements on China-based companies seeking to register securities with the SEC. In February 2023, the CSRC released the Overseas Listing Trial Measures and five relevant guidelines which became effective as of March 31, 2023. According to the Overseas Listing Trial Measures, where Chinese companies that have directly or indirectly listed securities in overseas markets conduct follow-on offering of equity securities in such overseas markets, they shall fulfill the filing procedures with and report relevant information to the CSRC. As the Overseas Listing Trial Measures have recently been promulgated and are subject to changes and may continue to evolve, we cannot assure you that we would not be deemed as an indirect overseas listed Chinese company under the Overseas Listing Trial Measures. If we are deemed as an indirect overseas listed Chinese company but fail to complete the filing procedures with the CSRC for any of our follow-on offerings or follow relevant reporting requirements thereunder, we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council. See also the section of our Annual Report titled "Part I —Item 1 — Business — Government Regulation – PRC Regulation – Regulations Relating to Overseas Listing". We are currently evaluating the implications and potential impact of the Overseas Listing Trial Measures and will continue to closely monitor the interpretation and implementation of the Overseas Listing Trial Measures. Due to our operations in China and stock listings in and outside of China, the Overseas Listing Trial Measures and any future PRC, U.S. or other rules and regulations that place restrictions on capital raising could adversely affect our business and results of operations and could significantly limit or completely hinder

our ability to offer or continue to offer our ADSs or ordinary shares to investors, and could cause the value of our ADSs or ordinary shares to significantly decline or become worthless.

In February 2023, the CSRC and other PRC governmental authorities jointly issued the revised Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (the "Revised Confidentiality Provisions"), which became effective as of March 31, 2023. According to the Revised Confidentiality Provisions, Chinese companies that directly or indirectly conduct overseas offerings and listings, shall strictly abide by the laws and regulations on confidentiality when providing or publicly disclosing, either directly or through their overseas listed entities, materials to securities services providers. In the event such materials contain state secrets or working secrets of government agencies, the Chinese companies shall first obtain approval from authorities, and file with the secrecy administrative department at the same level with the approving authority; in the event that such materials, if divulged, will jeopardize national security or public interest, the Chinese companies shall comply with procedures stipulated by national regulations. The Chinese companies shall also provide a written statement of the specific sensitive information provided when providing materials to securities service providers, and such written statements shall be retained for inspection. As the Revised Confidentiality Provisions recently took effect, their interpretation and implementation remain substantially uncertain.

Currently, these statements and regulatory actions have had no impact on our daily business operations, the ability to accept foreign investments and list our securities on a U.S. or other foreign exchange. However, since these statements and regulatory actions are new, it is highly uncertain how the legislative or administrative regulation making bodies will further respond and what existing or new laws or regulations or detailed implementations and interpretations will be further modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on our daily business operations, the ability to accept foreign investments and list our securities on a U.S., Hong Kong, or other stock exchanges. There are still substantial uncertainties as to how PRC governmental authorities will regulate overseas listing in practice and whether we are required to obtain any specific regulatory approvals from PRC governmental authorities for our offshore offerings. If PRC regulatory agencies later promulgate new rules or explanations requiring that we obtain their approvals for our future offshore offerings, we may be unable to obtain such approvals in a timely manner, or at all, and such approvals may be rescinded even if obtained. Any such circumstance could significantly limit or completely hinder our ability to continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. In addition, implementation of industry-wide regulations directly targeting our operations could cause the value of our securities to significantly decline. Therefore, investors of our company face potential uncertainty from actions taken by the PRC government affecting our business.

The audit reports included in our previous annual reports on Form 10-K filed with the SEC have historically been prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board (the "PCAOB"), and as such, investors have previously been deprived of the benefits of such inspections.

Ernst & Young Hua Ming LLP, our auditor from fiscal year 2014 to fiscal year 2021, is required to undergo regular inspections by the PCAOB as an auditor of companies that are publicly traded in the United States and a firm registered with the PCAOB. Since Ernst & Young Hua Ming LLP is located in China, a jurisdiction where the PCAOB had been unable to conduct inspections without the approval of the Chinese authorities, Ernst & Young Hua Ming LLP was not previously inspected by the PCAOB. Additionally, because we have substantial operations within the PRC, a jurisdiction where the PCAOB was previously unable to conduct inspections without the approval of the Chinese government authorities, Ernst & Young Hua Ming LLP and the audit work that it has carried out for us in the PRC has not historically been able to be inspected independently and 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 auditors' audits and their quality control procedures. As a result, to the extent that any components of our auditor's work papers had been located in China, such work papers had not been subject to inspection by the PCAOB. As a result, we and investors of our ADSs, ordinary shares and RMB Shares had been deprived of the benefits of such PCAOB inspections, which could cause investors and potential investors of our securities to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

To the extent the Holding Foreign Companies Accountable Act is further revised or similar legislation is enacted, our ADSs may be at risk of delisting and our ADSs and ordinary shares potentially prohibited from trading in the over-the-counter market. The delisting of our ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.

In December 2020, the Holding Foreign Companies Accountable Act ("HFCAA"), was signed into law as part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law. The HFCAA states if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for three consecutive years beginning in 2021, the SEC shall prohibit securities from being traded on a national securities exchange or in the over-the-counter trading market in the U.S. Following the filing of our annual report on Form 10-K for fiscal year ended December 31, 2021, which was audited by Ernst & Young Hua Ming LLP, the SEC added us to its list of Commission-Identified Issuers identified under HFCAA. In December 2022, the Accelerating Holding Foreign Companies Accountable Act ("AHFCAA") was signed into law, which amended the HFCAA to shorten the three-year period to two years.

However, as our global business expanded, we built substantial organizational capabilities outside of the PRC and we evaluated, designed and implemented business processes and control changes which enabled us to engage Ernst & Young LLP, located in Boston, Massachusetts, United States, as our independent registered public accounting firm for the audits of our financial statements and internal control over financial reporting for the fiscal year ended December 31, 2022. We expect that this will satisfy the PCAOB inspection requirements for the audit of our consolidated financial statements, subject to compliance with SEC and other requirements prior to the two-year deadline of the AHFCAA.

Given that Ernst and Young LLP (United States) now serves as the principal accountant to audit our consolidated financial statements, we expect to be able to comply with the HFCAA and AHFCAA and certify that we have retained a registered public accounting firm that the PCAOB has determined it is able to inspect or investigate which would preclude a further finding by the SEC that we are a Commission-Identified Issuer and therefore the delisting of our ADSs from the Nasdaq Global Select Market.

Furthermore, in August 2022, the PCAOB signed a Statement of Protocol with the CSRC and the Ministry of Finance of the People's Republic of China, for opening access for the PCAOB to inspect and investigate completely registered public accounting firms in mainland China and Hong Kong. The PCAOB staff members conducted on-site inspections and investigations in late 2022. In December 2022, the PCAOB announced that it has secured complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong, which would include Ernst & Young Hua Ming LLP, and confirmed that until such time as the PCAOB issues any new determination, there are no Commission-Identified Issuers at risk of having their securities subject to a trading prohibition under the HFCAA.

Additionally, in October 2021, Nasdaq adopted additional listing criteria applicable to companies that primarily operate in jurisdictions where local regulators impose secrecy laws, national security laws or other laws that restrict U.S. regulators from accessing information relating to the issuer (a "Restrictive Market"). Under this rule, whether a jurisdiction permits PCAOB inspection would be a factor in determining whether a jurisdiction is deemed by Nasdaq to be a Restrictive Market. China may be considered to be a Restrictive Market and, as a result, Nasdaq may impose on us additional continued listing criteria or deny continued listing of our securities on Nasdaq, and we cannot assure you whether Nasdaq or regulatory authorities would apply additional and more stringent criteria to us after considering the effectiveness of our auditor's audit procedures and quality control procedures, adequacy of personnel and training, or sufficiency of resources, geographic reach or experience as it relates to our audit.

We may be subject to enforcement under the HFCAA, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by any rules that may be adopted by the SEC under the HFCAA in the future. If we failed to comply with those rules, it is possible that our ADSs would be delisted. The risk and uncertainty associated with a potential delisting would have a negative impact on the price of our ADSs, ordinary shares and RMB Shares. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares, which are listed for trading on the HKEx. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong or may have to incur increased costs or suffer losses in order to do so. Failure to adopt effective contingency plans may also have a material adverse impact on our business and the price of our ADSs, ordinary shares and RMB Shares.

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

A large portion of our operations are conducted in China through our Chinese subsidiaries. Our Chinese subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. The Chinese 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.

Furthermore, China's legal system is still developing. The laws, rules and regulations are subject to interpretation and enforcement by PRC regulatory agencies and courts. In particular, on account of the relatively new implementation of certain laws, rules and regulations, the non-precedential nature of court decisions, and the discretion such laws, rules and regulations give to the relevant regulator in enforcement, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent. In addition, the legal system is based in part on government policies and rules which may quickly be amended from time to time. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

China's Foreign Investment Law and its implementing rule came into force in January 2020. The Foreign Investment Law and its 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 legal requirements for both foreign and domestic investments. There are still uncertainties with respect to the interpretation and implementation of the Foreign Investment Law and its 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 its implementation may maintain their structure and corporate governance for a five-year transition period. It is uncertain whether governmental authorities may require us to adjust the structure and corporate governance of certain of our Chinese subsidiaries in such transition period. Failure to take timely and appropriate measures to meet any of these or similar regulatory requirements could materially affect our current corporate governance practices and business operations and our compliance costs may increase significantly. In addition, the Security Review Rules, effective as of January 18, 2021, embody China's continued efforts to provide a legal regime for national security review comparable to similar procedures in other jurisdictions, such as CFIUS review in the United States. There are still uncertainties with respect to the interpretation, implementation and enforcement of the Security Review Rules. For example, national security remains undefined and there is no clear guidance on whether the biotechnology industry requires security review and what factors the regulatory authority may consider in determining whether there are security concerns. It is difficult to evaluate the impact of the Security Review Rules on our existing investments or potential investments in China.

It may be difficult for overseas regulators to conduct investigations or collect evidence within China. In China, there are legal and other obstacles to providing information needed for regulatory investigations or litigations initiated outside China. According to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the PRC territory, which may increase the difficulties you face in protecting your interests. According to the Revised Confidentiality and Archives Administration Provisions, where overseas securities regulators or relevant competent authorities request to inspect, investigate or collect evidence from Chinese domestic companies concerning their overseas offering and listing or their securities firms and securities service providers that undertake securities business for such Chinese domestic companies, such inspection, investigation and evidence collection must be conducted under the cross-border regulatory cooperation mechanism, and the CSRC or competent authorities of the Chinese government will provide necessary assistance pursuant to bilateral and multilateral cooperation mechanism. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of a mutual and practical cooperation mechanism. For risks associated with investing in us as a Cayman Islands company, see also the risk factor entitled "—Risks Related to Our Ordinary Shares, ADSs, and RMB Shares—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, Chinese law or U.S. law, our shareholders may have fewer shareholder rights than they would have under Hong Kong law, Chinese law or U.S. law and may face difficulties in protecting their interests."

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

In addition, the PRC government has announced its plans to enhance its regulatory oversight of China-based companies listed overseas and cross-border law enforcement cooperation. The Securities Opinions called for:

- tightening oversight of data security, cross-border data flow and administration of classified information, as well as amendments to relevant regulation to specify responsibilities of overseas listed China-based companies with respect to data security and information security;
- enhanced oversight of overseas listed companies as well as overseas equity fundraising and listing by China-based companies; and
- extraterritorial application of China's securities laws.

There are uncertainties with respect to the interpretation and implementation of the Securities Opinions and the Overseas Listing Trial Measures. The PRC government may promulgate relevant laws, rules and regulations to impose additional obligations and liabilities on overseas listed China-based companies regarding data security, cross-border data flow, and compliance with China's securities laws. As a company with operations in China and stock listings in and outside of China, it is uncertain whether or how these laws, rules and regulations and their interpretation and implementation may affect us. However, among other things, our ability to obtain external financing through the issuance of equity securities overseas could be adversely affected if restrictions on overseas fundraising are imposed on companies like us.

The filing or other procedures with, the CSRC or other Chinese regulatory authorities may be required in connection with issuing our equity securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to complete such filing or other procedures. If we fail to complete a filing with the CSRC, our future offering application may be impacted and we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council.

Pursuant to the Securities Opinions, Chinese regulators are required to accelerate rulemaking related to the overseas issuance and listing of securities outside of China, and update the existing laws and regulations related to data security, cross-border data flow, and administration of classified information. The Securities Opinions emphasized the need to strengthen the administration over illegal securities activities and the need to strengthen the supervision over overseas listings by Chinese companies.

Numerous regulations, guidelines and other measures have been or are expected to be adopted under the umbrella of or in addition to the Cyber Security Law and Data Security Law. As the relevant regulations, guidelines and measures are subject to change and continue to evolve, we cannot assure investors that we will be able to comply with new regulatory requirements relating to our future overseas capital-raising activities outside of China and we may become subject to more stringent requirements with respect to matters including data privacy and cross-border investigation and enforcement of legal claims.

Furthermore, in February 2023, the CSRC released the Overseas Listing Trial Measures and five relevant guidelines, which took effect on March 31, 2023, requiring Chinese companies that have already directly or indirectly offered and listed securities in overseas markets to fulfil their filing obligations and report relevant information to the CSRC within three working days after conducting a follow-on offering of equity securities on the same overseas market. The Overseas Listing Trial Measures may continue to evolve. We may have to go through the filing process for any follow-on offerings we conduct on the NASDAQ Global Select Market or Hong Kong Stock Exchange within three working days of the completion of our follow-on offerings. If we fail to complete a filing with the CSRC for any of our follow-on offerings, we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council.

As of the date of this report, we have not received any inquiry, notice, warning or sanction regarding completing filing or other procedures in connection with offering our equity securities on the Nasdaq Global Select Market or Hong Kong Stock Exchange from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to securities offerings and other capital markets activities outside of China. If it is determined in the future that the filing or other procedure with the CSRC or any other regulatory authority is required for issuing our equity securities on the Nasdaq Global Select Market or Hong Kong Stock Exchange, it is uncertain whether we will be able to and how long it would take for us to complete the filing or other procedure, despite our best efforts. If we, for any reason, are unable to complete, or experience significant delays in completing, the requisite relevant filing or other procedure(s), we may face sanctions by the CSRC or other Chinese regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operations in China, delay or restrict the repatriation of funds into China or take other actions that could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of our ADSs, ordinary shares, and RMB Shares. In addition, if the CSRC or other regulatory authorities later promulgate new rules requiring that we obtain their approvals or complete filing or other procedures for any future public offerings on the Nasdaq Global Select Market or Hong Kong Stock Exchange, we may be unable to obtain a waiver of such requirements, if and when procedures are established to obtain such a waiver. Any uncertainties and/or negative publicity regarding such a requirement could have a material adverse effect on the trading price of our ADSs, ordinary shares, and RMB Shares.

To operate our general business activities currently conducted in China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the SAMR. Each of our Chinese subsidiaries has obtained a valid business license from the local counterpart of the SAMR, and no application for any such license has been denied. The pharmaceutical industry in which we operate is also highly regulated in China. Our Chinese subsidiaries are required to obtain applicable licenses from competent Chinese government authorities for our operations in China, including drug manufacturing licenses, drug trade license, clinical trial authorizations, drug registration certificates, licenses for use of experimental animals,

pollutant discharge licenses and permits for urban sewage discharge into drainage pipe network. We believe our PRC subsidiaries have obtained all applicable licenses and permits which are material to our business operations in China.

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

PRC regulations and rules concerning mergers and acquisitions set forth additional procedures and requirements that could make merger and acquisition activities of PRC-based companies by foreign investors more time-consuming and complex. See also the risk factor entitled "—Risks Related to Our Industry, Business and Operations—We incur significant costs as a result of operating as a public company, 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." These rules, among others, 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. Although we believe that our business is not in an industry related to national security, we cannot preclude the possibility that the competent PRC government authorities may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions and investment in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Moreover, according to the Anti-Monopoly Law, the SAMR shall be notified in advance of any concentration of undertaking if certain filing thresholds are triggered. We may grow our business in part by acquiring complementary businesses in China. Complying with the requirements of the laws and regulations mentioned above and other PRC regulations to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the SAMR, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain or expand our market share. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

In December 2020, the NDRC and the MOFCOM promulgated the Foreign Investment Security Review Measures, which came into effect on January 18, 2021. Under the Foreign Investment Security Review Measures, investments in military, national defense-related areas or in locations in proximity to military facilities, or investments that would result in acquiring the actual control of assets in certain key sectors, such as critical agricultural products, energy and resources, equipment manufacturing, infrastructure, transport, cultural products and services, IT, Internet products and services, financial services and technology sectors, are required to be approved by designated governmental authorities in advance. Official guidance for these measures has not been issued by the designated office in charge of such security review yet, therefore there are great uncertainties with respect to the interpretation and implementation of the Foreign Investment Security Review Measures. If any of our business operations were to fall under the foregoing categories, we would need to take further actions in order to comply with these laws, regulations and rules, which may materially and adversely affect our current corporate structure, business, financial condition and results of operations.

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 until the liquidation of the enterprise. 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 September 30, 2023 and December 31, 2022, these restricted assets totaled $3.8 billion and $3.5 billion, 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, the People's Bank of China ("PBOC") and China's State Administration of Foreign Exchange ("SAFE") promulgated a series of measures relating to oversight of capital flow, 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 oversight of capital flow, and more regulations and substantial vetting process may be put forward by the SAFE for cross-border transactions. 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 PRC 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 tax residency has a tax treaty with China that provides for a reduced withholding rate arrangement and such non-PRC resident enterprises constitute the beneficiary of such income.

Pursuant to an arrangement between mainland China and the Hong Kong Special Administrative Region (the "Hong Kong Tax Treaty") and relevant tax regulations of the PRC, subject to certain conditions, a reduced withholding tax rate of 5% will be available for dividends from PRC entities provided that the recipient holds at least 25% shares of the PRC entities and can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. The China government has adopted multiple regulations which stipulate 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." We own the PRC subsidiaries through BeiGene (Hong Kong) Co., Limited ("BeiGene HK"), a company incorporated under the laws of Hong Kong on November 22, 2010 and a wholly owned subsidiary of the Company. 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 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, PRC regulations specify 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.

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 these regulations, in the absence of guidance specifically applicable to us, we have applied the guidance set forth in the regulations 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 shares and any gain realized from the transfer of our ordinary shares 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), which may be reduced or exempted according to relevant tax treaties between PRC and the non-PRC resident enterprise/individual ADS holders' or shareholders' tax resident jurisdictions.

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 Chinese regulations, 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 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. However, the sale of our ordinary shares or ADSs originally purchased from a stock exchange by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under these regulations.

There are uncertainties as to the application of these regulations, which 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 these regulations or to establish that we and our non-resident enterprises should not be taxed under these regulations, 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 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 these regulations, 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.

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

The PRC government exerts oversight on the conversion 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 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. Since a portion of our revenue is denominated in RMB, any existing and future regulations 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 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.

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 PRC regulations, 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. Moreover, failure to comply with the various foreign exchange registration requirements could result in liability under PRC law for circumventing applicable foreign exchange restrictions.

The pharmaceutical industry in China is highly regulated, and such regulations are subject to change, which may affect approval and commercialization of our medicines 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 medicines. In recent years, the regulatory framework in China for pharmaceutical companies has undergone significant changes, which we expect will continue. While we believe our strategies regarding 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 medicines in China and reduce the current benefits we believe are available to us from developing and manufacturing medicines in China.

Chinese authorities have become increasingly active in enforcing laws affecting the pharmaceutical industry. Specifically, the Chinese authorities have recently increased anti-bribery efforts to address improper payments and other benefits received by physicians, staff and hospital administrators in connection with the sales, marketing and purchase of pharmaceuticals products. 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 actions 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 costs.

Risks Related to Our Ordinary Shares, ADSs, and RMB Shares

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

The trading price of our ordinary shares, ADSs, and/or RMB Shares can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control, 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 medicines or drug candidates; variations in the level of expenses related to our existing medicines 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; the performance and fluctuation of the market prices of other companies with significant business operations in China that have listed their securities in Hong Kong, Shanghai or the United States; 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, ADSs or RMB Shares; sales or perceived potential sales of additional ordinary shares, ADSs or RMB Shares by us, our executive officers and directors or our shareholders; general economic and market conditions and overall fluctuations in the United States, Hong Kong or Shanghai equity markets; changes in accounting principles; trade disputes or U.S.-China government relations; and changes or developments in the United States, PRC, the European Union 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, ADSs, and/or RMB Shares, regardless of our actual operating performance.

The characteristics of capital markets in the United States, Hong Kong and Shanghai are different, which may cause volatility in the market price of our ordinary shares, ADSs, and RMB Shares.

Our ordinary shares are listed on the HKEx in Hong Kong under the stock code "06160", our ADSs are listed on the Nasdaq in the United States under the symbol "BGNE", and our RMB Shares are listed on the STAR Market in the PRC under the stock code "688235". Under current PRC laws and regulations, our ADSs and ordinary shares listed on the Nasdaq and the HKEx are not interchangeable or fungible with the RMB Shares listed on the STAR Market, and there is no trading or settlement between either the Nasdaq or the HKEx on the one hand, and the STAR Market on the other hand. The three markets 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 major differences, the trading prices of our ordinary shares, ADSs, and RMB Shares 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/or RMB Shares, and vice versa. Because of the different characteristics of the U.S., Hong Kong and Shanghai equity markets, the historic market prices of our ordinary shares, ADSs, and RMB 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, ADSs, and/or RMB Shares in the public market could cause the ordinary share, ADS, and/or RMB Share price to fall.

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

As of November 1, 2023, 1,359,497,624 ordinary shares, par value $0.0001 per share, were outstanding, of which 871,833,599 ordinary shares were held in the form of 67,064,123 ADSs, each representing 13 ordinary shares, and 115,055,260 were RMB Shares.

We filed a registration statement on Form S-3 with the SEC on behalf of certain shareholders on May 11, 2020, registering 300,197,772 ordinary shares, including 224,861,338 ordinary shares in the form of 17,297,026 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. Amgen also has specified registration rights upon expiration of a lock-up period. 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, ADSs and/or RMB Shares could decline.

In addition, in the future, we may issue additional ordinary shares, ADSs, RMB Shares, or other equity or debt securities convertible into ordinary shares, ADSs, or RMB Shares 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, ADS, and/or RMB Share price to decline.

The triple listing of our ADSs, ordinary shares and RMB Shares may adversely affect the liquidity and value of our ADSs, ordinary shares and/or RMB Shares.

Our ADSs are traded on the Nasdaq, our existing ordinary shares maintained on our Cayman register in Cayman Islands and Hong Kong register in Hong Kong, are traded on the HKEx, and our RMB Shares are traded on the STAR Market. The triple listing of our ADSs, ordinary shares and RMB Shares may dilute the liquidity of these securities in one or all three markets and may adversely affect the maintenance of an active trading market for ADSs in the United States, the ordinary shares in Hong Kong, and/or the RMB Shares in the PRC. The price of our ADSs, ordinary shares and/or RMB Shares could also be adversely affected by trading of our securities on other markets. We may decide at some point in the future to delist our RMB Shares from the STAR Market, and our shareholders may approve such delisting. We cannot predict the effect such delisting of our RMB Shares on the STAR Market would have on the market price of our ADSs on the Nasdaq or our ordinary shares on the HKEx.

We face increased regulatory scrutiny and compliance costs due to our listing on the STAR Market of the SSE.

We are subject to the applicable laws, rules and regulations governing public companies listed on the STAR Market in addition to the various laws, rules and regulations that we are subject to in the United States and Hong Kong. The listing and trading of our equity securities in multiple jurisdictions and multiple markets will lead to increased compliance obligations and costs for us, and we may face the risk of significant intervention by regulatory authorities in these jurisdictions and markets, such as inquiries, investigations, enforcement actions and other regulatory proceedings by regulatory authorities. In addition, we may be subject to securities litigation filed with the courts in China by the investors with respect to the RMB Shares traded on the STAR Market.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares, ADSs and/or RMB Shares 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, ADSs and/or RMB Shares 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, ADSs and/or RMB Shares will likely depend entirely upon any future price appreciation of the ordinary shares, ADSs and/or RMB Shares. There is no guarantee that the ordinary shares, ADSs and/or RMB Shares will appreciate in value or even maintain the price at which you purchased the ordinary shares, ADSs and/or RMB Shares. You may not realize a return on your investment in the ordinary shares, ADSs and/or RMB Shares and you may even lose your entire investment in the ordinary shares, ADSs and/or RMB Shares.

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, ADSs and/or RMB Shares and trading volume could decline.

The trading market for the ordinary shares, ADSs and RMB Shares 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, ADSs and/or RMB Shares or publishes inaccurate or unfavorable research about our business, the market price for the ordinary shares, ADSs and/or RMB Shares 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, ADSs and/or RMB Shares to decline significantly.

Because we are a Cayman Islands company, our shareholders may have fewer shareholder rights than they would have under Hong Kong law, Chinese law or U.S. law and may face difficulties in protecting their 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 courts 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, mainland China and the United States. In particular, the Cayman Islands has a less developed body of securities law than Hong Kong, mainland China 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, with the exception that 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 shareholders to obtain the information needed to establish facts necessary for a shareholder action 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, mainland China or U.S. federal court. As a result, shareholders may be limited in their ability to protect their interests if they are harmed in a manner that would otherwise enable them 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, mainland China 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 shareholders to bring an action against us or against these individuals in Hong Kong or in the United States in the event that shareholders believe that their rights have been infringed under the securities laws of Hong Kong, the United States or otherwise. In addition, some of our directors and executive officers reside outside of China. To the extent our directors and executive officers reside outside of China or their assets are located outside of China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if shareholders are successful in bringing an action, the laws of the Cayman Islands and China may render them 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, 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 shareholders of a Hong Kong company, a Chinese company or a U.S. company.

Voting rights of our ADS holders are limited by the terms of the deposit agreement. The depositary for the ADSs will give us a discretionary proxy to vote the ordinary shares underlying our ADS holders' ADSs if they do not vote at shareholders' meetings, except in limited circumstances, which could adversely affect their interests.

Holders of our ADSs may exercise their voting rights with respect to the ordinary shares underlying their ADSs only in accordance with the provisions of the deposit agreement. Upon receipt of voting instructions from ADS holders in the manner set forth in the deposit agreement, the depositary for the ADSs will endeavor to vote the holder's 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 21 calendar days and the minimum notice period required for convening an extraordinary general meeting is 14 calendar days. When a general meeting is convened, ADS holders may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their ordinary shares to allow them to cast their 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 ADS holders or carry out their voting instructions in a timely manner. We will make reasonable efforts to cause the depositary to extend voting rights to our ADS holders in a timely manner, but our ADS holders may not receive the voting materials in time to ensure that they can vote or instruct their agent to vote their 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, ADS holders may not be able to exercise their right to vote and they may lack recourse if the ordinary shares underlying their ADSs are not voted as they requested.

Under the deposit agreement for the ADSs, the depositary will give us a discretionary proxy to vote the ordinary shares underlying ADS holders' ADSs at shareholders' meetings if such holders 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 ADS holders fail to give voting instructions to the depositary, they cannot prevent the ordinary shares underlying their ADSs from being voted, absent the situations described above, and it may make it more difficult for such ADS holders 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, our amended and restated articles of association permit our directors to vary all or any of the rights attaching to any class of shares in issue without the consent of shareholders but only if such variation is considered by the directors not to have a material adverse effect upon such holders. 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 specific courts 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). Our amended and restated memorandum and articles of association further state that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act") and provide that any person or entity purchasing or otherwise acquiring any interest in any of our securities is deemed to have notice of and consented to these provisions; provided, however, that shareholders cannot and will not be deemed to have waived our compliance with U.S. federal securities laws and rules and regulations thereunder.

These provisions 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 these provisions 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, Hong Kong and mainland China. 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, Hong Kong or Chinese 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 ADSs may be subject to limitations on transfer of their ADSs.

ADSs are transferable only 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 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 ADS holders' right to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary 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, holders of ADSs may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they 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 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 our Hong Kong public offering in 2018, we 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 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 a 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 ADSs may not receive distributions on our ordinary shares or any value for them if it is illegal or impractical to make them available.

The depositary of the ADSs has agreed to ADS holders 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. ADS holders will receive these distributions in proportion to the number of our ordinary shares that their ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by the depositary. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that holders of ADSs 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 such holders. These restrictions may materially reduce the value of our ADSs.

Holders of 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 our ordinary shares, ADSs, and/or RMB Shares and deprive shareholders of an opportunity to receive a premium for their ordinary shares, ADSs, and/or RMB Shares.

Our directors, executive officers and principal shareholders beneficially owned approximately 54% of our outstanding ordinary shares as of November 1, 2023. 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, ADSs, and/or RMB Shares. 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 composition of our income and assets, we believe that we were not a PFIC for the taxable year ended December 31, 2022. 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, including our use of proceeds from any equity offerings, 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. The determination of whether we will be or become a PFIC may also depend, in part, on how, and how quickly, we use our liquid assets and the cash raised in equity offerings. 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.

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 generally will 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, Use of Proceeds and Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c)

There were no trading arrangements for the purchase or sale of our securities entered into, modified or terminated by our directors or officers during the quarterly period covered by this report.

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#	Settlement and Termination Agreement, dated as of August 1, 2023, by and between the Registrant, BeiGene Switzerland GmbH, Bristol-Myers Squibb Company, Celgene Corporation, Celgene Switzerland LLC, Celgene Kappa Holdings LLC, Celgene Holdings East Corporation and Celgene Logistics Sàrl	X			
10.2#	Mutual Termination and Release Agreement, dated September 17, 2023, by and between BeiGene Switzerland GmbH and Novartis Pharma AG	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			

Certain portions of the exhibit have been omitted by means of redacting a portion of the text and replacing it with "[…***…]", because they are both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.
* 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: November 9, 2023

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

Date: November 9, 2023

By: /s/ Julia Wang
Julia Wang
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

SETTLEMENT AND TERMINATION AGREEMENT

This SETTLEMENT AND TERMINATION AGREEMENT (this "Agreement"), dated as of August 1, 2023 (the "Effective Date"), is entered into by and among Bristol-Myers Squibb Company, a Delaware corporation ("BMS"), Celgene Corporation, a Delaware corporation ("Celgene Corporation"), Celgene Switzerland LLC, a Delaware limited liability company ("Celgene Switzerland"), Celgene Holdings East Corporation, a New Jersey corporation ("Celgene East"), Celgene Kappa Holdings LLC, a Delaware limited liability company ("Celgene Kappa") and Celgene Logistics Sàrl ("Celgene Logistics"), a corporation incorporated under the laws of Switzerland, on the one hand (collectively, with BMS, Celgene Corporation, Celgene Switzerland, Celgene East, Celgene Kappa and Celgene Logistics, "Celgene"), and BeiGene, Ltd., an exempted company incorporated under the laws of the Cayman Islands, and BeiGene Switzerland GmbH, a company incorporated in Switzerland ("BeiGene Switzerland", and together with BeiGene, Ltd., "BeiGene"). BMS, Celgene Corporation, Celgene Switzerland, Celgene East, Celgene Kappa, Celgene Logistics, BeiGene Switzerland, and BeiGene, Ltd., are sometimes referred to herein individual as a "Party" and collectively, the "Parties." Except as otherwise defined herein, capitalized terms have the meanings assigned to them in the LSA, QA, PVA, and SSA as defined below.

WHEREAS, the Parties entered into a License and Supply Agreement by and between Celgene Logistics and BeiGene, dated as of July 5, 2017 (the "LSA"), an Amended and Restated Quality Agreement by and between Celgene Logistics and BeiGene Switzerland dated as of October 1, 2018 (the "QA"), a Share Subscription Agreement by and between Celgene Switzerland and BeiGene, dated as of July 5, 2017 (the "SSA"), and a Pharmacovigilance Agreement by and between BMS and BeiGene, Ltd., dated October 21, 2022 ("PVA").

WHEREAS, pursuant to the SSA, Celgene Switzerland acquired, and currently holds the legal title to 32,746,416 ordinary shares of BeiGene, Ltd. (the "Acquired BeiGene Shares"), which are currently held in book-entry form and registered in the register of members of BeiGene, Ltd. with BeiGene's principal share registrar, Mourant Governance Services (Cayman) Limited, in the Cayman Islands.

WHEREAS, BeiGene filed a request for arbitration against Celgene Logistics and BMS on June 26, 2020, alleging breach of contract and breach of the implied covenant of good faith and fair dealing for alleged breaches of the LSA, and the QA, and on September 4, 2020, Celgene Logistics brought counterclaims against BeiGene alleging breaches of contract, unjust enrichment, and breach of the implied covenant of good faith and fair dealing (the "Arbitration");

WHEREAS, BMS, on behalf of Celgene, has on multiple occasions, including by letter dated February 6, 2023, requested that BeiGene register a transfer in BeiGene, Ltd.'s Register of Members of the Acquired BeiGene Shares and otherwise remove all restrictions on Celgene's ability to sell such shares;

WHEREAS, the Parties have other disputes and potential claims against each other arising under or relating to the LSA, the QA, and SSA (the "Potential Claims", and together with the Arbitration, the "Disputes");

WHEREAS, the Parties entered into a letter agreement (the "Side Letter") dated as of the date hereof; and

WHEREAS, the Parties now desire to, among other things, (1) terminate the LSA and QA; (2) fully and finally resolve the Arbitration and all disputes, claims, proceedings, controversies or causes of action that now exist concerning, relating to, or arising from the LSA, the QA, the SSA and the Potential Claims and Disputes, including, without limitation, those claims raised or which could have been raised; (3) provide for certain payments by BMS, on behalf of Celgene, to BeiGene, which shall take the form of a transfer by Celgene Switzerland of 23,273,108 of the Acquired BeiGene Shares to BeiGene, Ltd., in accordance with the terms and conditions of this Agreement; and (4) convert 9,473,308 of the Acquired BeiGene Shares (the "Remaining BeiGene Shares") into 728,716 unrestricted book-entry American Depositary Shares (the "ADSs") of BeiGene, Ltd. and for BeiGene to provide to Celgene Switzerland, full possession, custody, and control over such ADS, free and clear of all legends, Liens (as defined herein), and transfer restrictions ("Unrestricted ADSs").

NOW, THEREFORE, in consideration of the mutual promises set forth below, and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

SECTION 1. Transfer of a Portion of Celgene's Acquired BeiGene Shares. Subject to the terms and conditions hereof, and in reliance on the representations, warranties, covenants and other agreements hereinafter set forth, Celgene shall transfer to BeiGene, Ltd., and BeiGene, Ltd. shall accept the transfer from Celgene of, 23,273,108 of the Acquired BeiGene Shares (the "Transferred Shares" and the "Transfer"). BeiGene, Ltd. will make no payment in exchange for the Transferred Shares. Celgene will make no payment in respect of the resolution of the Disputes and the release of BeiGene Claims (as defined in Section 9(a)). The Transfer and the Deposit (as defined below) shall take place remotely via the exchange of signatures to the closing deliverables as set forth in Articles II and III of the Side Letter on the 10th business day immediately following the Effective Date or on such date as the Parties otherwise agree in writing (which date is designated as the "Closing Date"). Celgene hereby agrees to transfer to BeiGene, Ltd., all of such Party's right, title and interest in the Transferred Shares, free and clear of any lien, pledge, claim, security interest, encumbrance, mortgage, assessment, charge, restriction or limitation of any kind, whether arising by agreement, operation of law or otherwise (collectively, "Liens"). Promptly following the Transfer, BeiGene, Ltd. shall arrange for its register of members to be updated to reflect the Transfer of the Transferred Shares. For the avoidance of doubt, the Transfer is conditional upon the substantially concurrent deposit of the Unrestricted ADS on the Closing Date in such DTC-eligible brokerage account or accounts as are designated by Celgene Switzerland (or its specified designee) and shall be ineffective until the Unrestricted ADS have been deposited in such DTC-eligible brokerage account or accounts as are designated by Celgene Switzerland (or its specified designee) (the "Deposit"). The consummation of the Transfer and the completion of the Deposit shall be referred to herein as the "Closing." In undertaking the Closing, the Parties acknowledge and agree that time is of the essence. If Closing does not occur on or prior to August 15, 2023, the Parties agree to discuss in good-faith a reasonable extension of the Closing Date. The Parties agree and acknowledge that the Transfer, as well as the rights provided to each other under this Agreement, constitute full and final satisfaction of the Parties' obligations with respect to the resolution of the Disputes and the release of the

BeiGene Claims and the Celgene Claims (each as defined in Section 9) other than the Parties' obligations expressly set forth under this Agreement.

SECTION 2. Termination of the LSA and QA. Subject to the provisions of Section 3 below and subject to and conditional upon the Closing, the LSA and the QA shall terminate as of December 31, 2023 ("Termination Date"), and all rights to the Products covered thereby shall revert to Celgene; provided, however, as follows: notwithstanding the termination of the LSA and QA as set forth in this Section 2 and the termination provisions governing the sale of Product in the Territory after termination set forth in Sections 9.1, 13.7, 13.3, and 16.4 in the LSA, (1) BeiGene shall be permitted to sell all inventory of the Products, including the Products to be delivered pursuant to Section 3 of this Agreement, past the Termination Date until the exhaustion of the inventory of the Products by BeiGene and, as to such inventory and sales, the terms and conditions of the LSA, QA, and PVA shall remain in full force and effect for those Products and Celgene shall continue to provide necessary support for such inventory and sales in accordance therewith, with the exception of those terms and conditions expressly excluded by this Agreement; and (2) the Parties shall reasonably cooperate in good faith to ensure an appropriate process and timing for BeiGene to wind down its sales and marketing of the Products and for the transition of the Products in the marketplace in a manner consistent with the intent of the Parties set forth herein. Upon the later of the Termination Date or the exhaustion of the inventory of the Product by BeiGene, BeiGene shall, pursuant to Section 13.7 of the LSA, promptly take all action that may be reasonably required to transfer all distributor lists, hospital lists, promotional materials and any other material information it has generated primarily for Selling the Product in the Territory, and BeiGene shall promptly transfer to Celgene or to the legal entity indicated by Celgene all documents controlled by BeiGene relating to the Product or the Registration necessary for a smooth transition of the right of BeiGene to sell Product back to Celgene. All rights granted by Celgene to BeiGene (including to any BeiGene Group member) under this Agreement shall revert to Celgene (and BeiGene shall reasonably cooperate with Celgene (or its designated Celgene Group member) to take all necessary steps to cancel all registrations made by BeiGene, if any, of the Trademark). Notwithstanding the foregoing, the Parties understand that BeiGene may be unable to complete the transfer of certain property until it exhausts its Product Inventory consistent with the provisions of Section 3 below; provided, however, that BeiGene must complete its transfer obligations as soon as commercially practicable after the earlier of (y) exhaustion of its Product inventory or (z) December 31, 2024 consistent with the provisions of Section 3 below.

SECTION 3. Pending Product Orders; Continued Right to Sell.

(a) BeiGene has submitted the following purchase orders for Product (as defined by the LSA) to be delivered in the Fall of 2023: […***…] (the "Fall 2023 Supply"). Notwithstanding the termination of the LSA and QA in Section 2 above, BMS shall supply to BeiGene and BeiGene shall be permitted to sell the entire Fall 2023 Supply through and past the Termination Date until full exhaustion and Celgene shall not sell itself or to any third-party any Product until complete exhaustion of inventory by BeiGene; provided, however, that BeiGene must use Commercially Reasonable Efforts to sell through the Product in its inventory, including the Fall 2023 Supply, in a commercially reasonable period of time and is not permitted to retain, or otherwise decline to sell, or otherwise withhold from sale any portion of the Product in its inventory, including the Fall 2023 Supply, to prevent Celgene from selling Product in

the Territory. BeiGene shall provide Celgene monthly updates on the status of its efforts to sell the Product in its inventory and such updates shall include the estimated amount of Product sold in the prior month, the estimated amount of Product in its inventory, and a projection as to when BeiGene expects to exhaust the Product in its inventory. If BeiGene does not exhaust the Product in its inventory, including the Fall 2023 Supply, by December 31, 2024, then (a) upon the election of Celgene, in regards to any remaining inventory held by BeiGene, Celgene will repurchase such remaining inventory at cost from BeiGene or the Parties shall agree on a mutually agreeable date after which Celgene will be automatically entitled to sell all Products within the Territory and (b) upon the election of Celgene, in regards to any remaining inventory in the possession of distributors and hospitals, Celgene will repurchase such remaining inventory from the distributors and hospitals, or the distributors and hospitals will be allowed to continue selling such inventory until exhausted. Celgene has submitted an application for renewal of the marketing authorization license to sell Revlimid in the Territory (as defined in the LSA). Such application is currently pending […***…]. Additionally, Celgene has applied for a one-off permit for the importation of the Fall 2023 Supply of Revlimid pending decision on the license renewal application. No delivery of orders of Revlimid in the Fall 2023 Supply shall be made prior to a final decision on Celgene's license renewal application. In the event that the license is renewed, Celgene shall deliver the Fall 2023 Supply of Revlimid within thirty (30) days of the date of said renewal. In the event that the license is not renewed Celgene will not deliver any orders of Revlimid and such orders will become fully null and void without payment or penalty. For the avoidance of doubt, Celgene will have no liability in the event that the marketing authorization license to sell Revlimid is not renewed or if BeiGene is unable to sell any Product in its inventory by December 31, 2024 for any reason whatsoever, including but not limited to any other regulatory action by Chinese authorities. Celgene will (i) provide prompt updates with respect to the Revlimid license renewal application and importation permit, including sharing any written correspondence, (ii) in good faith consider BeiGene's reasonable input for regulatory interactions and (iii) invite one BeiGene representative to observe scheduled, non-administrative meetings with appropriate health authorities. […***…]. BeiGene will inform Celgene within forty-five (45) days of complete exhaustion of Product inventory by BeiGene. Notwithstanding LSA Sections 2.6, 13.4, and 13.12, Celgene shall have no obligation to repurchase any unsold inventory of Revlimid or Vidaza in the Territory, except as otherwise set forth under this Section 3. For the avoidance of doubt, the rights and obligations under this Section 3 are subject to and conditional upon the Closing.

(b) BeiGene agrees to bear the risk of loss of any unsold inventory of Product, including the Fall 2023 Supply, subject to the arrangements under Section 3(a).

SECTION 4. Conversion of Celgene's Remaining Acquired BeiGene Shares.

(a) On or before the Closing Date, BeiGene shall:

i. Deliver or cause to be delivered to Citibank, N.A. – New York, as depositary for the ADSs (with a copy to Celgene Switzerland), a duly executed copy of the consent in such form attached to the Side Letter;

ii. Deliver or cause to be delivered to BeiGene, Ltd.'s principal share registrar, Mourant Governance Services (Cayman) Limited, in the Cayman Islands (with a

copy to Celgene Switzerland), a duly executed copy of the issuance instruction letter in such form attached to the Side Letter;

iii. Cause BeiGene, Ltd.'s principal share registrar, Mourant Governance Services (Cayman) Limited, in the Cayman Islands to deliver to Citibank, N.A. – Hong Kong, as custodian for the Shares represented by ADSs (with a copy to Celgene Switzerland):

(1) an original share certificate relating to the Remaining BeiGene Shares in the name of Citi (Nominees) Limited; and

(2) a certified extract of the updated Register of Members of BeiGene, Ltd. reflecting issuance of the Remaining BeiGene Shares in the name of Citi (Nominees) Limited.

(b) On or before the Closing Date, Celgene Switzerland shall:

i. Deliver or cause to be delivered to Citibank, N.A. – New York, as depositary of the ADSs and BeiGene, Ltd.'s principal share registrar, Mourant Governance Services (Cayman) Limited (with a copy to BeiGene, Ltd.), the duly executed copies of the Letter of Transmittal, the Instrument of Transfer and the Representation Letter, in such forms attached to the Side Letter; and

ii. Pay, or cause to pay, a fee of […***…] to Citibank, N.A. – New York, as depositary for the ADSs, in accordance with the wire instructions attached as an exhibit to the Side Letter.

(c) BeiGene represents and warrants that the actions listed under Section 4(a) and 4(b) above are the only actions that need to be taken in connection with the conversion of the Remaining BeiGene Shares to Unrestricted ADSs. To the extent that any other actions are required to be taken in connection with the conversion of the Remaining BeiGene Shares to Unrestricted ADSs following the Closing Date, BeiGene shall promptly take such actions, including but not limited to:

i. Providing such consents, approvals, documents, opinions, instructions and directions as may be required by BeiGene, Ltd.'s principal share registrar, Mourant Governance Services (Cayman) Limited, in the Cayman Islands, BeiGene's Hong Kong share registrar, the Central Clearing and Settlement System of the Hong Kong Stock Exchange, HKSCC Nominees Limited and Citibank, N.A. – New York, as depositary for the ADSs (or such other depositary of the ADSs), as applicable, from BeiGene to enable the deposit of the Remaining BeiGene Shares into BeiGene's ADS program and the issuance the corresponding Unrestricted ADSs;

ii. Removing, or causing to remove, any stop transfer notations or other transfer restrictions (if any) in its records in respect of the Remaining BeiGene Shares and

taking all necessary actions as required (including causing the delivery of any opinions that may be required by BeiGene, Ltd.'s principal share registrar, Mourant Governance Services (Cayman) Limited, in the Cayman Islands, BeiGene's Hong Kong share registrar, the Central Clearing and Settlement System of the Hong Kong Stock Exchange, and HKSCC Nominees Limited and Citibank N.A., as applicable, to ensure that the Unrestricted ADSs issued to Celgene Switzerland (or its specified designee) in respect of the Remaining BeiGene Shares are treated on the same terms as the unrestricted ADSs outstanding as of the date of this Agreement; and

iii. Causing Citibank, N.A. – New York, as depositary for the ADSs (or such other depositary of the ADSs) to transfer the Unrestricted ADSs issued to the order of Celgene Switzerland (or its specified designee) in the Depository Trust Company ("DTC") to such DTC-eligible brokerage account or accounts as are designated by Celgene Switzerland (or its specified designee).

(d) For the avoidance of doubt, the representations, covenants and warranties contained in the SSA that survive in accordance with the terms of the SSA shall continue to apply to the Remaining BeiGene Shares and Unrestricted ADSs.

SECTION 5. Mutual Representations and Warranties of the Parties. Each Party represents and warrants to the other Parties of the Effective Date and as of the Closing Date (other than "Affiliates" of such first Party, which shall mean, with respect to any Person, any other Person which, at the time of determination, directly or indirectly (through one or more intermediaries), controls, is controlled by, or is under common control with such Person. For the purposes of this definition, "control" (including correlative meanings, the terms "controlled by." "controlling," or "under common control" means (a) the direct or indirect ownership of fifty percent (50%) or more of the voting stock or other voting interests or interest in capital or profits of the Person, or (b) the ability to otherwise control or direct the decisions of the board of directors or equivalent governing body of the Person):

(a) **Authority**. Such Party is duly-organized or incorporated, validly existing and in good standing (or to the extent such concept is not applicable in the relevant jurisdiction, is up to date in filing its corporate returns) under any applicable federal, state, local or foreign (including common law), statute, ordinance, rule, regulation, or court order ("Applicable Law") of the jurisdiction of its incorporation or organization and has full corporate power and authority to execute and deliver this Agreement and to perform its obligations under this Agreement;

(b) **Enforceability**. This execution of this Agreement and the performance by such Party of its obligations hereunder have been duly-authorized. This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

(c) **Consents and Filings**. No government authorization, consent or approval of any Person, license, exemption of or filing or registration with any federal, state or local governmental authority, domestic or foreign, or any other third party, under any Applicable Laws or contract in effect as of the Effective Date, is necessary in connection with the execution and delivery of this Agreement, or for the performance by such Party of its obligations under this Agreement except for the filings pursuant to applicable securities Laws (including the rules and regulations of the Securities and Exchange Commission or any national/foreign securities exchange) solely to disclose the consummation of the transactions contemplated by this Agreement, which have been made or will be made in a timely manner; and

(d) **Access to Information**. (i) The terms of this Agreement are commercially reasonable and (ii) such Party is fully aware of the terms of this Agreement and has voluntarily, and without coercion or duress of any kind, entered into this Agreement intending to be legally bound by its terms.

"Person" as defined in this Agreement shall mean any individual, a limited liability company, a joint venture, a corporation, a company, a partnership, an association, a business trust, a governmental authority, a regulatory or statutory authority, a stock exchange, a division or operating group of any of the foregoing or any other entity or organization.

SECTION 6. Representations and Warranties of Celgene. As of the Effective Date and as of the Closing Date, Celgene represents and warrants to BeiGene as follows:

(a) **Ownership of Shares**. Celgene collectively owns all legal right, title and interest in and to all of the Acquired BeiGene Shares, free and clear of all Liens. Upon transfer of the Transferred Shares, subject to the terms and conditions of this Agreement, BeiGene, Ltd. shall acquire valid and unencumbered title to the Transferred Shares. No Person has any agreement, option, understanding or commitment (oral or in writing) with Celgene or any of their Affiliates, or any right or privilege capable of becoming an agreement option or commitment, for the purchase or acquisition of any of the Transferred Shares.

(b) **Transfer for Own Account**. Celgene Switzerland is transferring the Transferred Shares for Celgene Switzerland's own account and for the account of any Celgene entity that may hold a beneficial interest in the Transferred Shares and not with a view to, or for sale in connection with, a distribution of said shares.

(c) **No Conflicts; Non-Contravention**. Neither the execution and delivery of this Agreement nor compliance with the terms and provisions hereof on the part of Celgene will violate or conflict with any Celgene entity's charter, certificate of incorporation, bylaws or other organizational or constitutive documents. Neither the execution and delivery of this Agreement nor compliance with the terms and provisions hereof on the part of Celgene will breach any statutes or regulations of any governmental authority, domestic or foreign, or will conflict with or result in a breach of any of the terms, conditions or provisions of any judgment, order, injunction, decree, agreement or instrument to which any Celgene entity or any of its Affiliates or other entities under common control with such Celgene entity is a party or by which it or its assets may be bound, or constitute a default thereunder or an event which with

the giving of notice or passage of time or both would constitute a default thereunder, or require the consent of any Person or entity (other than consents obtained on or before the Closing Date), which, in each of the foregoing cases, would have any material adverse impact on Celgene's ability to perform its obligations hereunder.

(d) **No Continuing Rights**. Celgene acknowledges that the terms of this Agreement represent the entire consideration to be paid for the Transferred Shares and that, after the Transfer (and subject to the Deposit), Celgene shall have no further rights with respect to the Transferred Shares (other than the right to the performance of BeiGene's obligations under this Agreement).

SECTION 7. Representations and Warranties of BeiGene. As of the Effective Date; and as of the Closing Date, BeiGene represents and warrants to Celgene as follows:

(a) **No Conflicts; Non-Contravention**. Neither the execution and delivery of this Agreement nor compliance with the terms and provisions hereof on the part of BeiGene will violate or conflict with any BeiGene entity's charter, certificate of incorporation, bylaws or other organizational or constitutive documents. Neither the execution and delivery of this Agreement nor compliance with the terms and provisions hereof on the part of BeiGene will breach any statutes or regulations of any governmental authority, securities exchange, domestic or foreign, or will conflict with or result in a breach of any of the terms, conditions or provisions of any judgment, order, injunction, decree, agreement or instrument to which any BeiGene entity or any of its Affiliates or other entities under common control with such BeiGene entity is a party or by which it or its assets may be bound, or constitute a default thereunder or an event which with the giving of notice or passage of time or both would constitute a default thereunder, or require the consent of any Person or entity (other than consents obtained on or before the Closing Date), which, in each of the foregoing cases, would have any material adverse impact on BeiGene's ability to perform its obligations hereunder.

SECTION 8. Available Information.

(a) **Adequate Information**. Celgene: (i) either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the transactions contemplated hereby, including, without limitation, the Transfer; (ii) has adequate information regarding the transactions contemplated hereby and the Acquired BeiGene Shares; (iii) has adequate information concerning the business and financial condition of BeiGene; (iv) has conducted, to the extent Celgene deemed necessary, an independent investigation of such matters as, in Celgene's judgment, is necessary for Celgene to make an informed decision with respect to the transactions contemplated hereby; and (v) has not relied upon BeiGene for any investigation into, assessment of, or evaluation with respect to the Acquired BeiGene Shares.

(b) **Excluded Information**.

i. Celgene acknowledges that BeiGene has advised Celgene that BeiGene and its directors, officers, advisors, counsel and other representatives possess non-public information relating to BeiGene's business and prospects and the Acquired

BeiGene Shares not known to Celgene (the "Excluded Information"), including, without limitation, the financial statements of BeiGene as of and for the period ended June 30, 2023, and Celgene chooses to effect the transactions contemplated hereby with full knowledge and appreciation of the existence of the Excluded Information and of Celgene's inability to assess the materiality of such Excluded Information and the possible positive or negative effect that public disclosure of such Excluded Information could have on (a) the trading price of the ADSs or ordinary shares of BeiGene, Ltd. upon public disclosure by BeiGene or otherwise of any such Excluded Information, which trading price could increase or decrease significantly upon such public disclosure, and (b) the value of the Transferred Shares that Celgene Switzerland intends to Transfer to BeiGene, Ltd. under Section 1 above, which value upon such public disclosure may become substantially different from the value of such Transferred Shares as of the date hereof and as of the Closing Date.

ii. BeiGene does not intend to disclose any of the Excluded Information until it has a duty to do so under Applicable Law or, if there is no such duty, BeiGene otherwise determines it would be in the best interests of its shareholders to disclose the Excluded Information.

iii. BeiGene makes no representations as to the materiality or lack of materiality of the Excluded Information, insofar as materiality determinations are inherently subjective and highly dependent on circumstances, and makes no commitment to disclose the Excluded Information publicly within any specific timeframe.

(c) **Reliance**. Celgene hereby acknowledges that BeiGene is relying on the acknowledgements and agreements in this Section 8 in entering into this Agreement with Celgene, and would not enter into this Agreement in the absence of such acknowledgments and agreements.

SECTION 9. Release of Claims.

(a) **BeiGene Claims Released**. BeiGene acknowledges and represents that the consideration provided by Celgene in this Agreement, including Celgene's release of claims, on its own behalf and on behalf of the Celgene Releasors (as defined in Section 9(d) below) is adequate and satisfactory in exchange for the release of Claims provided by BeiGene, on its own behalf and on behalf of the BeiGene Releasors (as defined in this Section 9(a) below), in this Section 9 and for the other commitments BeiGene makes in this Agreement. Subject to and conditional upon the Closing, BeiGene, on its own behalf and on behalf of its parents, subsidiaries, Affiliates, partnerships, joint ventures, predecessors and successors, and, with respect to each such entity, any other Persons acting by, through, under or in concert with any of the Persons or entities listed above, and their successors and assigns (collectively, the "BeiGene Releasors"), effective as of the Closing Date, absolutely, irrevocably and unconditionally releases, relinquishes, waives, acquits and forever discharges all known and unknown claims, counterclaims, promises, causes of action, charges, complaints, demands, liabilities, obligations, agreements, controversies, damages, suits, entitlements, costs, losses, debts and expenses or similar rights of any type, including professional fees and legal expenses, that the BeiGene Releasors currently may

have with respect to the Celgene Releasors arising from or relating to (i) the Amended and Restated Exclusive License and Collaboration Agreement ("ELCA") by and among BeiGene, Ltd. and Celgene Corporation and Celgene Switzerland, originally executed on July 5, 2017, and entered into as of August 31, 2017, (ii) the SSA, (iii) the LSA, (iv) the QA, (v) the Sale and Purchase Agreement between Celgene East and BeiGene (Hong Kong) Co., Ltd., dated July 5, 2017 ("SPA"), (vi) the PVA, and (vii) any and all matters arising in relation to BeiGene and the Celgene Releasors' collaboration to distribute and develop therapeutic compounds, whether known or unknown, including any threatened claims, that have been or could have been asserted in arbitration or any other forum (the foregoing being referred to as "BeiGene Claims"), provided, however, that nothing contained herein shall prevent any Party to this Agreement from initiating a legal action to enforce any term or provision of this Agreement.

(b) **BeiGene Representations**. BeiGene, on its own behalf and on behalf of the BeiGene Releasors, represents that as of the Effective Date and as of the Closing Date, it has not assigned to any third party any BeiGene Claim, in whole or in part, that, but for such assignment, would be subject to the release in the preceding paragraph.

(c) **BeiGene Covenant Not to Sue**. BeiGene, on behalf of itself and on behalf of the BeiGene Releasors, affirms and agrees that, aside from the currently pending Arbitration, the BeiGene Releasors have not filed or commenced, caused to be filed or commenced or are presently party to any lawsuit, proceeding or arbitration against the Celgene Releasors. Subject to and conditional upon the Closing, BeiGene, on behalf of itself and on behalf of the BeiGene Releasors, further agrees not to file or commence any lawsuit, proceeding or arbitration against any Celgene Releasor or become a party to a lawsuit, proceeding or arbitration, in each case, on the basis of any BeiGene Claim that the BeiGene Releasors have released pursuant to this Agreement. If any BeiGene Releasor files or commences any lawsuit, proceeding or arbitration against any Celgene Releasor asserting any BeiGene Claim that BeiGene, on its own behalf and on behalf of the BeiGene Releasors, has released pursuant to this Agreement, BeiGene will be liable to the Celgene Releasor for attorneys' fees, other defense costs, and any other damages that such lawsuit, proceeding or arbitration causes. BeiGene, on its own behalf and on behalf of the BeiGene Releasors, understands that this is an affirmative promise not to sue the Celgene Releasors, which is in addition to release of BeiGene Claims in the preceding paragraphs.

(d) **Celgene Claims Released**. Celgene acknowledges and represents that the consideration provided by BeiGene in this Agreement, including BeiGene's release of claims, on its own behalf and on behalf of the BeiGene Releasors, is adequate and satisfactory in exchange for the release of Claims provided by Celgene, on its own behalf and on behalf of the Celgene Releasors, in this Section 9 and for the other commitments Celgene makes in this Agreement. Subject to and conditional upon the Closing, Celgene, on its own behalf and on behalf of its parents, subsidiaries, Affiliates, partnerships, joint ventures, predecessors and successors, and, with respect to each such entity, any other Persons acting by, through, under or in concert with any of the Persons or entities listed above, and their successors and assigns (collectively, the "Celgene Releasors"), effective as of the Closing Date, absolutely, irrevocably and unconditionally releases, relinquishes, waives, acquits and forever discharges all known and unknown claims, counterclaims, promises, causes of action, charges, complaints, demands, liabilities, obligations, agreements, controversies, damages, suits, entitlements, costs, losses, debts and expenses or similar rights of any type, including professional fees and legal expenses, that the Celgene Releasors (a) currently may

have with respect to the BeiGene Releasors arising from or relating to (i) the ELCA, (ii) the SSA, (iii) the LSA, (iv) the QA, (v) the SPA, (vi) the PVA, (vii) Celgene's ownership of shares of BeiGene Ltd., and (vii) any and all matters arising in relation to BeiGene and the Celgene Releasors' collaboration to distribute and develop therapeutic compounds, whether known or unknown, including any threatened claims, that have been or could have been asserted in arbitration or any other forum, and (b) may now or hereafter have with respect to the BeiGene Releasors arising from or relating to, directly or indirectly, the existence, possession or non-disclosure of any Excluded Information, including, without limitation, pursuant to Sections 11, 12 and 17 of the Securities Act of 1933, as amended (the "Securities Act"), or Sections 10(b) and 20A of the Securities Exchange Act of 1934, as amended (together with the Securities Act, the "Acts"), or the rules and regulations promulgated by the U.S. Securities and Exchange Commission under the Acts (the foregoing (a) and (b) collectively being referred to as "Celgene Claims"), provided however that nothing contained herein shall prevent any Party to this Agreement from initiating a legal action to enforce any term or provision of this Agreement, including the indemnity provided for in Section 10 of this Agreement.

(e) **Celgene Representations**. Celgene, on its own behalf and on behalf of the Celgene Releasors, represents that as of the Effective Date and as of the Closing Date, it has not assigned to any third party any Celgene Claims, in whole or in part, that, but for such assignment, would be subject to the release in the preceding paragraph.

(f) **Celgene Covenant Not to Sue**. Celgene, on behalf of itself and on behalf of the Celgene Releasors, affirms and agrees that, aside from the currently pending Arbitration, the Celgene Releasors have not filed or commenced, caused to be filed or commenced or are presently party to any lawsuit, proceeding or arbitration against the BeiGene Releasors. Subject to and conditional upon the Closing, Celgene, on behalf of itself and on behalf of the Celgene Releasors, further agrees not to file or commence any lawsuit, proceeding or arbitration against any BeiGene Releasor or become a party to a lawsuit, proceeding or arbitration, in each case, on the basis of any Celgene Claims that the Celgene Releasors have released pursuant to this Agreement. If any Celgene Releasor files or commences any lawsuit, proceeding or arbitration against any BeiGene Releasor asserting any Celgene Claim that Celgene, on its own behalf and on behalf of the Celgene Releasors, has released pursuant to this Agreement, Celgene will be liable to the BeiGene Releasors for attorneys' fees, other defense costs, and any other damages that such lawsuit, proceeding or arbitration causes. Celgene, on its own behalf and on behalf of the Celgene Releasors, understands that this is an affirmative promise not to sue the BeiGene Releasors, which is in addition to its release of Celgene Claims in the preceding paragraphs.

(g) **Termination of Ongoing Proceedings**. Subject to and conditional upon the Closing, the BeiGene Releasors agree to terminate with prejudice all proceedings ongoing as of the Closing Date against the Celgene Releasors, including the Arbitration. Subject to and conditional upon the Closing, the Celgene Releasors agree to terminate with prejudice all proceedings ongoing as of the Closing Date against the BeiGene Releasors, including the Arbitration. Each Party hereby disclaims any right to collect or enforce upon any remedy awarded in any ongoing proceeding. Each Party shall bear its own fees, costs, and expenses incurred in relation to all proceedings terminated under this paragraph. The Parties will jointly instruct the Arbitration Court of the International Chamber of Commerce ("ICC") (i) to close ICC Case No. 25447/MK/PDP, (ii) to make payment to the arbitrators as though their award had

been issued by the ICC; (iii) to return any unused funds held by the ICC to the Parties to that arbitration in proportion to the amounts paid by each, and (iv) to destroy all records of the Arbitration, including all draft or signed copies of the arbitral award. The Parties represent and warrant that they will not seek copies of any draft or final arbitral award from the ICC or any member of the tribunal presiding over the Arbitration.

(h) **California Law**. Each Party acknowledges that it has read and understands Section 1542 of the California Civil Code that reads as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

EACH PARTY HEREBY EXPRESSLY WAIVES AND RELINQUISHES ALL RIGHTS AND BENEFITS UNDER THAT SECTION AND ANY LAW OF ANY JURISDICTION OF SIMILAR EFFECT WITH RESPECT TO THE RELEASE OF ANY CLAIMS HEREIN.

SECTION 10. Indemnity.

(a) **BeiGene Indemnity**. Subject to and conditional upon the Closing, BeiGene shall indemnify, defend, and hold harmless Celgene and its Affiliates, and their respective officers, directors, employees and agents and their respective successors, heirs and assignees and representatives (the "Celgene Indemnitees"), from and against any and all claims, third-party claims, threatened claims, damages, losses, liabilities, costs (including reasonable legal expenses, costs of litigation, and reasonable attorneys' fees), or judgments of any kind incurred by such Celgene Indemnitee from and after the Effective Date to the extent arising out of or relating to, directly or indirectly, any pending or threatened action at law, suit in equity, or governmental investigation (a "Claim") arising out of or relating to, directly or indirectly, (a) BeiGene's commercialization, marketing, and sale, including any decisions or actions taken by Chinese regulatory authorities relating to its commercialization, marketing, and sale, of Abraxane in China prior to March 25, 2020, or (b) BeiGene's commercialization, marketing, and sale, including any decisions or actions taken by Chinese regulatory authorities relating to its commercialization, marketing, and sale, of Revlimid and Vidaza in China, including BeiGene's obligations to comply with the Pregnancy Prevention Process for Revlimid, excluding such losses arising from the negligence, recklessness or willful misconduct of a Celgene Indemnitee.

(b) Subject to and conditional upon the Closing, Celgene shall indemnify, defend and hold harmless BeiGene and its Affiliates, and their respective officers, directors, employees and agents and their respective successors, heirs and assignees and representatives (the "BeiGene Indemnitees") from and against any and all Claims arising out of or relating to, directly or indirectly, (a) any injury or health complications to patients, and damages arising therefrom, that are attributable to the use of Abraxane, Revlimid or Vidaza sold by or on behalf of BeiGene that did not conform with the specifications as set out in the LSA at the time the products were placed by Celgene in the custody of the carrier for transfer to BeiGene; or (b) the actual or alleged infringement of the intellectual property rights of any third party as a

result of the sale, offer for sale, commercialization or import of Revlimid or Vidaza by BeiGene, except to the extent that such losses from Claims: (i) are subject to indemnification of a Celgene Indemnitee by BeiGene pursuant to Section 10(a) above or (ii) arise from the negligence, recklessness or willful misconduct of a BeiGene Indemnitee.

(c) **Indemnification Procedure**. Any Celgene Indemnitee or BeiGene Indemnitee seeking indemnification hereunder shall promptly notify BeiGene or Celgene, as applicable, in writing of the relevant Claim, setting forth such claim in reasonable detail. The failure to give such notice shall not affect such the Celgene Indemnitee's or BeiGene Indemnitee's right to indemnification hereunder except to the extent that BeiGene or Celgene, as applicable, shall have been materially prejudiced by such failure.

SECTION 11. Miscellaneous.

(a) **Entire Agreement**. This Agreement, the SSA, the LSA, the SPA, the PVA, the ELCA, the QA and the Side Letter represent the entire agreement between the Parties and their respective subsidiaries relating to the subject matter of this Agreement; provided that in the event of any conflict between the terms of this Agreement and the terms of any of the agreements or arrangements set forth in this sentence, this Agreement shall control. This Agreement may not be modified or canceled in any manner, nor may any provision of it or any legal remedy with respect to it be waived, except by a writing signed all Parties. The waiver by a Party of any breach hereof or default in the performance hereof shall not be deemed to constitute a waiver of any other breach or default or any succeeding breach or default. Each Party acknowledges that no other Party has made any representations or promises to it with respect to the subject matter hereof, other than those in or referred to by this Agreement.

(b) **Binding Effect; Assignment**.

i. No Party (the "Assigning Party") may, without the prior written consent of one of the other Parties that is not an Affiliate of the Assigning Party, assign or transfer any of its rights and obligations hereunder, in whole or in part (whether by operation of law, through a merger, consolidation, sale of all or substantially all of the Assigning Party's assets or that portion of the Assigning Party's business pertaining to the subject matter of this Agreement or otherwise); provided that no such consent is required for (a) an assignment or transfer by Celgene, in whole or in part, to an Affiliate of Celgene (and an Affiliate of Celgene may assign this agreement to another Affiliate of Celgene); and (b) an assignment or transfer by BeiGene, in whole or in part, to an Affiliate of BeiGene (and an Affiliate of BeiGene may assign this Agreement to another Affiliate of BeiGene); for the avoidance of doubt, Celgene Switzerland (or its specified designee) shall be free to transfer the Remaining BeiGene Shares and, following the conversion of such shares into ADS in accordance with Section 4 hereof, the corresponding Unrestricted ADS without the consent of BeiGene.

ii. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assignees, and no other Person shall have any right, benefit or obligation hereunder.

(c) **Interpretation**. Each Party has cooperated in the drafting and preparation of this Agreement; therefore, any interpretation thereof shall not be construed against any Party. This Agreement shall be construed as a whole according to its fair meaning. Unless the context indicates otherwise, the term "or" shall be deemed to include the term "and" and the singular or plural number shall be deemed to include the other. Captions are intended solely for convenience of reference and shall not be used in the interpretation of this Agreement. All references to "dollars" and "$" in this Agreement shall mean United States dollars.

(d) **Authority to Enter Agreement**. The Persons executing this Agreement hereby represent and warrant that they have the authority to bind the entity upon whose behalf this Agreement is executed.

(e) **Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same agreement and shall become effective when each Party has signed and delivered a copy to the other Party. Any manual signature on this Agreement that is faxed, scanned, photocopied, emailed or otherwise electronically transmitted in any generally accepted format, and any electronic signature valid under the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. § 7001, et. seq. shall for all purposes have the same validity, legal effect and admissibility in evidence as an original manual "wet ink" signature, and the Parties hereby waive any objection to the contrary.

(f) **Severability**. In the event that any provision of this Agreement, or the application of any such provision to any entity or Person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to entities or Persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, shall not be impaired or otherwise affected and shall continue to be valid and enforceable to the fullest extent permitted by law.

(g) **Survival**. The representations, warranties, acknowledgements and agreements of the Parties shall survive the execution and delivery of this Agreement and shall in no way be affected by any investigation of the subject matter thereof made by or on behalf of any Party. Sections 5, 6, 7, 12, 13 and 15 shall survive the termination of this Agreement.

(h) **Celgene's Tax Obligations**. Celgene shall be solely responsible for paying any taxes imposed on income or gain realized by them in connection with the Transfer of the Transferred Shares or the sale of any remaining Acquired BeiGene Shares contemplated hereby. For the avoidance of doubt, none of BMS, Celgene or any of their respective Affiliates are responsible for any taxes of BeiGene or any of its Affiliates, including without limitation any taxes arising from the sale of Products, any taxes incurred in connection with the Transfer of the Transferred Shares or any other taxes arising from or related to the transactions contemplated herein.

(i) **Further Actions**. The Parties hereby agree to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

(j) **Fees and Expenses**. Except as otherwise set forth herein, all fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby, including fees and expenses of financial advisors, financial sponsors, legal counsel, and other advisors, shall be paid by the Party incurring such expenses whether or not the transactions contemplated hereby are consummated.

(k) **Notices**. All notices, deliveries and other communications pursuant to this Agreement will be in writing and in English, and will be deemed given if delivered personally or delivered by globally recognized express delivery service to the Parties at the addresses set forth below or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such notice, delivery or communication will be deemed to have been delivered and received (a) in the case of personal delivery, on the date of such delivery, and (b) in the case of a globally recognized express delivery service, on the business day that receipt by the addressee is confirmed pursuant to the service's systems.

If to Celgene:

Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: Senior Vice President and Associate General Counsel, Transactions Law

and

Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: Executive Vice President, Strategy & Business Development

with a copy (which shall not constitute notice) to:

Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022

Attention: Sophia Hudson and Matt Solum

If to BeiGene:

BeiGene, Ltd.
c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
Attention: Chief Financial Officer

with a copy to:

BeiGene USA, Inc.
55 Cambridge Parkway, Suite 700W
Cambridge, MA 02142
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
620 Eighth Avenue
New York, NY 10018
Attention: Edwin O'Connor

Each of the Parties shall hereafter notify the other in accordance with this Section 11(k) of any change of address to which notices and other communications are to be sent

SECTION 12. Dispute Resolution.

(a) **Governing Law**. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the laws of any other jurisdiction.

(b) **Forum**. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the courts located in the City of New York, County of New York, State of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement. EACH OF THE PARTIES TO THIS AGREEMENT HEREBY AGREES THAT JURISDICTION AND VENUE IN ANY SUIT, ACTION OR PROCEEDING BROUGHT BY ANY PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT SHALL PROPERLY AND EXCLUSIVELY LIE IN THE FEDERAL COURTS LOCATED IN THE CITY OF NEW YORK, COUNTY OF NEW YORK, STATE OF NEW YORK UNLESS FEDERAL JURISDICTION IS UNAVAILABLE IN WHICH CASE SUCH SUIT, ACTION OR PROCEEDING SHALL BE BROUGHT IN THE STATE COURTS LOCATED IN THE CITY OF NEW YORK, COUNTY OF NEW YORK, STATE OF NEW YORK.

(c) **WAIVER OF JURY TRIAL**. EXCEPT AS LIMITED BY APPLICABLE LAW, EACH PARTY HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTION OF ANY PARTY IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE, AND ENFORCEMENT HEREOF.

(d) **Limitation of Liability**. IN NO EVENT SHALL ANY CELGENE PARTY OR BEIGENE PARTY BE RESPONSIBLE FOR ANY INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES INCURRED BY THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT OR THE PERMITTED HEREUNDER, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR OPPORTUNITIES, UNLESS SUCH RESPONSIBILITY ARISES IN RELATION TO DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF ANY PARTY.

(e) **Waiver of Arbitration Rights**. The Parties agree that any dispute (including any suit, action or proceeding seeking equitable relief) arising out of or in connection with this Agreement shall not be subject to resolution through arbitration. The Parties hereby expressly disclaim any right to arbitration of disputes arising out of or in connection with this Agreement which may have existed as a matter of prior agreements between the Parties.

SECTION 13. Injunctive Relief; Specific Performance. The Parties hereby acknowledge that irreparable damage would occur in the event that any of the provisions of this Agreement, the Side Letter, the LSA, the ELCA, the SSA, the SPA, the PVA or the QA were not performed in accordance with their specific terms or were otherwise breached, including in connection BeiGene's commercialization, marketing, and sale of Revlimid and Vidaza in China and BeiGene's obligations to comply with the Pregnancy Prevention Process for Revlimid, and that the Parties would not have any adequate remedy at law. Accordingly, the Parties shall be entitled to seek an injunction or injunctions to prevent breaches or threatened breaches of this Agreement, the LSA, or the QA and to enforce specifically the terms and provisions of this Agreement, the LSA, and the QA, in addition to any and all other rights and remedies at law or in equity, and all such rights and remedies shall be cumulative. Any requirements for securing or posting of any bond with such remedy are waived.

SECTION 14. Mutual Non-Disparagement. Each Party hereby agrees not to take any action or make any statement, written, oral, or otherwise, which disparages the other Party or such other Party's respective management, officers, directors, agents, or employees or which disrupts or impairs any of their normal operations, including actions or statements that could harm the reputation of the other Party with their respective clients, suppliers, regulators, employees or the public.

SECTION 15. Confidentiality.

(a) **Nondisclosure**. Each Party agrees that, (i) a Celgene Party receiving confidential or proprietary information ("Confidential Information") of a BeiGene Party or (ii) a BeiGene Party receiving Confidential Information of a Celgene Party (such Party receiving Confidential Information in clause (i) or clause (ii), the "Receiving Party", and such other Party in clause (i) or clause (ii), the "Disclosing Party"), in each case ((i) and (ii)), before or after the Effective Date shall: (x) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than reasonable efforts; (y) not disclose such Confidential Information to any third party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below; and (z) not use such Confidential Information for any purpose except those permitted by this Agreement, the LSA, QA, PVA, SSA, SPA, and ELCA (it being understood that this clause (z) shall not create or imply any rights or licenses not expressly granted under this Agreement or any other written agreement among the Parties).

BeiGene shall ensure that all applicable Affiliates of BeiGene comply with the provisions of this Section 15. Celgene shall ensure that all applicable Affiliates of Celgene comply with the provisions of this Section 15.

(b) **Exceptions**. The obligations of Section 15(a) shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent written evidence:

(1) is publicly disclosed by the Disclosing Party or its Affiliates, either before or after it was or is disclosed to the Receiving Party hereunder or under the LSA, QA, PVA, SSA, SPA, and ELCA;

(2) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party (and the applicable evidence thereof shall be contemporaneous);

(3) is subsequently disclosed to the Receiving Party or any of its Affiliates by a third party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(4) is published by a third party or otherwise becomes publicly available or enters the public domain through no fault (whether by action or inaction) of the Receiving Party, either before or after it was or is disclosed to the Receiving Party; or

(5) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon the Disclosing Party's Confidential Information

(c) **Authorized Disclosure**. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party and Confidential Information deemed to belong to all Parties under Section 15(d) to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(1) subject to Section 15(e), complying with Applicable Laws (including the rules and regulations of the Securities and Exchange Commission or any national/foreign securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;

(2) in connection with the enforcement of this Agreement; and

(3) disclosure, solely on a "need to know basis," to Affiliates, service providers, subcontractors, shareholders, equity-holders, investors, acquirers or other potential financial partners, and each of the Parties' respective directors, employees, attorneys and contractors, each of whom, prior to disclosure,

must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Section 15 (but of shorter duration if customary); provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 15(c)(3) to treat such Confidential Information as required under this Section 15.

If and whenever any Confidential Information is disclosed in accordance with this Section 15(c), such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). The Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make any disclosures pursuant to Section 15(c)(1) or Section 15(c)(2) sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information (including seeking a confidential treatment order or protective or limiting order, as applicable), and the Receiving Party will provide reasonable assistance to the Disclosing Party with respect thereto; provided that in any event, the Receiving Party will use reasonable measures to ensure confidential treatment of such information and, with respect to disclosures pursuant to Section 15(c)(1) shall only disclose such Confidential Information of the Disclosing Party as is necessary to comply with such Applicable Laws or judicial process.

(d) **Terms of this Agreement, and the LSA, QA, PVA, SSA, SPA, and ELCA**. Subject to Section 15(c) above and to the extent not already publicly disclosed as of the Effective Date, the Parties acknowledge that the existence of this Agreement and all of the respective terms of this Agreement and each of the LSA, QA, PVA, SSA, SPA, and ELCA shall be treated as Confidential Information of all Parties, with each Party treated as the Receiving Party, and thus may be disclosed only as permitted as expressly set forth herein. Each Party will also be permitted to disclose the terms of this Agreement under appropriate and customary confidentiality and non-use provisions, on a need to know basis, to a bona fide service provider, potential or actual collaborators, (sub)licensee, subcontractor, distributor, shareholder, equity-holder, lender, investor, acquirer or other potential financial partner with whom a Party has entered into good faith negotiations regarding a proposed transaction; provided that the disclosing Party redacts information that it reasonably believes is not relevant to the proposed transaction.

(e) **Public Disclosure.** Each Party agrees not to make any press release or comment, statement, disclosure or other public announcement (including by means of advertising or sales promotional materials) (collectively "Disclosure") disclosing information concerning or relating to this Agreement, the transactions contemplated hereby, use the name of any of the other Parties (other than an Affiliate of such Party or as permitted in the LSA), or its employees, except for (i) the securities disclosure statements and responsive statements and Q&A as set forth in the Side Letter, or (ii) other Disclosure as required by Applicable Law or as requested by any securities exchange, *provided* that the Party that is required or requested to make such Disclosure shall promptly notify in writing the other Parties of such requirement or request (which notice shall include a copy of the proposed Disclosure), give such Parties reasonable opportunities to review such proposed Disclosure and consider and incorporate any comments that the other Parties may have on the proposed Disclosure in good faith. To

the extent this Agreement is required to be publicly filed pursuant under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, any other Applicable Laws or the rules of a securities exchange, the filing Party shall use reasonable and diligent efforts to redact such portions of this Agreement as requested by the non-filing Party and, if required, use reasonable and diligent efforts to obtain confidential treatment of such portions of this Agreement that any such other Party requests be kept confidential, and shall only disclose Confidential Information that it is advised by counsel is legally required to be disclosed.

(f) **Equitable Relief**. Given the nature and value of the Confidential Information and the competitive damage and irreparable harm that might result to the Disclosing Party upon any unauthorized disclosure, use or transfer of its Confidential Information to any third party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Section 15. If the Receiving Party becomes aware of any breach or threatened breach of this Section 15 by a third party to whom the Receiving Party disclosed the Disclosing Party's Confidential Information, the Receiving Party shall promptly notify the Disclosing Party and cooperate with the Disclosing Party to regain possession of its Confidential Information and prevent any further breach. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Section 15 without furnishing proof of actual damages.

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Signature Page Follows)

This SETTLEMENT AGREEMENT AND RELEASE OF CLAIMS is hereby executed in counterparts on this 1st day of August, 2023, and is hereby signed under penalty of perjury under the laws of the state of New York.

IN WITNESS WHEREOF, the undersigned Parties, by their respective authorized counsel, to hereby execute this Agreement as of the day and date first set forth above.

BEIGENE, LTD.

By: /s/ Chan Lee

Printed Name: Chan Lee

Title: SVP, General Counsel

BEIGENE SWITZERLAND GMBH

By: /s/ Michael Schoen

Printed Name: Michael Schoen

Title: Managing Director

CELGENE SWITZERLAND LLC

By: /s/ Kimberly M. Jablonski

Printed Name: Kimberly M. Jablonski

Title: Manager

CELGENE HOLDINGS EAST CORPORATION

By: /s/ Kimberly M. Jablonski

Printed Name: Kimberly M. Jablonski

Title: Director

CELGENE LOGISTICS SÀRL

By: /s/ Alain Claude Georges

Printed Name: Alain Claude Georges

Title: Director

CELGENE LOGISTICS SÀRL

By: /s/ David Pignolet

Printed Name: David Pignolet

Title: Director

CELGENE CORPORATION

By: /s/ Kimberly M. Jablonski

Printed Name: Kimberly M. Jablonski

Title: Director

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Kimberly M. Jablonski

Printed Name: Kimberly M. Jablonski

Title: Corporate Secretary

CELGENE KAPPA HOLDINGS LLC

By: /s/ Kimberly M. Jablonski

Printed Name: Kimberly M. Jablonski

Title: Manager

MUTUAL TERMINATION AND RELEASE AGREEMENT

This **MUTUAL TERMINATION AND RELEASE AGREEMENT** (this "Agreement"), dated as of September 17, 2023, is entered into by and between Novartis Pharma AG, a Swiss corporation ("Novartis") and BeiGene Switzerland GmbH, a Swiss corporation ("BeiGene"). Each of Novartis and BeiGene may be referred to herein as a "Party" and collectively as the "Parties."

WHEREAS, the Parties entered into that certain Collaboration and License Agreement, dated January 11, 2021, as amended (the "Tisle Agreement").

WHEREAS, the Parties entered into that certain Manufacturing Technology Transfer Agreement, dated June 28, 2021 (the "Technology Transfer Agreement"), and Master Supply Agreement, dated June 28, 2021 (the "Master Supply Agreement" and together with the Technology Transfer Agreement, the "Ancillary Agreements").

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the Tisle Agreement.

WHEREAS, the Parties have determined that it is in the best interest of both Parties to terminate the Tisle Agreement and desire to settle and release any and all claims, controversies and disputes between them arising out of, or relating to, the Tisle Agreement.

NOW, THEREFORE, in consideration of the promises and of the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each of the Parties, intending to be legally bound, agrees as follows:

1. Termination of the Tisle Agreement. The Parties hereby acknowledge and agree the Tisle Agreement is terminated by mutual agreement of the Parties, with immediate effect and without any further notice to or action by any Party (and, for the avoidance of doubt, the Master Supply Agreement is simultaneously terminated as a result of such Tisle Agreement termination). The Parties also hereby acknowledge and agree that the Technology Transfer Agreement is terminated by mutual agreement of the Parties, with immediate effect and without any further notice to or action by any Party.

2. Effects of Termination of the Tisle Agreement. The Parties acknowledge and agree that the provisions of Section 15.7 of the Tisle Agreement shall not apply to the termination of the Tisle Agreement pursuant this Agreement, except for Section 15.7.1 which shall be deemed to apply to the termination of the Tisle Agreement pursuant to this Agreement. Furthermore, in furtherance of the mutual releases set forth in this Agreement, (i) notwithstanding Section 15.8 of the Tisle Agreement, neither Party shall have any liability to the other Party for any Damages or other liabilities that arose prior to its termination pursuant hereto; and (ii) notwithstanding Section 15.8.2 of the Tisle Agreement, only Article 1 (to the extent the definitions are used in other surviving provisions), Section 10.1, Section 10.2 (solely in respect of Joint Patents), Section 10.3 (solely in respect of Joint Patents), Article 12, Article 14 (solely with respect to Third Party Claims arising prior to the date of this Agreement and any Third Party Claims arising from any Existing Clinical Trials and any Additional Combination Trials), and Article 16 of the Tisle Agreement shall survive this termination of the Tisle Agreement.

3. Right of Reference.

(a) BeiGene grants to Novartis a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference or use" (as defined in US FDA 21 CFR §314.3(b)), or similar "right of reference" as defined in Applicable Laws in the relevant part of the Territory, to permit FDA and such other applicable Regulatory Authorities to cross-reference the appropriate INDs for the Licensed Compound solely as necessary for Novartis to obtain the IND for the Existing Clinical Trials and any Additional Combination Trials. Upon Novartis' request, BeiGene shall provide Novartis a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such rights of reference, and shall execute any additional documents or instruments necessary to allow such cross-referencing.

(b) Novartis grants to BeiGene a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference or use" (as defined in US FDA 21 CFR §314.3(b)), or similar "right of reference" as defined in Applicable Laws in the relevant part of the Territory, to permit FDA and such other applicable Regulatory Authorities to cross-reference the INDs for the Existing Clinical Trials and any Additional Combination Trials for which Novartis is the sponsor solely as necessary to support any BeiGene INDs for the Licensed Compound. Upon BeiGene's request, Novartis shall provide BeiGene a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such rights of reference, and shall execute any additional documents or instruments necessary to allow such cross-referencing.

4. Transfer. To the extent not already transferred or otherwise provided by Novartis to BeiGene during the Term of the Agreement, in accordance with the provisions of Section 15.7.1(c) of the Tisle Agreement, within […***…] after the date hereof, the Parties shall negotiate in good faith and enter into a Transition Plan in respect of the Development of the Licensed Compound and Licensed Product in the Novartis Territory, from Novartis to BeiGene in a manner consistent with Applicable Law and standards of ethical conduct of human Clinical Trials; provided, that Novartis shall not be required to transfer to BeiGene sponsorship of any Clinical Trials in the Novartis Territory for a Combination Regimen of the Licensed Compound and Licensed Products; and provided, further, that Novartis shall not be required to transfer to BeiGene sponsorship of, and Novartis shall continue to conduct, after the date of this Agreement, the Existing Clinical Trials. "Existing Clinical Trials" means the Clinical Trials in respect of Monotherapies and Combination Regimens being conducted by or on behalf of Novartis as of the date of this Agreement, as more particularly set forth on Exhibit A. The high-level key terms of the Transition Plan are set forth on Exhibit B. BeiGene and Novartis will amend or enter into a new pharmacovigilance agreement within […***…] after this Agreement, and Novartis will use good faith efforts to transition the global safety database for the Licensed Product to BeiGene as soon as reasonably possible. The November purchase order under the Master Supply Agreement for supply of Licensed Product and Licensed Compound is hereby cancelled and Novartis agrees to reimburse BeiGene for […***…] due under such purchase order. BeiGene will invoice Novartis for such amount, and Novartis shall pay such invoice within sixty (60) days after receipt.

5. Costs. Promptly after termination date, Novartis shall provide BeiGene with the list of all ongoing clinical development-related work packages, together with an estimate of the related out-of-pocket expenses. […***…]. For any new or planned clinical development-related work packages for tislelizumab not yet initiated as of the termination date that BeiGene elects to continue, Novartis would transfer any related data and/or materials to BeiGene during the Transition period, […***…]. For clarity […***…].

6. Future Supply by Novartis. Within […***…] after the date of this Agreement, the Parties shall negotiate in good faith and enter into one or more supply

agreement(s) providing for clinical or commercial supply of the Licensed Compound, as well as the technical transfer to BeiGene of the Know-How and Materials owned or Controlled by Novartis in order to enable BeiGene and its designees to Manufacture the Licensed Compound (such agreement or agreement(s), the "**Novartis Supply Agreement**"), the terms of which shall include the terms set forth on Exhibit C hereto.

7. Clinical Trials.

(a) If Novartis desires to conduct any Clinical Trials other than the Existing Clinical Trials in respect of a Combination Regimen in the Field ("Additional Combination Trials"), it will notify BeiGene in writing, which notice will include a proposed protocol synopsis for such Additional Combination Trial not less than […***…] prior to the proposed date of initiation of such Additional Combination Trial. Within […***…] after receipt of such notice and proposed protocol synopsis, BeiGene will provide notice to Novartis to either approve or deny such Additional Combination Trial, such approval not to be unreasonably withheld. If BeiGene approves such Additional Combination Trial, Novartis may thereafter conduct such Additional Combination Trial at its sole cost and expense. Novartis shall provide BeiGene with summary updates of the material Development activities […***…] with respect to the conduct of any Additional Combination Trial that includes one or more proprietary pipeline products of such Party. Novartis will provide BeiGene a copy of the body of the clinical study report with respect to each Additional Combination Trial […***…] no later than […***…] following completion of such final clinical study report. […***…].

(b) BeiGene hereby grants to Novartis a non-exclusive, transferrable, worldwide, license, with the right to grant sublicenses, under the BeiGene Patents, BeiGene's interest in Joint Inventions and Joint Patents, and the BeiGene Know-How, in each case, to conduct (including all aspects of Development) the Existing Clinical Trials, and any Additional Combination Trials which BeiGene has approved in accordance with Section 6(b). In the event Novartis desires to conduct any approved Additional Combination Trials, Novartis shall be free to use its supply or manufacture such quantities of Licensed Compound or Licensed Product as needed for such Additional Combination Trial, or, if Novartis desires BeiGene to supply Licensed Compound or Licensed Product for such Additional Combination Trial, the Parties shall promptly negotiate and enter into a clinical trial collaboration and supply agreement ("CTCSA") in respect of such Additional Combination Trial, in a form to be negotiated by the Parties in good faith within […***…] after the execution of this Agreement, pursuant to which BeiGene shall supply quantities of Licensed Compound or Licensed Product, and Novartis shall conduct such Additional Combination Trial, on the terms set forth in the CTCSA. If Novartis intended to use its supply or manufacture Licensed Compound and/or Licensed Product for such Additional Clinical Trial, BeiGene and Novartis will enter into a clinical trial collaboration agreement (a "CTCA") on terms substantially similar to the CTCSA (other than supply by BeiGene) in a form to be negotiated by the Parties in good faith within […***…] after the execution of this Agreement. Pursuant to any CTCSA entered into between the Parties, BeiGene shall supply quantities of Licensed Compound and/or Licensed Product to Novartis (i) at […***…], and (ii) at […***…] if supplied from the BeiGene Manufacturer under a BeiGene Supply Agreement; and (b) […***…].

(c) With respect to any Existing Clinical Trials, the license granted to BeiGene under Section 15.7.1(e) shall include any Novartis IP developed in the course of performing the Existing Clinical Trials that is necessary or reasonably useful to Develop and Commercialize the Licensed Product. Further, Novartis agrees to provide to BeiGene with written reports […***…] with a summary update of the material Development activities […***…] with respect to the Licensed Compound and the Licensed Product in the Existing Clinical

Trials sponsored by Novartis since Novartis's prior report. Novartis will provide BeiGene a copy of the body of the clinical study report with respect to each Existing Clinical Trial for which Novartis is the sponsor […***…] no later than […***…] following completion of such final clinical study report.

(d) Quality Agreement. Within […***…] after this Agreement, the Parties will negotiate in good faith one or more Quality Agreements in connection with the CTCSA(s) and Novartis Supply Agreement. In the event of a discrepancy between the CTCSA or the Novartis Supply Agreement and the Quality Agreement, the Quality Agreement shall govern with respect to quality matters.

8. Trademark Assignment. In connection with the exploitation of the Licensed Products, Novartis has registered the mark TEVIMBRA® as a Novartis Trademark in a number of jurisdictions in the Territory. Novartis hereby assigns all right, title and interest in and to such TEVIMBRA® mark to BeiGene. In order to perfect such assignment of the TEVIMBRA® mark to BeiGene, the Parties shall, concurrently with the execution of this Agreement, enter into a trademark assignment agreement in respect of the TEVIMBRA® mark in the form attached hereto as Exhibit D.

9. Public Disclosure. Notwithstanding anything to the contrary contained herein, in the Prior CDA, or in the surviving provisions of the Tisle Agreement, except to the extent required to comply with the requirements of Applicable Law or the rules of any Regulatory Authority (in which case Section 12.5 of the Tisle Agreement shall apply), or in connection with required communications with contract manufacturing organizations, contract research organizations, clinical sites, investigators, or Regulatory Authorities in connection with the Transition Plan, and as explicitly agreed in this Section 8, no Party shall make any press release or similar public announcement or communication relating to the Licensed Compound, Licensed Products or the Tisle Agreement (including, in each case, the negotiation, pendency or termination thereof) or the terms of this Agreement, without obtaining the prior written consent of the other Party. The Parties have agreed to the BeiGene Press Release attached as Exhibit E to this Agreement, and the Novartis Reactive Statement document attached as Exhibit F.

10. Novartis Release of BeiGene. Novartis, for and on behalf of itself and its predecessors in interest, and its and their respective past and present, direct and indirect Affiliates, associates, members, shareholders, directors, managers, partners, officers, employees, lenders, insurers, attorneys, agents and representatives, and each of their relatives, heirs, executors, administrators, representatives, successors and assigns, whether a natural person, individual, corporation (including any not for profit corporation), general or limited partnership, limited liability partnership, joint venture, estate, trust, firm, company (including any limited liability company or joint stock company), association, organization or other entity (collectively, the "Novartis Release Parties"), hereby settles and acknowledges the full and complete satisfaction of, and hereby unconditionally and irrevocably releases, acquits and forever discharges BeiGene, for and on behalf of itself and its predecessors in interest, and its and their respective past and present, direct and indirect Affiliates, associates, members, shareholders, directors, managers, partners, officers, employees, lenders, insurers, attorneys, agents and representatives, and each of their relatives, heirs, executors, administrators, representatives, successors and assigns, whether a natural person, individual, corporation (including any not for profit corporation), general or limited partnership, limited liability partnership, joint venture, estate, trust, firm, company (including any limited liability company or joint stock company), association, organization or other entity (collectively, the "BeiGene Release Parties") from, any and all manner of claims, demands, suits, causes of action, liabilities, attorneys' fees, damages, executions, obligations, judgments, orders, debts, sums of money, liens, contracts, agreements

and covenants of every kind and nature, whether known or unknown, suspected or unsuspected, concealed or hidden, choate or inchoate, vested or contingent, in law or equity, existing by statute, common law, contract or otherwise, whether now known or unknown, suspected or unsuspected, fixed or contingent, and whether or not concealed or hidden ("Claims"), that the Novartis Release Parties may have against the BeiGene Release Parties, from the beginning of the world to the date hereof, by reason of any matter, cause or thing whatsoever arising from or relating in any way to the Licensed Compound, Licensed Products, the Ancillary Agreements and the Tisle Agreement (including, in each case, the negotiation, pendency or termination thereof); but specifically excluding the right to enforce the terms of this Agreement, the Prior CDA and the surviving provisions of the Tisle Agreement and, for the avoidance of doubt, any matters unrelated to the Licensed Compound, Licensed Products, the Ancillary Agreements or the Tisle Agreement, including in the ordinary course of business of the Parties. Novartis acknowledges that this release is a general release and represents that it has been advised by its counsel of the legal and practical effect of a general release and recognizes that it is executing and delivering this release, intending hereby and thereby to be legally bound by the terms and provisions thereof of its own free will, without promises or threats of the exertion of duress. Novartis acknowledges that this release encompasses all its known and unknown claims by reason of any matter, cause or thing whatsoever arising from or relating in any way to the Licensed Compound, Licensed Products, the Ancillary Agreements and the Tisle Agreement (including, in each case, the negotiation, pendency or termination thereof). Novartis represents and warrants that it has not, and the other Novartis Release Parties have not, heretofore assigned or transferred, or purported to assign or transfer, to any Person any of the Claims released by it hereunder.

11. BeiGene Release of Novartis. BeiGene, for and on behalf of itself and the other BeiGene Release Parties, hereby settles and acknowledges the full and complete satisfaction of, and hereby unconditionally and irrevocably releases, acquits and forever discharges each of Novartis and the other Novartis Release Parties from, any and all manner of Claims that the BeiGene Release Parties may have against the Novartis Release Parties, from the beginning of the world to the date hereof, by reason of any matter, cause or thing whatsoever arising from or relating in any way to the Licensed Compound, Licensed Products, the Ancillary Agreements and the Tisle Agreement (including, in each case, the negotiation, pendency or termination thereof); but specifically excluding the right to enforce the terms of this Agreement, the Prior CDA and the surviving provisions of the Tisle Agreement and, for the avoidance of doubt, any matters unrelated to the Licensed Compound, Licensed Products, the Ancillary Agreements or the Tisle Agreement, including in the ordinary course of business of the Parties. BeiGene acknowledges that this release is a general release and represents that it has been advised by its counsel of the legal and practical effect of a general release and recognizes that it is executing and delivering this release, intending hereby and thereby to be legally bound by the terms and provisions thereof of its own free will, without promises or threats of the exertion of duress. BeiGene acknowledges that this release encompasses all its known and unknown claims by reason of any matter, cause or thing whatsoever arising from or relating in any way to the Licensed Compound, Licensed Products, the Ancillary Agreements and the Tisle Agreement (including, in each case, the negotiation, pendency or termination thereof). BeiGene represents and warrants that it has not, and the other BeiGene Release Parties have not, heretofore assigned or transferred, or purported to assign or transfer, to any Person any of the Claims released by it hereunder.

12. Waiver of Unknown Claims.

(a) Novartis, for and on behalf of itself and the other Novartis Release Parties, and BeiGene, for and on behalf of itself and the other BeiGene Release Parties, each

hereby waives any and all rights or benefits conferred under any Applicable Law now in effect or in effect in the future imposing restrictions upon or prohibiting any waiver, settlement, release or discharge of unknown or unsuspected Claims. Without limiting the foregoing, with respect to any and all of Claims released hereunder, Novartis, for and on behalf of itself and the other Novartis Release Parties, and BeiGene, for and on behalf of itself and the other BeiGene Release Parties, each hereby waive the provisions, rights and benefits of California Civil Code § 1542 (to the extent it applies herein), which provides:

(i) A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

(b) Novartis, for and on behalf of itself and the other Novartis Release Parties, and BeiGene, for and on behalf of itself and the other BeiGene Release Parties, each expressly waive, and shall be deemed to have waived, any and all provisions, rights and benefits conferred by any law of any state or territory of the United States, or principle of common law or foreign law, that is similar, comparable or equivalent in effect to California Civil Code § 1542.

(c) Each of Novartis, on behalf of itself, as applicable, and the other Novartis Release Parties, and BeiGene, on behalf of itself and the other BeiGene Release Parties, acknowledges that it may hereafter discover Claims or facts in addition to or different from those which they now know or believe to exist, and which, if known or suspected at the time of execution and delivery of this Agreement, may have materially affected this Agreement or a Party's willingness to enter into this Agreement. Nevertheless, each of Novartis, on behalf of itself, as applicable, and the other Novartis Release Parties, and BeiGene, on behalf of itself and the other BeiGene Release Parties, accept and assume the risk of such additional or different Claims or facts, and agree that it intends to fully, finally and forever settle and release all Claims that now exist, may exist, or previously existed, whether known or unknown, foreseen or unforeseen, or suspected or unsuspected as set forth in this Agreement, and that this Agreement shall be and shall remain effective notwithstanding any such additional or different Claims or facts. Each of the Parties agrees and represents that this Agreement is executed voluntarily by it with full knowledge of the fact that it prohibits them from taking any action based on such additional or different Claims or facts.

13. Covenant Not to Sue. Each of Novartis, on behalf of itself, as applicable, and the other Novartis Release Parties, and BeiGene, on behalf of itself and the other BeiGene Release Parties, agrees not to bring, file, claim, sue or cause, assist, or permit to be brought, filed, or claimed (i) any action or demand regarding or in any way related to the Claims released by it hereunder, or (ii) any action or demand challenging or disputing in any manner the enforceability of the releases under this Agreement, and further agrees that this Agreement will constitute and may be pleaded as, a bar to any such action or challenge, appeal, inquiry, dispute or other proceeding to contest, as that case may be. For purposes of clarity, the covenant not to sue contained herein shall not affect any Party's rights to enforce the obligations of any other Party under this Agreement, the Prior CDA or the surviving provisions of the Tisle Agreement or, for the avoidance of doubt, any matters unrelated to the Licensed Compound, Licensed Products, the Ancillary Agreements or the Tisle Agreement.

14. No Admission. Nothing contained in this Agreement constitutes or shall be deemed or construed to be an admission by any Party of the truth or falsity of any Claim or

any assertion by any other Party related to the facts or circumstances giving rise to any Claim. Nothing contained in this Agreement constitutes or shall be deemed or construed to be an admission by any Party of any fault or liability of any kind to any of the other Parties or to any other Person in connection with the Claims released pursuant to this Agreement, all such fault or liability being expressly denied.

15. Representations and Warranties. Each of the Parties hereby represents and warrants as follows, as of the date of this Agreement:

(a) Such Party has full corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance by such Party of this Agreement have been duly and validly authorized and no additional corporate or stockholder authorization or consent is required in connection with the execution, delivery and performance by such Party of this Agreement.

(b) The execution, delivery and performance by such Party of this Agreement does not and will not (i) violate any provision of the certificate of incorporation, bylaws or other organizational documents of such Party, or (ii) violate or result in a breach of or constitute a default under any Applicable Law to which such Party is subject.

(c) This Agreement constitutes a valid and legally binding obligation of such Party, enforceable against it in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium, or similar Applicable Law of general applicability relating to or affecting creditors' rights and to general equity principles.

(d) Such Party has received advice from attorneys of its choice with respect to the advisability of executing this Agreement and, prior to the execution of this Agreement, its attorneys have reviewed this Agreement.

(e) Such Party has carefully read this Agreement, knows and understands the contents of this Agreement, and signs this Agreement voluntarily.

(f) Novartis hereby represents and warrants that as of the date of this Agreement there are no Novartis Patents in existence (other than any Joint Patents, in the case a Joint Patent could also be considered a Novartis Patent).

16. Entire Agreement. This Agreement contains the entire agreement between the Parties hereto with respect to the subject matter hereof and thereof and supersedes all prior agreements and understandings, oral or written, with respect to such subject matter, except for the Prior CDA and the surviving provisions of the Tisle Agreement. Each Party acknowledges and agrees that, in entering into this Agreement, such Party has not relied on any promises or assurances, written or oral, that are not reflected in this Agreement.

17. Amendment; Waiver. Any provision of this Agreement may be amended or waived if, and only if, such amendment or waiver is in writing and signed, in the case of an amendment, by Novartis and BeiGene, or in the case of a waiver, by the Party against whom the waiver is to be effective. No failure or delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

18. No Assignment or Benefit to Third Parties. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors, legal representatives and permitted assigns. No Party may assign any of its rights or delegate any of its obligations under this Agreement, by operation of Applicable Law or otherwise, without the prior written consent of the other Party. Nothing in this Agreement, express or implied, is intended to confer upon any Person other than the Parties, and the Novartis Release Parties and BeiGene Release Parties as expressly provided herein, and their respective successors, legal representatives and permitted assigns, any rights or remedies under or by reason of this Agreement. Nothing in this Agreement, express or implied, is intended to confer upon any Person other than the Parties hereto and the Persons expressly referred to herein any rights or remedies under or by reason of this Agreement. Without limiting the generality of the foregoing, the Parties expressly confirm their agreement that, in addition to Novartis and BeiGene, the other Novartis Release Parties and BeiGene Release Parties, as the case may be, shall also enjoy the benefits of the releases for their benefit made herein. In this regard, the Parties agree that such Persons shall have the right to enforce those provisions directly against the applicable releasing Person.

19. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the state of New York without giving effect to principles or rules of conflict of laws to the extent such principles or rules would require or permit the application of laws of another jurisdiction.

20. Jurisdiction and Venue; Service of Process. Each Party agrees that it shall bring any action or proceeding in respect of any claim arising out of or related to this Agreement exclusively in the United States District Court for the Southern District of New York or any New York State court sitting in New York City and the appropriate appellate courts therefrom (the "Chosen Courts"), and solely in connection with claims arising under this Agreement (a) irrevocably submits to the exclusive jurisdiction of the Chosen Courts, (b) waives any objection to laying venue in any such action or proceeding in the Chosen Courts, (c) waives any objection that the Chosen Courts are an inconvenient forum or do not have jurisdiction over any Party and (d) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with Section 16.2 of the Tisle Agreement. Each Party irrevocably waives any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement.

21. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same Agreement.

22. Headings. The heading references herein are for convenience purposes only, and shall not be deemed to limit or affect any of the provisions hereof.

23. Precedence. To the extent there is any conflict between this Agreement, the Technology Transfer Agreement, the Master Supply Agreement, or the Tisle Agreement, this Agreement shall govern, unless this Agreement expressly states otherwise.

24. Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any Person or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefor in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the

remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction.

25. Expenses. All costs and expenses incurred in connection with this Agreement and the termination of the Tisle Agreement shall be borne by the Party incurring such costs and expenses.

26. Interpretation. The language used in this Agreement has been chosen by the Parties to express their mutual intent, and no rule of construction shall be applied against or in favor of either Party, and no Party shall be deemed the drafter of this Agreement, and the Parties waive any statute, principle or rule of law to the contrary. In this Agreement, unless the express context otherwise requires: (a) "or" is used in the inclusive sense of "and/or"; (b) the words "hereof," "herein," "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) the terms defined in the singular have a comparable meaning when used in the plural, and vice versa; (d) wherever the word "include," "includes," or "including" is used in this Agreement, it shall be deemed to be followed by the words "without limitation".

[*Remainder of page intentionally left blank.*]

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be executed as of the date first above written.

NOVARTIS PHARMA AG

By: /s/ Jen Malone
Name: Jen Malone
Title: Head of Oncology Strategy

By: /s/ Mark Temples
Name: Mark Temples
Title: Executive Director, BD&L Partnering

BEIGENE SWITZERLAND GMBH

By: /s/ Michael Schoen
Name: Michael Schoen
Title: Managing Director

Exhibits Omitted from Mutual Termination and Release Agreement

Pursuant to Regulation S-K, Item 601(a)(5), the exhibits to the Mutual Termination and Release Agreement, as listed below, have not been filed. The Registrant agrees to furnish supplementally a copy of any omitted exhibits to the U.S. Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

Exhibit A: Existing Clinical Trials
Exhibit B: High-Level Transition Plan Key Terms
Exhibit C: Terms of Supply & Tech Transfer
Exhibit D: Trademark Assignment Agreement
Exhibit E: BeiGene Press Release
Exhibit F: Novartis Reactive Statement

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: November 9, 2023

/s/ JOHN V. OYLER

John V. Oyler

Chief Executive Officer and Chairman

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Julia Wang, 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: November 9, 2023

/s/ JULIA WANG

Julia Wang

Chief Financial 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 September 30, 2023 (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.

Date: November 9, 2023

/s/ JOHN V. OYLER

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

Date: November 9, 2023

/s/ JULIA WANG

Julia Wang
Chief Financial Officer
(Principal Financial and Accounting Officer)