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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024
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 May 3, 2024, 1,359,524,369 ordinary shares, par value $0.0001 per share, were outstanding, of which 866,105,747 ordinary shares were held in the form of 66,623,519 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

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PART I. FINANCIAL INFORMATION

Item 1. 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 March 31, 2024	Three Months Ended March 31, 2023
		$	$
Revenues			
Product revenue, net	11	746,918	410,291
Collaboration revenue	3	4,734	37,510
Total revenues		751,652	447,801
Cost of sales - product		124,935	81,789
Gross profit		626,717	366,012
Operating expenses			
Research and development		460,638	408,584
Selling, general and administrative		427,427	328,499
Amortization of intangible assets		—	187
Total operating expenses		888,065	737,270
Loss from operations		(261,348)	(371,258)
Interest income, net		16,160	16,016
Other income, net		1,762	18,303
Loss before income taxes		(243,426)	(336,939)
Income tax expense	8	7,724	11,492
Net loss		(251,150)	(348,431)
Net loss per share, basic and diluted	12	(0.19)	(0.26)
Weighted-average shares outstanding—basic and diluted		1,355,547,626	1,354,164,760
Net loss per American Depositary Share ("ADS"), basic and diluted	12	(2.41)	(3.34)
Weighted-average ADSs outstanding—basic and diluted		104,272,894	104,166,520

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 March 31,	
	2024	2023
	$	$
Net loss	(251,150)	(348,431)
Other comprehensive income (loss), net of tax of nil:		
Foreign currency translation adjustments	(32,163)	13,347
Unrealized holding income (loss), net	(35)	5,056
Comprehensive loss	(283,348)	(330,028)

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

BEIGENE, LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	As of March 31, 2024	As of December 31, 2023
		$ (unaudited)	$ (audited)
Assets			
Current assets:			
Cash and cash equivalents		2,793,370	3,171,800
Short-term investments	4	—	2,600
Accounts receivable, net		435,294	358,027
Inventories, net	5	447,345	416,122
Prepaid expenses and other current assets	9	231,741	254,865
Total current assets		3,907,750	4,203,414
Property, plant and equipment, net	6	1,417,992	1,324,154
Operating lease right-of-use assets		87,747	95,207
Intangible assets, net	7	55,171	57,138
Other non-current assets	9	199,021	125,362
Total non-current assets		1,759,931	1,601,861
Total assets		5,667,681	5,805,275
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		356,575	315,111
Accrued expenses and other payables	9	569,438	693,731
Tax payable	8	27,324	22,951
Operating lease liabilities, current portion		19,401	21,950
Research and development cost share liability, current portion	3	81,986	68,004
Short-term debt	10	826,965	688,366
Total current liabilities		1,881,689	1,810,113
Non-current liabilities:			
Long-term bank loans	10	199,027	197,618
Operating lease liabilities, non-current portion		17,722	22,251
Deferred tax liabilities	8	16,437	16,494
Research and development cost share liability, non-current portion	3	143,544	170,662
Other long-term liabilities	9	48,901	50,810
Total non-current liabilities		425,631	457,835
Total liabilities		2,307,320	2,267,948
Commitments and contingencies	17		
Shareholders' equity:			
Ordinary shares, $0.0001 par value per share; 9,500,000,000 shares authorized; 1,359,524,369 and 1,359,513,224 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively		136	135
Additional paid-in capital		11,705,069	11,598,688
Accumulated other comprehensive loss	14	(131,644)	(99,446)
Accumulated deficit		(8,213,200)	(7,962,050)
Total shareholders' equity		3,360,361	3,537,327
Total liabilities and shareholders' equity		5,667,681	5,805,275

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	Three Months Ended March 31, 2024	2023
		$	$
Operating activities:			
Net loss		(251,150)	(348,431)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		25,293	20,011
Share-based compensation expenses	13	88,667	75,322
Gain on deconsolidation of a subsidiary		(3,735)	—
Amortization of research and development cost share liability	3	(13,136)	(17,398)
Other items, net		848	780
Changes in operating assets and liabilities:			
Accounts receivable		(80,025)	(136,487)
Inventories		(37,264)	(13,027)
Other assets		(4,401)	(50,408)
Accounts payable		46,300	(22,589)
Accrued expenses and other payables		(79,309)	(38,681)
Deferred revenue		—	(33,066)
Other liabilities		(660)	197
Net cash used in operating activities		(308,572)	(563,777)
Investing activities:			
Purchases of property, plant and equipment		(156,578)	(125,585)
Purchase of intangible asset		(4,674)	—
Proceeds from sale or maturity of investments		2,655	376,962
Purchase of in-process research and development		(31,800)	—
Other investing activities		(19,434)	(10,314)
Net cash (used in) provided by investing activities		(209,831)	241,063
Financing activities:			
Proceeds from long-term loan	10	9,053	—
Repayment of long-term loan	10	(3,579)	(1,457)
Proceeds from short-term loans	10	142,028	—
Repayment of short-term loans	10	—	(50,000)
Proceeds from option exercises and employee share purchase plan		14,791	31,589
Net cash provided by (used in) financing activities		162,293	(19,868)
Effect of foreign exchange rate changes, net		(22,438)	11,311
Net decrease in cash, cash equivalents, and restricted cash		(378,548)	(331,271)
Cash, cash equivalents, and restricted cash at beginning of period		3,185,984	3,875,037
Cash, cash equivalents, and restricted cash at end of period		2,807,436	3,543,766
Supplemental cash flow information:			
Cash and cash equivalents		2,793,370	3,538,644
Short-term restricted cash		11,445	159
Long-term restricted cash		2,621	4,963
Income taxes paid		2,490	7,616
Interest expense paid		11,440	5,017
Supplemental non-cash information:			
Capital expenditures included in accounts payable and accrued expenses		100,473	64,013
Increase in equity investment from deconsolidation of a subsidiary		40,798	—

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, 2023	1,359,513,224	135	11,598,688	(99,446)	(7,962,050)	3,537,327
Use of shares reserved for share option exercises	(3,634,952)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	3,646,097	1	15,662	—	—	15,663
Share-based compensation	—	—	88,667	—	—	88,667
Deconsolidation of a subsidiary	—	—	2,052	—	—	2,052
Other comprehensive loss	—	—	—	(32,198)	—	(32,198)
Net loss	—	—	—	—	(251,150)	(251,150)
Balance at March 31, 2024	1,359,524,369	136	11,705,069	(131,644)	(8,213,200)	3,360,361
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

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 oncology company discovering and developing innovative 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® (zanubrutinib), a small molecule inhibitor of Bruton's Tyrosine Kinase ("BTK") 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 PARTRUVIX® (pamiparib), a selective small molecule inhibitor of PARP1 and PARP2. The Company has obtained approvals to market BRUKINSA in the United States ("U.S."), the People's Republic of China ("China" or the "PRC"), the European Union ("EU"), the United Kingdom ("UK"), Canada, Australia, and additional international markets; TEVIMBRA (tislelizumab) in the U.S., EU and China; and PARTRUVIX in China. By leveraging its strong commercial capabilities, the Company has in-licensed the rights to distribute additional 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 Beijing Novartis Pharma Co., Ltd. ("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. Recognizing the importance of clinical trial activities in its industry and the challenges associated with outsourcing to third-party contract research organizations ("CROs"), the Company has built its own 3,000+ person internal clinical team and is largely CRO-free.

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 at the Princeton West Innovation Park 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 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 March 31, 2024, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023, and the condensed consolidated statements of shareholders' equity for the three months ended March 31, 2024 and 2023, 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, 2023 (the "Annual Report").

The unaudited interim condensed consolidated 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 months ended March 31, 2024 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.

Recent accounting pronouncements

New accounting standards which have not yet been adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting* (Topic 280): Improvements to Reportable Segment Disclosures. This update requires disclosure of incremental segment information on an annual and interim basis. This update is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024. Early adoption is permitted. This guidance should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740): Improvements to Income Tax Disclosures. This update requires that public entities on an annual basis, (1) in the rate reconciliation, disclose specific categories and provide additional information for reconciling items that meet a quantitative threshold; (2) about income taxes paid, disclose the amount of income taxes paid (net of refunds received) disaggregated by federal, state, and foreign taxes and by individual jurisdiction in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received); and (3) disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) disaggregated by federal, state, and foreign. This update is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. This guidance should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the 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, 2023.

There have been no material changes to the Company's significant accounting policies as of and for the three months ended March 31, 2024, 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 March 31, 2024 and December 31, 2023:

As of March 31, 2024	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	803,170	—	—
Time deposits	42,861	—	—
Prepaid expenses and other current assets:			
Convertible debt instrument	—	—	4,668
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	1,954	222	—
Convertible debt instrument	—	—	4,603
Total	847,985	222	9,271

As of December 31, 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	1,052,149	—	—
Time deposits	42,852	—	—
Short-term investments (Note 4):			
U.S. Treasury securities	2,600	—	—
Prepaid expenses and other current assets:			
Convertible debt instrument	—	—	4,668
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	3,046	542	—
Convertible debt instrument	—	—	4,215
Total	1,100,647	542	8,883

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"), a publicly-traded biotechnology company. The common stock investment is measured and carried at fair value and classified as a Level 1 investment. The warrants to purchase additional shares of common stock are measured using the Black-Scholes option-pricing valuation model and classified as a Level 2 investment. 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 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, net. There were no fair value adjustments for the three months ended March 31, 2024.

As of March 31, 2024 and December 31, 2023, 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. For detailed descriptions of each arrangement, see the Company's Form 10-K for the year ended December 31, 2023 filed with the U.S. Securities and Exchange Commission on February 26, 2024.

Out-Licensing Arrangements

For the three months ended March 31, 2024, the Company's collaboration revenue consisted primarily of revenue generated under the Novartis broad markets agreement. For the three months ended March 31, 2023, 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 months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
Revenue from Collaborators	$	$
Research and development service revenue	—	6,817
Right to access intellectual property revenue	—	26,249
Other	4,734	4,444
Total	4,734	37,510

Novartis

Tislelizumab Collaboration and License

In September 2023, the Company and Novartis agreed to mutually terminate the tislelizumab 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.

No collaboration revenue was recognized in connection with the tislelizumab collaboration and license agreement during the three months ended March 31, 2024 due to termination of the agreement in 2023. The following table summarizes collaboration revenue recognized for the three months ended March 31, 2023:

	Three Months Ended March 31,	
	2024	2023
	$	$
Research and development service revenue	—	5,025
Other [1]	—	3,464
Total	—	8,489

(1) Represents revenue recognized on 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 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 following table summarizes collaboration revenue recognized in connection with the China broad markets agreement for the three months ended March 31, 2024 and the terminated ociperlimab option, collaboration and license agreement for the three months ended March 31, 2023:

	Three Months Ended March 31,	
	2024	2023
	$	$
Research and development service revenue	—	1,792
Right to access intellectual property revenue	—	26,249
China broad markets agreement	4,347	980
Total	4,347	29,021

In-Licensing Arrangements - Commercial

Amgen

During the three months ended March 31, 2024 and 2023, the Company recorded the following amounts related to its collaboration arrangement with Amgen. For a detailed description of the arrangement and related rights and obligation, see the Company's Form 10-K for the year ended December 31, 2023 filed on February 26, 2024.

Amounts recorded related to the Company's portion of the co-development funding on the pipeline assets for the three months ended March 31, 2024 and 2023 were as follows:

	Three Months Ended March 31,	
	2024	2023
	$	$
Research and development expense	13,484	17,817
Amortization of research and development cost share liability	13,136	17,398
Total amount due to Amgen for BeiGene's portion of the development funding	26,620	35,215

	As of March 31, 2024
Remaining portion of development funding cap	457,031

As of March 31, 2024 and December 31, 2023, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of	
	March 31, 2024	December 31, 2023
	$	$
Research and development cost share liability, current portion	81,986	68,004
Research and development cost share liability, non-current portion	143,544	170,662
Total research and development cost share liability	225,530	238,666

The total reimbursement paid under the commercial profit-sharing agreement for product sales is classified in the income statement for the three months ended March 31, 2024 and 2023 as follows:

	Three Months Ended March 31,	
	2024	2023
	$	$
Cost of sales - product	8,569	(2,827)
Research and development	(705)	3,080
Selling, general and administrative	(18,153)	(11,836)
Total	(10,289)	(11,583)

The Company purchases commercial inventory from Amgen to distribute in China. Inventory purchases amounted to $62,226 and $19,131 during the three months ended March 31, 2024 and 2023, respectively. Net amounts payable to Amgen was $93,561 and $55,474 as of March 31, 2024 and December 31, 2023, 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 incurred under these arrangements for the three months ended March 31, 2024 and 2023 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 March 31,	
		2024	2023
Payments due to collaboration partners	**Classification**	**$**	**$**
Upfront payments	Research and development expense	27	—
Development milestone payments	Research and development expense	35,000	—
Total		35,027	—

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 March 31, 2024 and December 31, 2023 was as follows:

	As of	
	March 31, 2024	December 31, 2023
	$	**$**
Short-term restricted cash	11,445	11,473
Long-term restricted cash	2,621	2,711
Total	14,066	14,184

In addition to the restricted cash balances above, the Company is required by the PRC securities law to use the proceeds from our offering on the STAR Market of the Shanghai Stock Exchange (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 March 31, 2024, the Company had cash remaining related to the STAR Offering proceeds of $960,961.

Short-Term Investments

As of December 31, 2023, the Company's short-term investments in available-for-sale debt securities consisted of U.S. Treasury securities in the amount of $2,600. During the three months ended March 31, 2024, the Company sold the entire investments in U.S. Treasury securities.

Investments in Equity Securities

The following table summarizes the Company's investments in equity securities:

	As of	
	March 31, 2024	December 31, 2023
Equity securities with readily determinable fair values (1)		
Fair value of Leap common stock	1,954	3,046
Fair value of Leap warrants	222	542
Equity securities without readily determinable fair values		
Pi Health, Inc. (2)	40,798	—
Other	54,919	55,860
Equity-method investments	41,119	25,981
Total	139,012	85,429

(1) Represents common stock and warrants to purchase additional shares of common stock of Leap Therapeutics, Inc. ("Leap"). The Company measures the investment in the common stock and warrants at fair value, with changes in fair value recorded to other income, net.

(2) In the first quarter of 2024, the Company divested the net assets comprising substantially all of its Pi Health business with a carrying value of $38,063. The consideration received for the divestiture consisted of preferred stock in a newly formed entity, Pi Health, Inc., with a fair value of $40,798 and cash consideration of $1,000. The transaction resulted in a pre-tax gain of $3,735 recorded within other income, net during the three months ended March 31, 2024. The Company will account for its investment prospectively as a private equity security without a readily determinable fair value and the divestiture is not treated as a discontinued operation in the Statement of Operations and therefore the historical results of operations of the Pi Health business will remain in the Company's continuing operations.

The following table summarizes unrealized (losses) gains related to equity securities recorded in other income, net for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	$	$
Equity securities with readily determinable fair values	(1,412)	(1,107)
Equity securities without readily determinable fair values	(797)	1,081
Equity-method investments	(856)	(144)

5. Inventories, Net

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

	As of	
	March 31, 2024	December 31, 2023
	$	$
Raw materials	157,735	148,772
Work in process	49,365	39,098
Finished goods	240,245	228,252
Total inventories, net	447,345	416,122

6. Property, Plant and Equipment, Net

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

	As of	
	March 31, 2024	December 31, 2023
	$	$
Land	65,485	65,485
Building	281,424	231,656
Manufacturing equipment	216,564	186,856
Laboratory equipment	210,513	205,349
Leasehold improvement	59,425	60,124
Software, electronics and office equipment	66,726	83,281
Property, plant and equipment, at cost	900,137	832,751
Less: accumulated depreciation	(265,002)	(249,212)
Construction in progress	782,857	740,615
Property, plant and equipment, net	1,417,992	1,324,154

The Company is making a significant investment in its future manufacturing and R&D center in the U.S., a 42-acre site that is being constructed in Hopewell, New Jersey. As of March 31, 2024, the Company had land and construction in progress of $652,369 related to the Hopewell facility.

In March 2024, the Company acquired a land use right and the facility currently being constructed on the land for $73,853 in Shanghai, China. Based on the relative fair values of the land use right and construction in progress, $28,887 of the total purchase price was allocated to the land use right and $44,966 was allocated to the construction in progress. As of March 31, 2024, title and risk of loss associated with the acquired properties were being transitioned to the Company. As such, the purchase price allocated to the land use right was recorded as a long-term prepaid as of March 31, 2024 and will be transferred to operating lease right-of-use asset upon the closing of the transaction. The Company plans to complete the construction of the facility and build a research and development center on the land.

Depreciation expense was $24,110 and $19,025 for the three months ended March 31, 2024 and 2023, respectively.

7. Intangible Assets

Intangible assets as of March 31, 2024 and December 31, 2023 are summarized as follows:

	As of					
	March 31, 2024			December 31, 2023		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
	$	$	$	$	$	$
Finite-lived intangible assets:						
Developed products	63,413	(8,913)	54,500	64,274	(7,807)	56,467
Other	8,987	(8,316)	671	8,987	(8,316)	671
Total finite-lived intangible assets	72,400	(17,229)	55,171	73,261	(16,123)	57,138

Developed products represent 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.

Amortization expense for developed products is included in cost of sales - product in the accompanying consolidated statements of operations. Amortization expense for other intangible assets is included in operating expenses in the accompanying consolidated statements of operations.

The weighted-average life for each finite-lived intangible assets is approximately 12 years. Amortization expense was as follows:

	Three Months Ended March 31,	
	2024	2023
	$	$
Amortization expense - Cost of sales - product	1,183	799
Amortization expense - Operating expense	—	187
Total	1,183	986

Estimated amortization expense for each of the five succeeding years and thereafter, as of March 31, 2024 is as follows:

Year Ending December 31,	Cost of Sales - Product	Operating Expenses	Total
	$	$	$
2024 (remainder of year)	3,533	67	3,600
2025	4,710	67	4,777
2026	4,710	67	4,777
2027	4,710	67	4,777
2028	4,710	67	4,777
2029 and thereafter	32,127	336	32,463
Total	54,500	671	55,171

8. Income Taxes

Income tax expense was $7,724 and $11,492 for the three months ended March 31, 2024 and 2023, respectively. The Company is anticipating a lower annual effective tax rate in 2024 due to the forecasted jurisdictional mix of consolidated pre-tax earnings, which is expected to increase in jurisdictions where the Company has tax attributes to offset current tax expense. The income tax expense for the three months ended March 31, 2024 and 2023 was primarily attributable to current U.S. tax expense determined after other special tax deductions and research and development tax credits and current China tax expense due to certain non-deductible expenses.

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 March 31, 2024, the Company will maintain a full valuation allowance against its net deferred tax assets.

As of March 31, 2024, the Company had gross unrecognized tax benefits of $14,924. 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 $660 in the three months ended March 31, 2024 primarily due to U.S. federal and state tax credits and incentives.

9. Supplemental Balance Sheet Information

Prepaid expenses and other current assets consist of the following:

	As of	
	March 31, 2024	December 31, 2023
	$	$
Prepaid research and development costs	66,772	60,476
Prepaid manufacturing cost	42,225	42,066
Prepaid taxes	32,686	37,320
Other receivables	31,818	37,859
Short-term restricted cash	11,445	11,473
Prepaid insurance	7,899	8,872
Other current assets	38,896	56,799
Total	231,741	254,865

Other non-current assets consist of the following:

	As of	
	March 31, 2024	December 31, 2023
	$	$
Prepayment of property and equipment (1)	30,834	4,144
Prepaid supply cost	13,044	18,122
Prepaid VAT	2,756	2,546
Rental deposits and other	6,151	8,195
Long-term restricted cash	2,621	2,711
Long-term investments (Note 4)	143,615	89,644
Total	199,021	125,362

(1) Includes payment for acquired land use right in Shanghai, China that was being transitioned to the Company as of March 31, 2024 (See Note 6).

Accrued expenses and other payables consist of the following:

	As of	
	March 31, 2024	December 31, 2023
	$	$
Compensation related	114,657	217,803
External research and development activities related	99,009	162,969
Commercial activities	74,747	87,572
Individual income tax and other taxes	47,229	30,083
Sales rebates and returns related	186,277	139,936
Other	47,519	55,368
Total	569,438	693,731

Other long-term liabilities consist of the following:

	As of	
	March 31, 2024	December 31, 2023
	$	$
Deferred government grant income	32,939	34,204
Pension liability	14,428	14,995
Asset retirement obligation	1,108	1,127
Other	426	484
Total	48,901	50,810

10. Debt

The following table summarizes the Company's short-term and long-term debt obligations as of March 31, 2024 and December 31, 2023:

Lender	Agreement Date	Line of Credit	Term	Maturity Date	Interest Rate	As of March 31, 2024		As of December 31, 2023	
						$	RMB	$	RMB
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	13,850	100,000	14,089	100,000
China Merchants Bank	January 22, 2020	RMB350,000	9-year	January 20, 2029	(2)	8,706	62,857	8,856	62,857
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(3)	6,220	44,910	5,636	40,000
China Merchants Bank	July 28, 2023	$380,000	1-year	December 25, 2024	(4)	300,000	2,166,065	300,000	2,129,321
China Minsheng Bank	December 20, 2023	$150,000	1-year	December 19, 2024	7.3%	150,000	1,083,032	150,000	1,064,660
China Industrial Bank	March 21, 2024	RMB 675,000	364-day	March 27, 2025	(5)	93,488	675,000	—	—
China Merchants Bank	June 5, 2023	RMB 400,000	1-year	June 4, 2024	3.2%	55,400	400,000	56,356	400,000
HSBC Bank	May 4, 2023	RMB 340,000	1-year	May 3, 2024	(6)	47,090	340,000	47,903	340,000
China Industrial Bank	May 30, 2023	RMB 200,000	1-year	May 29, 2024	2.8%	27,699	200,000	28,177	200,000
Shanghai Pudong Development Bank	November 14, 2023	RMB 700,000	1-year	(7)	2.9%	96,950	700,000	49,312	350,000
Other short-term debt (8)						27,562	199,000	28,037	199,000
Total short-term debt						826,965	5,970,864	688,366	4,885,838
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	58,170	420,000	59,174	420,000
China Merchants Bank	January 22, 2020	RMB350,000	9-year	January 20, 2029	(2)	34,823	251,429	37,638	267,143
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(3)	39,554	285,590	42,337	300,500
China CITIC Bank	July 29, 2022	RMB480,000	10-year	July 28, 2032	(9)	66,480	480,000	58,469	415,000
Total long-term bank loans						199,027	1,437,019	197,618	1,402,643

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 March 31, 2024. 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 was in the process of substituting the land use right with the real estate interest in BeiGene Guangzhou Factory as collateral of the loan as of March 31, 2024.

2. The outstanding borrowings bear floating interest rates benchmarking against prevailing interest rates of certain PRC financial institutions. The loan interest rate was 4.1% as of March 31, 2024. The loan is secured by Guangzhou Factory's second land use right and certain fixed assets in the second phase of the Guangzhou manufacturing facility's build out. The Company repaid $2,189 (RMB15,714) during the three months ended March 31, 2024.

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 March 31, 2024. 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 $1,390 (RMB10,000) during the three months ended March 31, 2024.

4. The outstanding borrowings bear floating interest rates benchmarking the secured overnight financing rate. The loan interest rate was 7.2% as of March 31, 2024.

5. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 2.6% as of March 31, 2024.

6. The outstanding borrowings bear floating interest rates benchmarking Hong Kong interbank market rate for RMB. The loan interest rate was 5.2% as of March 31, 2024.

7. $48,475 (RMB350,000) of the outstanding borrowings matures on November 21, 2024 and March 19, 2025, respectively.

8. During the two years ended December 31, 2023, 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, 2024. The weighted average interest rate for the short-term working capital loans was approximately 3.2% as of March 31, 2024.

9. 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 $9,053 (RMB65,000) during the three months ended March 31, 2024. The weighted average loan interest rate was 3.9% as of March 31, 2024. The loan is secured by BeiGene Suzhou Co., Ltd.'s land use right and certain fixed assets that will be placed into service upon completion of the small molecule manufacturing campus in Suzhou, China.

The Company has numerous financial and non-financial covenants on its debt obligations with various banks and other lenders. Some of these covenants include cross-default provisions that could require acceleration of repayment of loans in the event of default. However, the Company's debt is primarily short-term in nature. Any acceleration would be a matter of months but may impact the Company's ability to refinance debt obligations if an event of default occurs. As of March 31, 2024, the Company was in compliance with all covenants of its material debt agreements.

Interest Expense

Interest expense recognized for the three months ended March 31, 2024 and 2023 was $12,404 and $4,574, respectively, among which, $9,209 and $344 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 U.S., China, and other regions, and tislelizumab in China; XGEVA®, BLINCYTO® and KYPROLIS® in China under a license from Amgen; and POBEVCY® in China under a license from Bio-Thera.

The table below presents the Company's net product sales for the three months ended March 31, 2024 and 2023.

	Three Months Ended March 31,	
	2024	2023
	$	$
Product revenue – gross	944,464	509,605
Less: Rebates and sales returns	(197,546)	(99,314)
Product revenue – net	746,918	410,291

The following table disaggregates net product sales by product for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	$	$
BRUKINSA®	488,515	211,382
Tislelizumab	145,277	114,850
XGEVA®	43,381	20,197
POBEVCY®	16,633	14,326
BLINCYTO®	14,366	10,946
KYPROLIS®	14,111	4,943
REVLIMID®	12,233	23,158
Other	12,402	10,489
Total product revenue – net	746,918	410,291

The following table presents the roll-forward of accrued sales rebates and returns for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	$	$
Balance at beginning of the period	139,936	41,817
Accrual	197,546	99,314
Payments	(151,205)	(62,399)
Balance at end of the period	186,277	78,732

12. Loss Per Share

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

	Three Months Ended March 31,	
	2024	2023
	$	$
Numerator:		
Net loss	(251,150)	(348,431)
Denominator:		
Weighted average shares outstanding for computing basic and diluted loss per share	1,355,547,626	1,354,164,760
Loss per share	(0.19)	(0.26)

For the three months ended March 31, 2024 and 2023, 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. 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.

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.

As of March 31, 2024, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,166,822. During the three months ended March 31, 2024, the Company granted options for 180,323 ordinary shares and restricted share units for 2,757,547 ordinary shares under the 2016 Plan. As of March 31, 2024, options and restricted share units for ordinary shares outstanding under the 2016 Plan totaled 60,637,471 and 65,397,709, respectively. As of March 31, 2024, share-based awards to acquire 36,894,454 ordinary shares were available for future grant under the 2016 Plan.

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 March 31, 2024, 919,678 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
February 29, 2024	1,021,397	$ 165.65	$ 12.74	$ 140.80	$ 10.83	$ 11,063
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

[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.

Share-Based Compensation Expense

The following table summarizes total share-based compensation expense recognized for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	$	$
Research and development	38,045	34,028
Selling, general and administrative	50,669	41,360
Total	88,714	75,388

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, 2023	(87,987)	35	(11,494)	(99,446)
Other comprehensive (loss) income before reclassifications	(32,163)	(35)	—	(32,198)
Net-current period other comprehensive (loss) income	(32,163)	(35)	—	(32,198)
Balance as of March 31, 2024	(120,150)	—	(11,494)	(131,644)

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, net in the consolidated statements of operations. The shares were constructively retired as of December 31, 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 March 31, 2024 and December 31, 2023, the net cash of the Company's PRC subsidiaries amounted to $1,660,848 and $1,837,790, respectively.

17. Commitments and Contingencies

Purchase Commitments

As of March 31, 2024, the Company had non-cancellable purchase commitments amounting to $93,511, of which $35,405 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $58,106 related to binding purchase obligations of inventory from Amgen. The Company does not have any minimum purchase requirements for inventory from Amgen.

Capital Commitments

The Company had capital commitments amounting to $61,577 for the acquisition of property, plant and equipment as of March 31, 2024, which were mainly for the Company's manufacturing and clinical R&D campus in Hopewell, New Jersey, additional capacity at the Guangzhou and Suzhou manufacturing facilities, and a 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 March 31, 2024, the Company's remaining co-development funding commitment was $457,031.

Funding Commitment

The Company had committed capital related to two equity method investments in the amount of $15,054. As of March 31, 2024, the remaining capital commitment was $8,905 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 U.S. and the PRC.

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

Total revenues by geographic area are presented as follows:

	Three Months Ended March 31,	
	2024	2023
	$	$
U.S. - total revenue	**351,456**	**164,483**
Product revenue	351,456	138,768
Collaboration revenue	—	25,715
China- total revenue	**320,376**	**247,681**
Product revenue	315,662	246,906
Collaboration revenue	4,714	775
Europe- total revenue	**66,860**	**30,521**
Product revenue	66,840	19,501
Collaboration revenue	20	11,020
Rest of world- total revenue	**12,960**	**5,116**
Product revenue	12,960	5,116
Collaboration revenue	—	—
Total Revenue	**751,652**	**447,801**

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, among other things, statements about: 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, including collaboration revenue, capital requirements and our need for additional financing; the potential benefits of strategic collaboration and licensing agreements and our ability to enter into and maintain strategic arrangements; our construction and operation of independent production facilities for small molecule medicines and large molecule biologics, as well as clinical R&D facilities, 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, 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. We do not assume any obligation to update any forward-looking statements where as a result of new information or otherwise, except as required by law. 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.

Non-GAAP Financial Measures

We provide certain financial measures that are not defined under accounting principles generally accepted in the United States of America ("GAAP"), commonly referred to as non-GAAP financial measures, including Adjusted Operating Expenses and Adjusted Income (Loss) from Operations and certain other non-GAAP measures, each of which include adjustments to GAAP figures. These non-GAAP measures are intended to provide additional information on our operating performance. Adjustments to our GAAP figures exclude, as applicable, non-cash items such as share-based compensation, depreciation and amortization. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. We maintain an established non-GAAP policy that guides the determination of what items may be excluded in non-GAAP financial measures. We believe that these non-GAAP measures, when considered together with the GAAP figures, can enhance an overall understanding of our operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of our historical and expected financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators BeiGene's management uses for planning and forecasting purposes and measuring our performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, GAAP financial measures. The non-GAAP financial measures used by BeiGene may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

Overview

BeiGene had another quarter of strong financial results. Supported by our tremendous global growth in revenue, we have now ascended into the top 15 of global oncology innovators based on total oncology sales. We also continue to make significant improvement in our operating leverage as we progress to sustainable profitability. We strengthened our hematology leadership with BRUKINSA, now the BTK inhibitor with the broadest label in the class, as we advance our innovative pipeline of therapies for hematologic malignancies. With TEVIMBRA now approved for use in the U.S. and Europe, we look forward to rapidly advancing our deep pipeline of solid tumor therapies to match our leadership in hematology and continue to solidify our reputation as a global oncology innovator.

Key highlights for the first quarter of 2024 are as follows:

- Total revenues of $752 million in the first quarter, including product revenue of $747 million, an 82% increase from the prior-year period;
- BRUKINSA revenue of $489 million, driven by growth in the U.S. and Europe of 153% and 243%, respectively, from the prior-year period; with recent fifth FDA approval, BRUKINSA now has the broadest label in the BTKi class;
- Rapidly advancing late-stage hematology pipeline; sonrotoclax in development both as a monotherapy and in combination with backbone therapy BRUKINSA; pivotal program initiated for BTK CDAC;
- Progressing potentially differentiated solid tumor programs with ADC, degrader platforms and targeted therapies in priority cancer types; and
- Significantly improved operating leverage and progress on path to sustainable profitability.

Recent Developments

Recent Business Developments

On April 23, 2024, we announced that the European Commission approved tislelizumab as a treatment for non-small cell lung cancer ("NSCLC") across three indications, including first- and second-line use.

On March 14, 2024, we announced that the U.S. Food and Drug Administration ("FDA") approved TEVIMBRA (tislelizumab-jsgr) as monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma ("ESCC") after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. TEVIMBRA will be available in the U.S. in the second half of 2024.

On March 13, 2024, together with The Max Foundation and the BeiGene Foundation, we announced that the first doses of BRUKINSA was administered for the treatment of adult patients with chronic lymphocytic leukemia ("CLL") to patients in Armenia and Nepal, as part of a three-year collaboration to provide access to the medicine in 29 low- and middle-income countries.

On March 7, 2024, we announced that the FDA granted accelerated approval to BRUKINSA (zanubrutinib) for the treatment of adult patients with relapsed or refractory ("R/R") follicular lymphoma ("FL"), in combination with the anti-CD20 monoclonal antibody obinutuzumab, after two or more lines of systemic therapy. The indication was approved under accelerated approval based on response rate and durability of response, marking BRUKINSA's fifth indication in B-cell malignancies in the U.S.

On February 29, 2024, we announced a new matching adjusted indirect comparison of the efficacy of BRUKINSA versus acalabrutinib in R/R CLL based on data from the Phase 3 ALPINE and Phase 3 ASCEND trials. The analysis suggests a progression-free survival and complete response advantage for BRUKINSA versus acalabrutinib, as well as potentially improved overall survival.

On February 27, 2024, we announced that the FDA accepted a Biologics License Application ("BLA") for TEVIMBRA (tislelizumab), in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction ("G/GEJ") adenocarcinoma. The FDA's action date on the BLA is expected in December 2024.

Results of Operations

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		Change	
	2024	2023	$	%
	(dollars in thousands)			
Revenues				
Product revenue, net	$ 746,918	$ 410,291	$ 336,627	82.0 %
Collaboration revenue	4,734	37,510	(32,776)	(87.4)%
Total revenues	751,652	447,801	303,851	67.9 %
Cost of sales - product	124,935	81,789	43,146	52.8 %
Gross profit	626,717	366,012	260,705	71.2 %
Operating expenses				
Research and development	460,638	408,584	52,054	12.7 %
Selling, general and administrative	427,427	328,499	98,928	30.1 %
Amortization of intangible assets	—	187	(187)	(100.0)%
Total operating expenses	888,065	737,270	150,795	20.5 %
Loss from operations	(261,348)	(371,258)	109,910	(29.6)%
Interest income, net	16,160	16,016	144	0.9 %
Other income, net	1,762	18,303	(16,541)	(90.4)%
Loss before income taxes	(243,426)	(336,939)	93,513	(27.8)%
Income tax expense	7,724	11,492	(3,768)	(32.8)%
Net loss	$ (251,150)	$ (348,431)	$ 97,281	(27.9)%

Comparison of the Three Months Ended March 31, 2024 and 2023

Revenue

Total revenue increased to $751.7 million for the three months ended March 31, 2024, from $447.8 million for the three months ended March 31, 2023, due to an increase in sales of BRUKINSA, tislelizumab, as well as our in-licensed products from Amgen, partially offset by a decrease in collaboration revenue. Collaboration revenue decreased due to termination of the Novartis collaborations in the prior year.

The following table summarizes the components of revenue for the three months ended March 31, 2024 and 2023, respectively:

	Three Months Ended March 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
Product revenue	$ 746,918	$ 410,291	$ 336,627	82.0 %
Collaboration revenue:				
Research and development service revenue	—	6,817	(6,817)	(100.0)%
Right to access intellectual property revenue	—	26,249	(26,249)	(100.0)%
Other	4,734	4,444	290	6.5 %
Total collaboration revenue	4,734	37,510	(32,776)	(87.4)%
Total Revenue	$ 751,652	$ 447,801	$ 303,851	67.9 %

Net product revenues consisted of the following:

	Three Months Ended March 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
BRUKINSA®	$ 488,515	$ 211,382	$ 277,133	131.1 %
Tislelizumab	145,277	114,850	30,427	26.5 %
XGEVA®	43,381	20,197	23,184	114.8 %
POBEVCY®	16,633	14,326	2,307	16.1 %
BLINCYTO®	14,366	10,946	3,420	31.2 %
KYPROLIS®	14,111	4,943	9,168	185.5 %
REVLIMID®	12,233	23,158	(10,925)	(47.2)%
Other	12,402	10,489	1,913	18.2 %
Total product revenue	$ 746,918	$ 410,291	$ 336,627	82.0 %

Net product revenue increased 82.0% to $746.9 million for the three months ended March 31, 2024, compared to $410.3 million in the prior-year period, primarily due to continued increases in sales of BRUKINSA globally, driven by significant growth in the U.S. and Europe. In addition, product revenues in the first quarter of 2024 were positively impacted by sales of tislelizumab and in-licensed products from Amgen in China.

Global sales of BRUKINSA totaled $488.5 million in the first quarter, representing a 131.1% increase compared to the prior-year period; U.S. sales of BRUKINSA totaled $351.5 million in the first quarter, compared to $138.8 million in the prior-year period, representing growth of 153.3%, as BRUKINSA gained share in treatment-naïve (TN) chronic lymphocytic leukemia (CLL), and emerged as the BTKi class leader in new-patient share in relapsed or refractory (R/R) CLL. BRUKINSA sales in Europe totaled $66.8 million in the first quarter, compared to $19.5 million in the prior-year period, representing growth of 242.8%, driven by continued gains in market share and additional reimbursements including France, which implemented reimbursement for BRUKINSA within CLL, Waldenström's macroglobulinemia (WM) and marginal zone lymphoma for the first time. BRUKINSA sales in China totaled $57.4 million, representing growth of 19.4%. BRUKINSA rest of world sales totaled $12.8 million in the first quarter, representing growth of 153.7% compared to the prior-year period.

Sales of tislelizumab in China totaled $145.2 million in the first quarter, compared to $114.9 million in the prior-year period, representing a 26.4% increase. In the first quarter, new patient demand from broader reimbursement and hospital listings continued to drive increased market penetration and market share for tislelizumab.

Collaboration revenue totaled $4.7 million for the three months ended March 31, 2024, primarily related to revenue generated under the Novartis broad markets marketing and promotion agreement. Collaboration revenue totaled $37.5 million for the three months ended March 31, 2023, of which $6.8 million was recognized from deferred revenue for R&D services performed during the three months ended March 31, 2023 under both the tislelizumab and ociperlimab collaborations, $26.2 million was recognized from deferred revenue for Novartis' right to access ociperlimab over the option period and $4.4 million was recognized related to the sale of tislelizumab and ociperlimab 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 $124.9 million for the three months ended March 31, 2024 from $81.8 million for the three months ended March 31, 2023, 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 $622.0 million for the three months ended March 31, 2024, compared to $328.5 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 83.3% for the three months ended March 31, 2024, from 80.1% in the comparable period of the prior year. The increase is primarily due to proportionally higher sales mix of global BRUKINSA compared to other products in the portfolio.

Research and Development Expense

Research and development expense increased by $52.1 million, or 12.7%, to $460.6 million for the three months ended March 31, 2024 from $408.6 million for the three months ended March 31, 2023. The following table summarizes external clinical, external non-clinical and internal research and development expense for the three months ended March 31, 2024 and 2023, respectively:

	Three Months Ended March 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 122,871	$ 128,596	$ (5,725)	(4.5)%
Upfront license and development milestone fees	35,028	—	35,028	NM
Amgen co-development expense[1]	13,484	17,817	(4,333)	(24.3)%
Total external research and development expenses	171,383	146,413	24,970	17.1 %
Internal research and development expenses	289,255	262,171	27,084	10.3 %
Total research and development expenses	$ 460,638	$ 408,584	$ 52,054	12.7 %
Adjusted research and development expenses[2]	$ 405,440	$ 361,696	$ 43,744	12.1 %

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended March 31, 2024 totaled $26.6 million, of which $13.5 million was recorded as R&D expense. The remaining $13.1 million was recorded as a reduction of the R&D cost share liability.

2. Adjusted research and development expense is intended to provide investors and others with information about our performance without the effect of items that, by their nature, tend to obscure core operating results due to potential variability across periods based on the timing, frequency and magnitude of such items. Refer to Non-GAAP Financial Measures and Non-GAAP Reconciliation in this MD&A for more information about, and a detailed reconciliation of, these items.

The increase in external research and development expenses in the first quarter was primarily attributable to higher development milestone fees, partially offset by a decrease in Amgen co-development expense and external clinical trial costs as we continue to internalize clinical trials.

Internal research and development expense increased $27.1 million, or 10.3%, to $289.3 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.

Selling, General and Administrative Expense

	Three Months Ended March 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
Selling, general and administrative expenses	$ 427,427	$ 328,499	$ 98,928	30.1 %
Adjusted selling, general and administrative expenses[1]	$ 372,146	$ 283,154	$ 88,992	31.4 %

1. Adjusted research and development expense is intended to provide investors and others with information about our performance without the effect of items that, by their nature, tend to obscure core operating results due to potential variability across periods based on the timing, frequency and magnitude of such items. Refer to Non-GAAP Financial Measures and Non-GAAP Reconciliation in this MD&A for more information about, and a detailed reconciliation of, these items.

Selling, general and administrative expense increased by $98.9 million, or 30.1%, to $427.4 million for the three months ended March 31, 2024, from $328.5 million for the three months ended March 31, 2023. The increase was primarily attributable to investing in the expansion of our commercial activities to support our product launches, primarily BRUKINSA in the U.S. and Europe to drive continued revenue and margin expansion. Selling, general and administrative expenses as a percentage of product sales were 57.2% in the first quarter of 2024 compared to 80.1% in the prior year period. We expect selling and marketing expenses to increase in 2024 as product sales increase and we expect selling, general and administrative expenses as a percentage of revenue to improve gradually throughout 2024.

Interest Income, Net

Interest income, net increased by $0.1 million, or 0.9%, to $16.2 million of net interest income for the three months ended March 31, 2024, from $16.0 million of net interest income for three months ended March 31, 2023. The increase in interest income, net, was primarily attributable to increased interest income resulting from higher interest rates on our cash balance and a decrease in interest expense as a result of higher interest capitalized related to Hopewell construction in process.

Other Income, Net

Other income, net was $1.8 million for the three months ended March 31, 2024, primarily due to the gain recognized on the divestiture of Pi Health, Inc. and government subsidy income in China, slightly offset by foreign exchange losses.

For the three months ended March 31, 2023, other income, net was $18.3 million, primarily due to government subsidy income in China.

Income Tax Expense

Income tax expense was $7.7 million for the three months ended March 31, 2024 as compared to $11.5 million for the three months ended March 31, 2023. We are anticipating a lower annual effective tax rate in 2024 due to the forecasted jurisdictional mix of consolidated pre-tax earnings, which is expected to increase in jurisdictions where we have tax attributes to offset current tax expense. The income tax expense for the three months ended March 31, 2024 and 2023 was primarily attributable to current U.S. tax expense determined after other special tax deductions and research and development tax credits and current China tax expense due to certain non-deductible expenses.

Non-GAAP Reconciliation

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Reconciliation of GAAP to adjusted cost of sales - products:		
GAAP cost of sales - products	$ 124,935	$ 81,789
Less: Depreciation	2,345	2,180
Less: Amortization of intangibles	1,183	799
Adjusted cost of sales - products	$ 121,407	$ 78,810
Reconciliation of GAAP to adjusted research and development:		
GAAP research and development	$ 460,638	$ 408,584
Less: Share-based compensation expenses	38,045	34,028
Less: Depreciation	17,153	12,860
Adjusted research and development	$ 405,440	$ 361,696
Reconciliation of GAAP to adjusted selling, general and administrative:		
GAAP selling, general and administrative	$ 427,427	$ 328,499
Less: Share-based compensation expenses	50,669	41,360
Less: Depreciation	4,612	3,985
Adjusted selling, general and administrative	$ 372,146	$ 283,154
Reconciliation of GAAP to adjusted operating expenses		
GAAP operating expenses	$ 888,065	$ 737,270
Less: Share-based compensation expenses	88,714	75,388
Less: Depreciation	21,765	16,845
Less: Amortization of intangibles	—	187
Adjusted operating expenses	$ 777,586	$ 644,850
Reconciliation of GAAP to adjusted loss from operations:		
GAAP loss from operations	$ (261,348)	$ (371,258)
Plus: Share-based compensation expenses	88,714	75,388
Plus: Depreciation	24,110	19,025
Plus: Amortization of intangibles	1,183	986
Adjusted loss from operations	$ (147,341)	$ (275,859)

Liquidity and Capital Resources

The following table represents our cash, short-term investments, and debt balances as of March 31, 2024 and December 31, 2023:

	As of	
	March 31, 2024	December 31, 2023
	(dollars in thousands)	
Cash, cash equivalents and restricted cash	$ 2,807,436	$ 3,185,984
Short-term investments	$ —	$ 2,600
Total debt	$ 1,025,992	$ 885,984

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 third quarter of 2023 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 a net loss of $251.2 million and $348.4 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $8.2 billion.

To date, we have financed our operations principally through proceeds from public and private offerings of our securities, proceeds from debt, sales of marketable securities and proceeds from our collaborations, together with product sales since September 2017. Based on our current operating plan, we expect that our existing cash and cash equivalents as of March 31, 2024 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. We have also financed our operations and investments with proceeds from debt incurred primarily from various banks both through our subsidiaries and BeiGene, Ltd. of $1.0 billion at March 31, 2024. The majority of those debt obligations, or approximately $827.0 million, owed by BeiGene, Ltd., have due dates within the next 12 months. We believe we will have sufficient cash and cash equivalents and other sources of capital to be able to repay and/or refinance those debt obligations.

On December 15, 2021, we completed our initial public offering on the STAR Market of the Shanghai Stock Exchange (the "STAR Offering"). The shares offered in the STAR Offering were issued to and subscribed for by permitted investors in the People's Republic of China ("PRC") in Renminbi ("RMB Shares"). The public offering price of the RMB Shares was RMB192.60 per ordinary share, or $391.68 per ADS. In this offering, we sold 115,055,260 ordinary shares. Net proceeds after deducting underwriting commissions and offering expenses were $3.4 billion (RMB 21.7 billion). As required by the PRC securities laws, the net proceeds from the STAR Offering must be used in compliance with the planned uses as disclosed in the PRC prospectus as well as our proceeds management policy for the STAR Offering approved by our board of directors. As of March 31, 2024, the Company had cash remaining related to the STAR Offering proceeds of $1.0 billion.

The following table provides information regarding our cash flows for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	(dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 3,185,984	$ 3,875,037
Net cash used in operating activities	(308,572)	(563,777)
Net cash (used in) provided by investing activities	(209,831)	241,063
Net cash provided by (used in) financing activities	162,293	(19,868)
Net effect of foreign exchange rate changes	(22,438)	11,311
Net decrease in cash, cash equivalents, and restricted cash	(378,548)	(331,271)
Cash, cash equivalents and restricted cash at end of period	$ 2,807,436	$ 3,543,766

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 $308.6 million of cash in the three months ended March 31, 2024, principally from our net loss of $251.2 million and an increase in our net operating assets and liabilities of $155.4 million, partially offset by non-cash charges of $97.9 million.

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

Operating activities used $563.8 million of cash in the three months ended March 31, 2023, principally from our net loss of $348.4 million and an increase in our net operating assets and liabilities of $294.1 million, partially offset by non-cash charges of $78.7 million.

The increase in working capital was driven largely by the seasonality of receivables and compensation-related payments. The non-cash charges were primarily driven by share-based compensation expense, depreciation and amortization expense, offset by amortization of the research and development cost share liability.

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 used $209.8 million of cash in the three months ended March 31, 2024, consisting of capital expenditures of $156.6 million, purchase of IPR&D assets of $31.8 million, purchase of intangible assets of $4.7 million, $19.4 million in purchases of long-term investments and other investing activities, partially offset by sales and maturities of investment securities of $2.7 million.

Investing activities provided $241.1 million of cash in the three months ended March 31, 2023, consisting of sales and maturities of investment securities of $377.0 million, partially offset by capital expenditures of $125.6 million, $10.3 million in purchases of long-term investments and other investing activities.

Financing Activities

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

Financing activities provided $162.3 million of cash in the three months ended March 31, 2024, consisting primarily of $9.1 million of net proceeds from long-term loans, $142.0 million of proceeds from short-term loans and $14.8 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 $3.6 million in repayments of long-term loans. Our borrowing and repayment cycle is dictated by the short-term maturities of our debt and the ability to increase our borrowings is dependent on interest rates, credit spreads, bank lending capacity and other factors. We expect to repay approximately $827.0 million of loans in the next 12 months and expect to be able to re-finance those on a consistent basis with our historical experience, with the cost of those borrowings depending on prevailing interest rates and credit spreads.

Financing activities used $19.9 million of cash in the three months ended March 31, 2023, consisting primarily of $1.5 million in repayment of long-term bank loans and $50.0 million in repayment of short-term bank loans, which were partially offset by $31.6 million from the exercise of employee share options and proceeds from the issuance of shares through our employee share purchase plan.

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 $22.4 million in the three months ended March 31, 2024, compared to a positive impact of $11.3 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 U.S. Securities and Exchange Commissions (“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 and product sales.

Contractual and Other Obligations

The following table summarizes our significant contractual obligations as of the payment due date by period as of March 31, 2024:

	Payments Due by Period		
	Total	Short Term	Long Term
	(dollars in thousands)		
Contractual obligations			
Operating lease commitments	$ 43,314	$ 18,390	$ 24,924
Purchase commitments	93,511	64,474	29,037
Debt obligations	1,025,992	826,965	199,027
Interest on debt	60,456	38,134	22,322
Co-development funding commitment	457,031	120,562	336,469
Funding commitment	8,905	2,213	6,692
Capital commitments	61,577	61,577	—
Total	$ 1,750,786	$ 1,132,315	$ 618,471

Operating Lease Commitments

We lease office facilities in the U.S. and Switzerland, and office and manufacturing facilities in China 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 March 31, 2024, non-cancellable purchase commitments amounted to $93.5 million, of which $35.4 million related to minimum purchase requirements for supply purchased from contract manufacturers and $58.1 million related to binding purchase obligations of inventory from Amgen. We do not have any minimum purchase requirements for inventory from Amgen.

Debt Obligations and Interest

Total debt obligations coming due in the next twelve months is $827.0 million. Total long-term debt obligations are $199.0 million. See Note 10 in the Notes to the Financial Statements for further detail of our debt obligations.

We have numerous financial and non-financial covenants on our debt obligations with various banks and other lenders. Some of these covenants include cross-default provisions that could require acceleration of repayment of loans in the event of default. However, our debt is primarily short-term in nature. Any acceleration would be a matter of months but may impact our ability to refinance debt obligations if an event of default occurs. As of March 31, 2024, we were in compliance with all covenants of our material debt agreements.

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 March 31, 2024, our remaining co-development funding commitment was $457.0 million.

Funding Commitment

Funding commitment represents our committed capital related to two equity method investments. As of March 31, 2024, our remaining capital commitment was $8.9 million and is expected to be paid from time to time over the investment period.

Capital Commitments

We had capital commitments amounting to $61.6 million for the acquisition of property, plant and equipment as of March 31, 2024, which were mainly for our manufacturing and clinical R&D campus in Hopewell, New Jersey, additional capacity at the Guangzhou and Suzhou manufacturing facilities, and a new building for Beijing Innerway Bio-tech Co., Ltd.

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 months ended March 31, 2024, as compared to those described in the section titled "Part I—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, 2023.

For new accounting policies adopted during the three months ended March 31, 2024, 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 Risk

We are exposed to risk related to changes in interest rates on our outstanding borrowings. We had $668.4 million of outstanding floating rate debt as of March 31, 2024. A 100-basis point increase in interest rates as of March 31, 2024 would increase our annual pre-tax interest expense by approximately $6.7 million.

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 1.7% in the three months ended March 31, 2024 and depreciated approximately 2.8% in the year ended December 31, 2023, 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 three months ended March 31, 2024.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation, required by paragraph (b) of Rules 13a-15 or 15d-15, promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act are effective, at a reasonable assurance level, as of March 31, 2024, to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in U.S. Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2024 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 I—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.

Pharmacyclics Litigation

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") that was later filed by BeiGene on November 1, 2023. On May 1, 2024, the USPTO granted BeiGene's PGR petition and is expected to issue a final decision on the validity of the '803 patent within 12 months.

ANDA Litigation

On March 8, 2024, the Company filed patent infringement suits under Hatch-Waxman Act against Sandoz Inc. ("Sandoz") and separately against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. (collectively "MSN") in the United States District Court for the District of New Jersey. The patent infringement suits are in response to Sandoz's and MSN's notices to the Company concerning the filings of Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA"), seeking FDA approval to market a generic version of BRUKINSA along with "Paragraph IV certifications" challenging certain BRUKINSA Orange Book patents for invalidity, unenforceability and/or non-infringement. According to the notices, neither Sandoz nor MSN have challenged BRUKINSA's composition of matter patent, which remains intact in protecting BRUKINSA from generic competition until its expiration in 2034.

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, 2023 (the "Annual Report").*

Summary of Risk Factors

Below is a summary of the material factors that make an investment in our 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 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 future 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 or are subject to unfavorable pricing regulations, our commercial success and business operations could be adversely affected.
- 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.
- We have incurred significant net losses since our inception and expect to incur net losses in the 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 comply with manufacturing regulations, provide us with insufficient quantities of product or provide product at unacceptable 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 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 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 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 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 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 recommending our medicines; 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, 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 ("U.S."), 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, 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 whether 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 future 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 and new studies may change the estimated incidence or prevalence of these cancers. 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 or are subject to unfavorable pricing regulations, 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 from government health administration authorities, private health insurers and other organizations. In the U.S. and 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, 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."

In the U.S., 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. Coverage may be more limited than the purposes for which the medicine is approved by the U.S. 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. 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.

In China, drug prices are typically lower than in the U.S. 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 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. Products included in the NRDL have typically been generic and essential drugs. BRUKINSA, tislelizumab, PARTRUVIX, 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.

The government in China also has a program for volume-based, centralized drug procurement with minimum quantity commitments to negotiate lower prices from drug manufacturers and reduce the price of drugs. The Chinese government awards contracts to the lowest bidders who can satisfy the quality and quantity requirements. The successful bidders are guaranteed a sale volume for at least a year, which gives an opportunity to gain or increase market share. 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 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. Also in 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. This 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.

Countries in Europe provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. 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. Furthermore, some countries require approval of the sale price of a medicine 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 medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine and negatively impact our revenues 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. 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 U.S. 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 have operations in the U.S., 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 U.S., 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:

- 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 U.S. 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;
- 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 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.

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, patient adherence to the dosing regimen 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.

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 clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to: regulators, institutional review boards, or ethics committees may not authorize us to conduct a clinical trial or may require us or our investigators to suspend or terminate clinical research or not rely on the results of our clinical research for various reasons, including noncompliance with regulatory requirements; our inability to reach agreements on acceptable terms with contract research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; manufacturing issues, including problems with supply quality, compliance with good manufacturing practice ("GMP"), or obtaining sufficient quantities of a drug candidate for use in a clinical trial; clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; the number of patients required for clinical trials 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 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; 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 or other materials necessary to conduct clinical trials 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 crises.

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 enroll in a trial being conducted by a competitor. 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 sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such 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.

We are currently focusing our pharmaceutical-industry activities in the major markets of the U.S., China, Europe, and other select countries and regions. These 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 that make for a more complex and costly regulatory compliance burden. 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 laws and regulations require the expenditure of substantial time and financial resources. Failure to comply with 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, in 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China previously supplied to us by BMS, and the drug was subsequently recalled by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the U.S. 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, 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 our approved products. 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."

In addition, the approval and commercialization for our medicines and drug candidates outside the U.S. subjects us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws. 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 Chinese authorities who recently increased 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 expect to 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 U.S., 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. If we submit an NDA or BLA to the FDA, we cannot be certain that a submission will be accepted for filing and review by the FDA.

Regulatory authorities outside of the U.S., 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 U.S. 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 are complex, costly, unpredictable and typically take many years following the commencement of preclinical studies and clinical trials and depend 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 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 allow time to review additional clinical data submitted by us, which was deemed a major amendment to the sNDA. Additionally, in 2022, the FDA deferred action on the BLA for tislelizumab as a second-line treatment for patients with unresectable or metastatic ESCC, citing only the inability to complete inspections due to COVID-19 related restrictions on travel.

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.

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.

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. 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 U.S. 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 U.S., 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, in 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China previously supplied to us by BMS, and the drug was subsequently recalled by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the U.S.

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. Failure to exhibit due diligence when conducting post-marketing requirements could result in withdrawal of approval for products. 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 U.S. 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 U.S. and China and certain approvals of tislelizumab, PARTRUVIX, 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. If we fail to conduct such studies in a timely manner or such studies fail to verify clinical benefit, such approval may be withdrawn. 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.

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 *"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 comply with manufacturing regulations, provide us with insufficient quantities of product or provide product at unacceptable quality levels or prices."*

Recently enacted and future legislation and regulations 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 U.S., 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."

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 expect to incur net losses in the 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 March 31, 2024 and December 31, 2023, we had an accumulated deficit of $8.2 billion and $8.0 billion, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative expenses associated with our operations.

We expect to continue to incur losses in the 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. In addition, we will continue to incur costs associated with operating as a public 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 $1.2 billion, $1.5 billion and $1.3 billion of net cash during the years ended December 31, 2023, 2022 and 2021, respectively, and used $308.6 million and $563.8 million of net cash during the three months ended March 31, 2024 and 2023, respectively. We recorded negative net cash flows from operating activities in 2023, 2022 and 2021 primarily due to our net losses of $0.9 billion, $2.0 billion and $1.5 billion, respectively. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future.

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 yet 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, 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.

Furthermore, our debt is primarily short-term in nature. As a result, we do not have many long-term commitments for funding. Our current debt also contains numerous financial and non-financial covenants, some of which include cross-default provisions that could require acceleration of repayment of loans in the event of default. Any acceleration may impact the Company’s ability to refinance debt obligations if an event of default occurs.

Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows and current debt structure, 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 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. Fluctuations in currencies may be affected by, among other things, changes in political and economic conditions and the foreign exchange policies proposed or adopted by certain governments. 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.

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. There is no guarantee that the federal government will 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 March 31, 2024, we had approximately $803.2 million invested in government money market funds and $42.9 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 $2.8 billion, $3.2 billion and $3.9 billion, restricted cash of $14.1 million, $14.2 million and $5.5 million and short-term investments of nil, $2.6 million and $665.3 million as of March 31, 2024, December 31, 2023 and 2022, respectively, most of which are deposited in financial institutions outside of China. As required by the PRC securities laws, the net proceeds from our offering on the STAR Market of the Shanghai Stock Exchange (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 unlikely to claim our deposits back in full.

As of December 31, 2023, our short-term investments consisted of U.S. Treasury securities, provided that as of March 31, 2024 we no longer held any U.S. Treasury securities. To the extent we invest in U.S. Treasury securities in the future, although we believe that such securities are of high credit quality and continually monitor the credit worthiness of these institutions, concerns about, or a default by, one institution in the U.S. market, could lead to significant liquidity problems, losses or defaults by other institutions, which in turn could adversely affect us.

Failure to meet ESG expectations or standards or achieve our ESG goals could adversely affect our business, results of operations, financial condition or stock price.

There has been an increased focus from regulators and stakeholders on environmental, social, and governance ("ESG") matters, including greenhouse gas emissions and climate-related risks; human capital management; diversity, equity, and inclusion; responsible sourcing and supply chain; human rights and social responsibility; and corporate governance and oversight. Given our commitment to ESG as part of our long-term strategy, we actively manage these issues and have established and publicly announced certain goals which we may refine in the future. These goals reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Evolving stakeholder expectations and our efforts and ability to manage these issues and accomplish our goals present numerous operational, regulatory, reputational, financial, legal, and other risks, any of which may be outside of our control or could have a material adverse impact on our business, including on our stock price. Further, there is uncertainty around the accounting standards and climate-related disclosures associated with emerging ESG laws and reporting requirements and the related costs to comply with the emerging regulations. Our failure or perceived failure to achieve our ESG goals or comply with ESG regulations could expose us to increased scrutiny from the investment community and enforcement authorities. Our reputation also may be harmed by the perceptions that our stakeholders have about our action or inaction on ESG-related issues.

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 valuable innovations including medicines, drug candidates and proprietary technologies by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect our innovations that we consider commercially important by filing patent applications in the U.S., the PRC, Europe and other territories, or relying on trade secrets or regulatory exclusivities.

However, filing, prosecuting and maintaining patents/patent applications on our medicines or drug candidates in all countries throughout the world could be prohibitively expensive. The patentability requirements across countries vary and the laws of different countries do not provide patent protection to pharmaceutical inventions to the same extent. Therefore, our patent applications may not be granted in all countries and the issued patents can have various scope and strength throughout the world. In addition, different countries may provide varying regulatory exclusivities to pharmaceutical drugs, and some countries provide no regulatory exclusivities. Consequently, we may not be able to have the same protection or exclusivities to our medicines or drug candidates in all countries throughout the world. Further, 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 length of exclusivities to our medicines or drug candidates. 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 be issued from our pending patent applications, we may no longer have exclusivities on the corresponding medicines or drug candidates.

Moreover, issued patents may be invalidated for a number of reasons, including known or unknown prior art, deficiencies in the patent applications or the lack of novelty or inventive step of the underlying invention or technology.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

****We have been and may further 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.***

Third parties may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. Litigation may be necessary to enforce or defend our intellectual property rights or to protect our trade secrets. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to challenge the validity or enforceability of our patents.

When a generic drug company files an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market a generic version of any of our products before the expiration of Orange Book listed patents ("OB Patents") covering such products, this will most likely trigger ANDA litigation. For example, on March 8, 2024, our subsidiaries, BeiGene USA, Inc. and BeiGene Switzerland GmbH, filed patent infringement suits against Sandoz Inc. ("Sandoz"), and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. (collectively "MSN"), in the United States District Court for the District of New Jersey, in response to Sandoz's and MSN's notices informing their filings of ANDAs with the FDA. For additional information on this litigation, please see the section of this Quarterly Report titled "Legal Proceedings". The success of ANDA litigation depends on the strength of the OB Patents and our ability to prove infringement. The outcome of ANDA litigation is inherently uncertain and may result in potential loss of market exclusivity for our products which may have a significant financial impact on product revenue.

Specifically, in patent litigation, defendants often challenge the validity and/or enforceability of the asserted patents, and there are numerous potential grounds upon which a patent can be found invalid and/or unenforceable. The validity of a patent can also be challenged before administrative bodies in the U.S. 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 of such proceedings is inherently uncertain and may result in losing the patent protection on our medicines or drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

Lawsuits claiming infringing of intellectual property rights of third parties could be costly and time consuming and could prevent or delay us from developing or commercializing our medicines or drug candidates.

We respect third parties' valid intellectual property rights and diligently manage any freedom to operate risks associated with our medicines and drug candidates. Nevertheless, we bear the risk that we may be sued by third parties for patent infringement. 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.

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, which could result in substantial upfront and/or royalty payment.

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

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. Our employees may also have access to trade secrets of our collaboration partners. 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.

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 comply with manufacturing regulations, provide us with insufficient quantities of product or provide product at unacceptable quality levels or prices.***

Although we manufacture commercial supply of tislelizumab, zanubrutinib, and pamiparib at our manufacturing facilities in China, and are progressing towards the completion of our 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.

Our 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;
- 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 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;

- manufacturers are subject to initial and ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the U.S. to ensure strict compliance with GMP requirements, chain of distribution 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, product liability claims, product seizure or recall and enforcement actions, including injunctions and criminal or civil prosecution;
- 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, in March 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China previously supplied to us by BMS, and the drug was subsequently recalled by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the U.S.

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.

For example, 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 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 certain territories, but that agreement was terminated in September 2023 and 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, terminated that agreement in July 2023 and regained full, global rights to develop, manufacture and commercialize ociperlimab.

Our strategic collaborations involve numerous risks. We may not achieve the revenue and cost synergies expected from our collaborations, 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. Additionally, strategic collaborations can be terminated for various reasons, including future acquisitions.

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 for our medicines and drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort. 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; 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 if we are unable to successfully integrate 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. 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 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 termination of AMG 510 from the Amgen 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 2023, we had approximately 9,000 employees, and we ended the year with close to 10,000 employees, an increase of over 10%. As of the date of this Quarterly Report, we had over 10,000 employees. 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 U.S., 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; and improving our operational, financial and management controls, reporting systems and procedures. 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.

Additionally, we are investing significant time, resources and capital into the expansion of our facilities, including the creation of additional capacity at our Guangzhou and Suzhou manufacturing facilities and the construction of our Hopewell facility. If actual demand for our medicines does not meet our future projections, we will likely incur increased costs related to idle capacity including, but not limited to, acceleration of the timing of depreciation or impairment charges, which may adversely affect our financial condition and results of operations.

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.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. 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.

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 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") applies to activities that involve sampling, biobanking, use of HGR materials and associated data, in China, and provision of such materials to non-PRC parties. The HGR Regulation prohibits both onshore or offshore entities established or actually controlled by non-PRC 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 non-PRC 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 non-PRC 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 and additional issued guidance has clarified many areas of the HGR Regulation. For information about applications under the HGR Regulation for clinical studies in China that may affect the Amgen collaboration, see the risk factor titled *"If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize."*

Additionally, the Cyberspace Administration of China ("CAC") released the final Measures of Cross-Border Data Transfer Security Assessment, effective as of September 2022, under which any transfer of certain "important data" out of China triggers 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. 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.

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 from initiating new clinical trials in China. So far, the HGR administration has disclosed a number of HGR violation cases.

To further enhance the administration of China HGR, in 2021, the Chinese government adopted amendments to the Criminal Code, 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 non-PRC parties or entities established or actually controlled by them without going through security review and assessment. Also in 2021, the PRC Biosecurity Law became effective, giving the Ministry of Science and Technology, China's major regulatory authority of HGR, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for Chinese HGR will continue to evolve and become even more rigorous. In addition, the interpretation and application of data protection laws in China 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 multiple manufacturing facilities in China. We are also constructing a commercial-stage biologics manufacturing and clinical R&D center in New Jersey, U.S., 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.

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 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, as well as shortages of qualified personnel, raw materials or key contractors.

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.

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. Furthermore, 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.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively restore our manufacturing capacity or restore 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 U.S., 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 Global Select 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, including applicable antitrust and trade regulation laws in the relevant U.S. and foreign jurisdictions in which we or the operations or assets we seek to acquire carry on business; 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 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"), have 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, under the Anti-Monopoly Law of the PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings issued by the State Council, a transaction by way of merger, acquisition or contractual arrangement that allow one market player to take control of or to exert decisive impact on another market player requires advanced notice to the State Administration for Market Regulation (the "SAMR") when such threshold is crossed and shall not be implemented without the clearance of prior notification. In addition, the Measures for Security Review of Foreign Investment and the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (the "Security Review Rules") 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 prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. 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. We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the U.S. under the jurisdiction of the Committee on Foreign Investment in the United States ("CFIUS") and other agencies, including the Foreign Investment Risk Review Modernization Act.

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. Furthermore, CFIUS, SAMR, MOFCOM, CSRC or other government agencies may make further determinations that increase the scrutiny of our future acquisitions in the U.S. or the PRC or prohibits such acquisitions. 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 U.S., 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, banking information of our vendors, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. 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 resulted 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 inadvertent 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 U.S., Europe, China, and many other jurisdictions where we operate, we are subject to laws and regulations that address privacy, personal information protection, use of artificial intelligence-based software and data security. 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 titled "*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 titled "*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 non-PRC 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. 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.

There remain uncertainties as to 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 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 actions taken by the Chinese government 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 fortified the facility to help prevent future interruptions. A significant disruption at our 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 crises 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 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 delays or other disruptions to required regulatory inspections of our development activities, regulatory filings, manufacturing operations, or clinical trial recruitment and progress. 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. Additionally, as seen in connection with the COVID-19 pandemic, public health crises may result in significant governmental measures being implemented to control the spread of a virus, including quarantines, travel restrictions, social distancing and business shutdowns. These measures may negatively affect our business by inducing absenteeism or employee turnover, disrupting our operations, increasing the risk of a cybersecurity incident, or other business disruptions outside of our control.

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 U.S., 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 U.S.; 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 U.S. 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 crises 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 U.S., 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 U.S. 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 U.S. or other governments. There is significant uncertainty about the future relationship between the U.S. and China with respect to trade policies, data sharing, 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 ("VIE") 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 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 VIE structures. 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 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. The interpretation and implementation of the Revised Confidentiality Provisions may continue to evolve.

Currently, these statements and regulatory actions have had no impact on our daily business operations or our ability to accept foreign investments and list our securities on a U.S. or other foreign exchange. However, it is highly uncertain how the legislative or administrative agencies will further interpret, modify or implement such laws and regulations, or if they will promulgate any new laws or regulations, and their potential impact 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.

Historically, there has been legislation implemented which put our ADSs at risk of potential delisting. 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, providing that if the SEC determines 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, U.S., as our independent registered public accounting firm for the audits of our financial statements and internal control over financial reporting commencing for the fiscal years ended December 31, 2022 and December 31, 2023. We believe that this satisfies the PCAOB inspection requirements for the audit of our consolidated financial statements prior to the two-year deadline of the AHFCAA. Given that Ernst and Young LLP (U.S.) has served as the principal accountant to audit our consolidated financial statements since 2022, we are compliant with the HFCAA and AHFCAA and can certify that we retained a registered public accounting firm that the PCAOB is able to inspect or investigate which would preclude any further finding by the SEC that we are a Commission-Identified Issuer and therefore the delisting of our ADSs from Nasdaq.

We may be subject to enforcement under 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 U.S., we are currently unable to predict the potential impact on our listing status by any rules that may be adopted by the SEC 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.

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 U.S. 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 the risk factor titled *"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."*

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.

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.

Numerous regulations, guidelines and other measures have been or are expected to be adopted in China under the umbrella of or in addition to the Cyber Security Law and Data Security Law. As the relevant regulations, guidelines and measures 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.

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. We may have to go through this filing process for any follow-on offerings we conduct on Nasdaq or Hong Kong Stock Exchange. 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 Nasdaq 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 Nasdaq 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 Nasdaq 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.

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 the risk factor titled "*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*." 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 January 2021, the Foreign Investment Security Review Measures promulgated by the NDRC and the MOFCOM came into effect. Pursuant to these 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, including the scope of key sectors. 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 March 31, 2024 and December 31, 2023, these restricted assets totaled $4.3 billion and $4.1 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).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 U.S.; 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 U.S., Hong Kong or Shanghai equity markets; changes in accounting principles; trade disputes or U.S.-China government relations; and changes or developments in the U.S., PRC, the EU or global regulatory environment.

In addition, the stock market, in general, and pharmaceutical and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, 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 Nasdaq in the U.S. 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 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 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 May 3, 2024, 1,359,524,369 ordinary shares, par value $0.0001 per share, were outstanding, of which 866,105,747 ordinary shares were held in the form of 66,623,519 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 9, 2023, registering 298,738,765 ordinary shares, including 222,835,028 ordinary shares in the form of 17,141,156 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 pursuant to its share purchase agreement. 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 and lead to increased compliance obligations and costs.

Our ADSs are traded on 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 U.S., 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 Nasdaq or our ordinary shares on the HKEx. Additionally, the listing and trading of our equity securities in multiple jurisdictions and multiple markets has resulted in 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.

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. Historically, we are aware of instances in which analysts have published inaccurate research about our business. 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 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 U.S. In particular, the Cayman Islands has a less developed body of securities law than Hong Kong, mainland China or the U.S. and less judicially interpreted body of corporate law than in Delaware.

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. Our directors have 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 U.S. 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 U.S. and a substantial portion of their assets are located outside of Hong Kong and the U.S. 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 U.S. in the event that shareholders believe that their rights have been infringed under the securities laws of Hong Kong, the U.S. 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 U.S., 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.

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 U.S. 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.

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 parties who bring actions or proceedings against us may 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 incur in connection with such claim, to the extent the claimant is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails.

The case law and potential legislative action on such fee-shifting articles are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such articles. 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, 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 it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs 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, under any provision of the deposit agreement 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 books or we have closed our 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 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 U.S. 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 distribute 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 distributions if it is unlawful or impractical. 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 registered or distributed pursuant to an exemption from registration. The depositary is not responsible for making a distribution available to 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. 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 53% of our outstanding ordinary shares as of May 3, 2024. 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, 2023. 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 U.S. 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 U.S. 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)

The following table describes for the quarterly period covered by this report each trading arrangement for the purchase or sale of Company securities adopted, modified or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement," or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K):

Name (*Title*)	**Action Taken (*Date of Action*)**	**Type of Trading Arrangement**	**Nature of Trading Arrangement**	**Duration of Trading Arrangement**	**Aggregate Number of Securities**
Chan Lee (Senior Vice President, General Counsel)	Modification (*February 28, 2024*)	Rule 10b5-1 trading arrangement	Sale	May 30, 2025	1,440 ADSs plus an additional number of ADSs subject to RSUs equal to the net number of shares resulting from applicable RSU vestings after sell-to-cover for withholding tax.

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†	Independent Director Compensation Policy, as amended		8-K (Exhibit 10.1)	3/20/2024	001-37686
10.2†	Consulting Agreement, dated January 23, 2024, by and between the Registrant and Thomas Malley	X			
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350	X			
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)	X			

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

SIGNATURES

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

BEIGENE, LTD.

Date: May 8, 2024

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

Date: May 8, 2024

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

Exhibit 10.2

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the "**Consulting Agreement**"), effective as of January 23, 2024, is entered into by BeiGene, Ltd., a Cayman Islands exempted company (the "**Company**"), and Thomas Malley (the "**Consultant**").

WHEREAS, the Company desires to retain the services of the Consultant and the Consultant desires to perform certain services for the Company on a consulting basis; and

WHEREAS, the Consultant is in the business of providing such services and has agreed to provide such services pursuant to the terms and conditions set forth in this Consulting Agreement.

NOW, THEREFORE in consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, the parties agree as follows:

1. Services to Be Performed. During the period starting on January 23, 2024 and ending on June 30, 2024, unless terminated earlier in accordance with the provisions of Section 4 below (the "**Consulting Period**"), the Consultant agrees to perform consulting and advisory services as may be reasonably requested by the Company from time to time, including but not limited to (i) providing strategic and corporate governance advice, and (ii) helping to facilitate the Company's relationship with the investment community (collectively, the "**Services**"). Consultant hereby agrees to devote his best efforts in the performance of the Services, including by making himself available to render the Services at such times and locations as the Consultant and the Company may mutually agree. The Consultant agrees to keep the Company updated, promptly upon the Company's request, of any progress, problems, and/or development of which the Consultant is aware regarding the Services. The Company shall have the right to require such updates in writing from the Consultant. The Consultant is responsible for providing the necessary equipment, tools, materials and supplies to perform the Services.

2. Independent Contractor Status. It is the express intention of the parties to this Consulting Agreement that the Consultant is an independent contractor and not an employee, agent, joint venturer or partner of the Company for any purposes whatsoever. The Consultant shall not be entitled to any benefits that the Company may make available to employees from time to time. The Consultant shall be solely responsible for all appropriate and/or necessary income taxes, withholding taxes, payroll contributions, unemployment insurance and social security taxes and for maintaining adequate workers' compensation insurance coverage for himself. Consultant shall assume and accept all responsibilities that are imposed on independent contractors by any statute, regulation, rule of law, or otherwise. Consultant is not the agent of Company and is not authorized and shall not have the power or authority to bind Company or incur any liability or obligation. While Company is entitled to provide Consultant with general guidance to assist Consultant in completing the scope of work to Company's satisfaction, Consultant is ultimately responsible for directing and controlling the performance of the task and the scope of work, in accordance with the terms and conditions of this Agreement. Consultant shall use its best efforts, energy and skill in its own name and in such manner as it sees fit. The Consultant retains the right to contract with other companies or entities for his services; provided, however, that such other engagements must not interfere with the Consultant's performance of the Services or violate the provision of the Confidentiality, Non-Solicitation and Assignment of Inventions Agreement by and between Consultant and the Company. Likewise, the Company retains a reciprocal right to contract with other companies and/or individuals for consulting services without restriction.

3. Compensation.

(a) In exchange for the full, prompt, and satisfactory performance of all Services to be rendered to the Company hereunder during the Consulting Period, the Company shall provide the Consultant the following compensation: (i) notwithstanding the terms of the BeiGene, Ltd. 2016 Share Option and Equity Incentive Plan and terms of the award agreement(s) thereunder, the share options granted by the Company to the Consultant on June 15, 2023 as a member of the Board of Directors of the Company shall continue to vest according to the original vesting schedule throughout the Consulting Period, and (ii) notwithstanding the terms of the BeiGene, Ltd. 2011 Option Plan and award agreement(s) thereunder, the exercise period of the vested options granted by the Company to the Consultant on January 25, 2016 as a member of the Board of Directors of the Company shall be extended to six months after January 22, 2024. Except as set forth above, all other unvested equity grants held by the Consultant that are not vested as of January 22, 2024 shall terminate immediately as of such date in accordance with the terms of the applicable equity plans. Consultant agrees that this will fully compensation him for all Consulting Services.

(b) The Company will reimburse the Consultant for reasonable and necessary out-of-pocket expenses incurred by him in connection with the performance of the Services hereunder; provided that the Consultant promptly provides and maintains a detailed expense account and receipts for such expenses. Additionally, any expenses in excess of $1,000 (aggregate per month) will need to be approved by the Company in writing prior to such cost being incurred.

4. Termination.

(a) The Company may, without prejudice to any right or remedy it may have due to any failure of the Consultant to perform his obligations under this Consulting Agreement, terminate the Consultation Period immediately upon thirty (30) days prior written notice to the Consultant. In the event of termination, the Consultant shall, upon request, perform such work as may be requested to transfer work in process to the Company or to a party designated by the Company.

(b) In the event of termination, the Consultant shall be entitled to payment for Services performed and/or expenses paid or incurred prior to the effective date of termination. Such payments shall constitute full settlement of any and all claims of the Consultant of every description against the Company.

(c) The Consultant expressly acknowledges that any termination of this Agreement will neither release nor discharge the Consultant from his obligations as specified in Sections 5, 7, 8 and 11 of this Agreement and his obligations under the attached Confidentiality, Non-Solicitation and Assignment of Inventions Agreement.

5. Restrictive Covenants. As a condition of his engagement with the Company, the Consultant shall be required to execute, and hereby agrees to execute, the attached Confidentiality, Non-Solicitation and Assignment of Inventions Agreement (the "**NDA**"), which is attached hereto as Exhibit A.

6. Other Agreements. The Consultant represents that his performance of all the terms of this Consulting Agreement and the performance of his duties as a consultant of the Company do not and will not breach any agreement with any third party to which the Consultant is a party (including without limitation any nondisclosure or non-competition agreement), and that the Consultant will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others, except for any confidential or proprietary information or material belonging to the Company which the Consultant used or accessed during his employment for the Company.

7. Return of Company Property. Upon termination of this Consulting Agreement or at any other time upon request by the Company, the Consultant shall promptly deliver to the Company all records, files, memoranda, notes, designs, data, reports, price lists, customer lists, drawings, plans, computer programs, software, software documentation, sketches, laboratory and research notebooks and other documents (and all copies or reproductions of such materials) in his possession, custody or control relating in any way to the business or prospective business of the Company.

8. Cooperation. The Consultant shall use his best efforts in the performance of his obligations under this Consulting Agreement. The Company shall provide such access to its information and property as may be reasonably required in order to permit the Consultant to perform his obligations hereunder. The Consultant shall cooperate with the Company's personnel, shall not interfere with the conduct of the Company's business and shall observe all rules, regulations and security requirements of the Company concerning the safety of persons and property.

9. Non-Assignability of Contract by Consultant. This Consulting Agreement is personal to the Consultant and he shall not have the right to assign any of his rights or delegate any of his duties without the express written consent of the Company; *provided*, that in the event that the Consultant establishes a partnership, corporation or other entity, one purpose of which is to provide the Consulting Services, the consultant may assign this Consulting Agreement to such partnership, corporation or other business entity with the advance written consent of the Company. Any non-consented-to assignment or delegation, whether express or implied or by operation of law, shall be void and shall constitute a breach and a default by the Consultant.

10. Assignment by the Company. This Agreement shall be binding upon and inure to the benefit of the Company's successors and assigns, including any corporation with which, or into which, the Company may be merged, or which may succeed to the Company's assets or business. Accordingly, this Agreement may be assigned by the Company to a person or entity which is an affiliate of the Company or a successor in interest to substantially all of the business operations of the Company.

11. Complete Agreement. This Consulting Agreement contains the entire understanding between the parties and supersedes, replaces and takes precedence over any prior understanding or oral or written agreement between the parties respecting the subject matter of this Consulting Agreement. There are no representations, agreements, arrangements, nor understandings, oral or written, between the parties relating to the subject matter of this Consulting Agreement that are not fully expressed herein.

12. Severability. In the event any provision of this Consulting Agreement shall be held invalid, the same shall not invalidate or otherwise affect in any respect any other term or terms of this Consulting Agreement, which term or terms shall remain in full force and effect.

13. Non-Waiver. No delay or omission by the Company in exercising any right under this Consulting Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar or waiver of any right on any other occasion.

14. Amendment. This Consulting Agreement may be amended or modified only by a written instrument executed by both the Company and the Consultant.

15. Counterparts. This Consulting Agreement may be executed in two (2) signed counterparts, each of which shall constitute an original, but all of which taken together shall constitute one and the same instrument.

16. Defend Trade Secrets Act of 2016; Other Notices. It is understood that pursuant to the federal Defend Trade Secrets Act of 2016, the Consultant will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. It is further understood that nothing contained in this Consulting Agreement limits the Consultant's ability to (1) communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company, or (2) share compensation information concerning the Consultant or others, except that this does not permit the Consultant to disclose compensation information concerning others that the Consultant obtains because his responsibilities require or allow access to such information.

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

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IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the day and year set forth above.

BEIGENE, LTD.

By: /s/ JOHN V. OYLER Date: January 23, 2024

Name: John V. Oyler
Title: Chairman & CEO

THOMAS MALLEY
/s/ THOMAS MALLEY Date: January 23, 2024

EXHIBIT A

CONFIDENTIALITY, NON-SOLICITATION AND ASSIGNMENT OF INVENTIONS AGREEMENT

BEIGENE, LTD.

Effective as of January 23, 2024

Thomas Malley

Dear Mr. Malley:

This letter is to confirm our understanding with respect to (i) your agreement to protect and preserve information and property which is confidential and proprietary to BeiGene, Ltd. or any present or future parent, subsidiary or affiliate thereof (collectively, the "**Company**"), (ii) certain restrictions on competition and solicitation of employees or consultants of the Company, and (iii) your agreement with respect to the ownership of inventions, ideas, copyrights and patents which may be used in the business of the Company (the terms and conditions agreed to in this letter are hereinafter referred to as the "**Agreement**").

In consideration of and as a condition of the compensation and other benefits of my engagement by the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby mutually acknowledged, we have agreed as follows:

1. Certain Acknowledgements and Agreements.

(i) We have discussed, and you recognize and acknowledge the competitive and proprietary aspects of the business of the Company.

(ii) You understand and acknowledge that the Company will be engaged in the research, development, manufacture, licensing or use of potential drugs directed against specific targets (such as genes, proteins, enzymes or other biological molecules) selected by the Company ("**Company Targets**"), including without limitation chemistry, pre-clinical studies, bio-marker discovery and clinical studies. You acknowledge that the Company will be free to select Company Targets in its sole discretion, and that the business of the Company may change over the course of your engagement and that this Agreement shall remain in full force and effect and shall apply to the Company's business and Company Targets as they exist at any time during your engagement.

(iii) You further acknowledge that, during the course of your performing services for the Company, the Company will furnish, disclose or make available to you Confidential Information (as defined below) related to the Company's business. You also acknowledge that such Confidential Information have been developed and will be developed by the Company through the expenditure by the Company of substantial time, effort and money and that all such Confidential Information could be used by you to compete with the Company. You also acknowledge that if you become employed or affiliated with any competitor of the Company in violation of your obligations in this Agreement, it is inevitable that you would disclose the Confidential Information to such competitor and would use such Confidential Information, knowingly or unknowingly, on behalf of such competitor. Further, in the course of your engagement, you will be introduced to customers and others with important relationships to the Company. You acknowledge that any and all "goodwill" created through such introductions belongs exclusively to the Company, including, without limitation, any goodwill created as a result of direct or indirect contacts or relationships between you and any customers of the Company.

(iv) For purposes of this Agreement, "**Confidential Information**" means non-public, confidential and proprietary information of the Company that the Company takes reasonable efforts to maintain as confidential, whether in written, oral, electronic or other form, including but not limited to, information and facts concerning business plans, customers, future customers, suppliers, licensors, licensees, partners, investors, affiliates or others, training methods and materials, financial information, sales prospects, client lists, inventions, or any scientific, technical or trade secrets of the Company or of any third party provided to you or the Company under a condition of confidentiality, provided that Confidential Information will not include information that is in the public domain other than through any fault or act by you. The term "trade secrets," as used in this Agreement, will be given its broadest possible interpretation and will include, without limitation, anything tangible or intangible or electronically kept or stored, which constitutes, represents, evidences or records or any secret scientific, technical, merchandising, production or management information, or any design, process, procedure, formula, invention, improvement or other confidential or proprietary information or documents, which is non-public and the Company takes reasonable efforts to maintain as confidential.

2. Non-Competition. During the Consulting Period (as defined in the Consulting Agreement by and between you and the Company), you shall not, without the prior written consent of the Company, for yourself or on behalf of any other, either as principal, agent, stockholder, employee, consultant, representative or in any other capacity, own, manage, operate or control, or be connected or employed by, or otherwise associate in any manner with, engage in or have a financial interest in any business anywhere in the world that is engaged in the research, development, manufacture, licensing or use of potential drugs directed against any Company Target, or in any other business in which you have any direct operating or scientific responsibility relating to the research, development, manufacture, licensing or use of potential drugs directed against any Company Target, except that nothing contained herein shall preclude you from: (a) purchasing or owning stock in any such competitive business if your holdings do not exceed three percent (3%) of the issued and outstanding capital stock of such business, or (b) serving on the Board of Directors of a publicly traded company.

3. Non-Solicitation. During the Consulting Period (as defined in the Consulting Agreement by and between you and the Company), you will not, without the prior written consent of the Company:

(i) Either individually or on behalf of or through any third party, directly or indirectly, (A) solicit, entice or persuade or attempt to solicit, entice or persuade any employee of or consultant to the Company to leave the services of the Company or any parent, subsidiary or affiliate of the Company for any reason, or (B) employ, cause to be employed, or solicit the employment of any employee of or consultant to the Company while any such person is providing services to the Company or within six months after any such person ceases providing services to the Company; or

(ii) Either individually or on behalf of or through any third party, directly or indirectly, interfere, with or attempt to interfere with, the relations between any employee of, or consultant to, the Company or any parent, subsidiary or affiliate the Company.

4. Reasonableness of Restrictions. You further recognize and acknowledge that (i) the types of employment and activities which are prohibited by Section 2 and Section 3 are narrow and reasonable in relation to the skills which represent your principal salable asset both to the Company and to your other prospective employers and (ii) the specific but broad geographical scope of the provisions of Section 2 is reasonable, legitimate and fair to you in light of the global nature of research and development activities for the development of drugs and in light of the limited restrictions on the type of employment prohibited herein compared to the types of employment for which you are qualified to earn your livelihood.

5. Protected Information. You will at all times, both during the period while you are performing services for the Company and after the termination of your provision of services to the Company for any reason or for no reason, maintain in confidence and will not, without the prior written consent of the Company, use, except in the course of performance of your duties for the Company or by court order, disclose or give to others any Confidential Information. In the event you are questioned by anyone not employed by the Company or by an employee of or a consultant to the Company not authorized to receive Confidential Information, in regard to any Confidential Information, or concerning any fact or circumstance relating thereto, you will promptly notify the Company. Upon the termination of your provision of services to the Company for any reason or for no reason, or if the Company otherwise requests, (i) you will return to the Company all tangible Confidential Information and copies thereof (regardless how such Confidential Information or copies are maintained) and (ii) you will deliver to the Company any property of the Company which may be in your possession, including products, materials, memoranda, notes, records, reports, or other documents or photocopies of the same. The terms of this Section 5 are in addition to, and not in lieu of, any statutory or other contractual or legal obligation that you may have relating to the protection of the Company's Confidential Information. The terms of this Section 5 will survive indefinitely any termination of your provision of services to the Company for any reason or for no reason.

6. Ownership of Ideas, Copyrights and Patents.

(a) Property of the Company. All ideas, discoveries, creations, manuscripts and properties, innovations, improvements, know-how, inventions, designs, developments, apparatus, techniques, methods, laboratory notebooks and formulae (collectively the "**Inventions**") which may be used or useful in the business of the Company, whether patentable, copyrightable or not, which you may conceive, reduce to practice or develop during the period while you are performing services for the Company and for one (1) year thereafter, alone or in conjunction with another or others, whether during or out of regular business hours, whether or not on the Company's premises or with the use of its equipment, and whether at the request or upon the suggestion of the Company or otherwise, will be the sole and exclusive property of the Company, and that you will not publish any of the Inventions without the prior written consent of the Company or its designee. Without limiting the foregoing, you also acknowledge that all original works of authorship which are made by you (solely or jointly with others) within the scope of your engagement or which relate to the business of the Company or a Company affiliate and which are protectable by copyright are "works made for hire" pursuant to the United States Copyright Act (17 U.S.C. Section 101). You hereby assign to the Company or its designee all of your right, title and interest in and to all of the foregoing. You further represent that, to the best of your knowledge and belief, none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights of any person, firm or corporation, and that you will use your best efforts to prevent any such violation.

(b) Cooperation. At any time during or after the period during which you are performing services for the Company, you will fully cooperate with the Company and its attorneys and agents in the preparation and filing of all papers and other documents as may be required to perfect the Company's rights in and to any of such Inventions, including, but not limited to, joining in any proceeding to obtain letters patent, copyrights, trademarks or other legal rights with respect to any such Inventions in the United States and in any and all other countries, provided that the Company will bear the expense of such proceedings, and that any patent or other legal right so issued to you personally will be assigned by you to the Company or its designee without charge by you.

(c) Licensing and Use of Innovations. With respect to any Inventions, and work of any similar nature (from any source), whenever created, which you have not prepared or originated in the performance of your engagement, but which you provide to the Company or incorporate in any Company product or system, you hereby grant to the Company a royalty-free, fully paid-up, non-exclusive, perpetual and irrevocable license throughout the world to use, modify, create derivative works from, disclose, publish, translate, reproduce, deliver, perform, dispose of, and to authorize others so to do, all such Inventions. You will not include in any Inventions you deliver to the Company or use on its behalf, without the prior written approval of the Company, any material which is or will be patented, copyrighted or trademarked by you or others unless you provide the Company with the written permission of the holder of any patent, copyright or trademark owner for the Company to use such material in a manner consistent with then-current Company policy.

(d) Prior Inventions. Listed on Exhibit 4(d) to this Agreement are any and all Inventions in which you claim or intend to claim any right, title and interest (collectively, "Prior Inventions"), including, without limitation, patent, copyright and trademark interests, which to the best of your knowledge will be or may be delivered to the Company in the course of your engagement, or incorporated into any Company product or system. You acknowledge that your obligation to disclose such information is ongoing during the period that you provide services to the Company.

(e) Prior Obligations. The Company acknowledges that you have prior and ongoing obligations to the National Institute for Biological Sciences ("NIBS"). Nothing in the Agreement shall conflict with, or is intended to conflict with, your obligations to NIBS. To the extent that you believe your provisions of services to the Company creates a conflict with your obligations to NIBS, you agree to notify the Company and the parties will work in good faith toward a resolution of the conflict.

7. Disclosure to Future Employers. You agree that during the Consulting Period you will provide, and that the Company, in its discretion, may similarly provide, a copy of the covenants contained in Sections 2, 3, 5 and 6 of this Agreement to any business or enterprise which you may directly or indirectly own, manage, operate, finance, join, control or in which you may participate in the ownership, management, operation, financing, or control, or with which you may be connected as an officer, director, employee, partner, principal, agent, representative, consultant or otherwise.

8. No Conflicting Agreements. You hereby represent and warrant that you have no commitments or obligations inconsistent with this Agreement and you will indemnify and hold the Company harmless against loss, damage, liability or expense arising from any claim based upon circumstances alleged to be inconsistent with such representation and warranty.

9. Name & Likeness Rights. You hereby authorize the Company to use, reuse, and to grant others the right to use and reuse, your name, photograph, likeness (including caricature), voice, and biographical information, and any reproduction or simulation thereof, in any form of media or technology now known or hereafter developed (including, but not limited to, film, video and digital or other electronic media), both during and after your engagement, for whatever purposes the Company deems necessary.

10. General.

(a) Notices. All notices, requests, consents and other communications hereunder will be in writing, will be addressed to the receiving party's address set forth above or to such other address as a party may designate by notice hereunder, and will be either (i) delivered by hand, (ii) sent by overnight courier, or (iii) sent by registered mail, return receipt requested, postage prepaid. All notices, requests, consents and other communications hereunder will be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving party at the address of such party set forth above, (ii) if sent by overnight courier, on the next business day following the day such notice is delivered to the courier service, or (iii) if sent by registered mail, on the fifth business day following the day such mailing is made.

(b) Entire Agreement. This Agreement and the Consulting Agreement embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement will affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

(c) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.

(d) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent will be deemed to be or will constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent will be effective only in the specific instance and for the purpose for which it was given, and will not constitute a continuing waiver or consent.

(e) Assignment. The Company may assign its rights and obligations hereunder in connection with a merger or consolidation or to any person or entity that succeeds to all or substantially all of the Company's business or that aspect of the Company's business in which you are principally involved. You may not assign your rights and obligations under this Agreement without the prior written consent of the Company and any such attempted assignment by you without the prior written consent of the Company will be void.

(f) Benefit. All statements, representations, warranties, covenants and agreements in this Agreement will be binding on the parties hereto and will inure to the benefit of the respective successors and permitted assigns of each party hereto. Nothing in this Agreement will be construed to create any rights or obligations except between the Company and you, and no person or entity other than the Company will be regarded as a third-party beneficiary of this Agreement.

(g) Governing Law. This Agreement and the rights and obligations of the parties hereunder will be construed in accordance with and governed by the law of the State of Delaware, U.S., without giving effect to the conflict of law principles thereof.

(h) Jurisdiction, Venue and Service of Process. Any legal action or proceeding with respect to this Agreement will be brought in the courts of Federal or State courts in the State of Delaware. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts.

(i) WAIVER OF JURY TRIAL. ANY ACTION, DEMAND, CLAIM OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT WILL BE RESOLVED BY A JUDGE ALONE AND EACH OF THE COMPANY AND YOU WAIVE ANY RIGHT TO A JURY TRIAL THEREOF.

(j) Severability. The parties intend this Agreement to be enforced as written. However, (i) if any portion or provision of this Agreement is to any extent declared illegal or unenforceable by a duly authorized court having jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, will not be affected thereby, and each portion and provision of this Agreement will be valid and enforceable to the fullest extent permitted by law and (ii) if any provision, or part thereof, is held to be unenforceable because of the duration of such provision or the geographic area covered thereby, the court making such determination will have the power to reduce the duration and/or geographic area of such provision, and/or to delete specific words and phrases ("blue-penciling"), and in its reduced or blue-penciled form such provision will then be enforceable and will be enforced.

(k) Headings and Captions. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and will in no way modify or affect the meaning or construction of any of the terms or provisions hereof.

(l) Injunctive Relief. You hereby expressly acknowledge that any breach or threatened breach of any of the terms and/or conditions set forth in Section 2, 3, 5 or 6 of this Agreement will result in substantial, continuing and irreparable injury to the Company. Therefore, in addition to any other remedy that may be available to the Company, the Company will be entitled to injunctive or other equitable relief by a court of appropriate jurisdiction in the event of any breach or threatened breach of the terms of Section 2, 3, 5 or 6 of this Agreement.

(m) No Waiver of Rights, Powers and Remedies. No failure or delay by a party hereto in exercising any right, power or remedy under this Agreement, and no course of dealing between the parties hereto, will operate as a waiver of any such right, power or remedy of the party. No single or partial exercise of any right, power or remedy under this Agreement by a party hereto, nor any abandonment or discontinuance of steps to enforce any such right, power or remedy, will preclude such party from any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The election of any remedy by a party hereto will not constitute a waiver of the right of such party to pursue other available remedies. No notice to or demand on a party not expressly required under this Agreement will entitle the party receiving such notice or demand to any other or further notice or demand in similar or other circumstances or constitute a waiver of the rights of the party giving such notice or demand to any other or further action in any circumstances without such notice or demand.

(n) Counterparts. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

(o) Opportunity to Review. You hereby acknowledge that you have had adequate opportunity to review these terms and conditions and to reflect upon and consider the terms and conditions of this Agreement, and that you have had the opportunity to consult with counsel of your own choosing regarding such terms. You further acknowledge that you fully understand the terms of this Agreement and have voluntarily executed this Agreement.

(p) Survival of Acknowledgements and Agreements. Your acknowledgements and agreements set forth in this Agreement will survive the termination of your provision of services to the Company for any reason or for no reason.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

If the foregoing accurately sets forth our agreement, please so indicate by signing and returning to us the enclosed copy of this letter.

Very truly yours,

BEIGENE, LTD.

By: /s/ JOHN V. OYLER
Name: John V. Oyler
Title: Chairman & CEO

Accepted and Approved:

/s/ THOMAS MALLEY
Print Name: Thomas Malley

January 23, 2024
Date

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, John V. Oyler, certify that:

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

Date: May 8, 2024

/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: May 8, 2024

/s/ JULIA WANG

Julia Wang
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

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

The Quarterly Report on Form 10-Q for the three months ended March 31, 2024 (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: May 8, 2024

/s/ JOHN V. OYLER

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

Date: May 8, 2024

/s/ JULIA WANG

Julia Wang
Chief Financial Officer
(Principal Financial Officer)