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BeOne Medicines Ltd.
百濟神州有限公司
(a corporation incorporated under the laws of Switzerland)
(Stock Code: 06160)

OVERSEAS REGULATORY ANNOUNCEMENT – FORM 10-Q

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

Please refer to the attached for the document which has been published by BeOne Medicines Ltd. on the website of the U.S. Securities and Exchange Commission on August 6, 2025.

By order of the Board
BeOne Medicines Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, August 6, 2025

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

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2025

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

BEONE MEDICINES LTD.

(Exact name of registrant as specified in its charter)

Switzerland	**98-1209416**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
c/o BeOne Medicines I GmbH **Aeschengraben 27** **Basel, Switzerland**	**4051**
(Address of principal executive offices)	(Zip Code)

+41 61 685 19 00

(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	**ONC**	**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 August 1, 2025, 1,430,372,987 ordinary shares, par value $0.0001 per share, were outstanding, of which 709,335,614 ordinary shares were held in the form of 54,564,278 American Depositary Shares, each representing 13 ordinary shares, and 115,055,260 were RMB shares which are ordinary shares issued to permitted investors in China and listed on the Science and Technology Innovation Board of the Shanghai Stock Exchange in Renminbi.

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 ☒

BeOne Medicines Ltd.

Quarterly Report on Form 10-Q

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From time to time, we may use our website, our X (formerly known as Twitter) account at x.com/BeOneMedicines, our LinkedIn account at linkedin.com/company/BeOneMedicines, our Facebook account at facebook.com/BeOneMedicines, and our Instagram account at instagram.com/BeOneMedicines to disclose material information and to comply with our disclosure obligations under Regulation FD. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.beonemedicines.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our X (formerly known as Twitter) posts, our LinkedIn posts and our Instagram posts are not incorporated into, and does not form a part of, this Quarterly Report.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	Note	Three Months Ended June 30,		Six Months Ended June 30,	
		2025	2024	2025	2024
		$	$	$	$
Revenues					
Product revenue, net	11	1,302,076	921,146	2,410,606	1,668,064
Collaboration revenue	3	13,224	8,020	21,973	12,754
Total revenues		1,315,300	929,166	2,432,579	1,680,818
Cost of sales - product		164,606	138,132	329,608	263,067
Gross profit		1,150,694	791,034	2,102,971	1,417,751
Operating expenses					
Research and development		524,896	454,466	1,006,783	915,104
Selling, general and administrative		537,913	443,729	997,201	871,156
Total operating expenses		1,062,809	898,195	2,003,984	1,786,260
Income (loss) from operations		87,885	(107,161)	98,987	(368,509)
Interest income, net		3,497	13,225	9,345	29,385
Other income (expense), net		8,167	(11,984)	12,117	(10,222)
Income (loss) before income taxes		99,549	(105,920)	120,449	(349,346)
Income tax expense	8	5,229	14,485	24,859	22,209
Net income (loss)		94,320	(120,405)	95,590	(371,555)
Earnings (loss) per share					
Basic	12	0.07	(0.09)	0.07	(0.27)
Diluted	12	0.06	(0.09)	0.07	(0.27)
Weighted-average shares outstanding—basic		1,408,166,754	1,361,082,567	1,399,159,898	1,358,315,145
Weighted-average shares outstanding—diluted		1,463,277,401	1,361,082,567	1,454,296,475	1,358,315,145
Earnings (loss) per American Depositary Share ("ADS")					
Basic	12	0.87	(1.15)	0.89	(3.56)
Diluted	12	0.84	(1.15)	0.85	(3.56)
Weighted-average ADSs outstanding—basic		108,320,520	104,698,659	107,627,684	104,485,780
Weighted-average ADSs outstanding—diluted		112,559,800	104,698,659	111,868,960	104,485,780

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

BEONE MEDICINES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Amounts in thousands of U.S. Dollars ("$"))

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Net income (loss)	94,320	(120,405)	95,590	(371,555)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	28,547	(9,236)	34,988	(41,399)
Other adjustments	76	406	302	371
Comprehensive income (loss)	122,943	(129,235)	130,880	(412,583)

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

BEONE MEDICINES LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	As of June 30, 2025	As of December 31, 2024
		$ (unaudited)	$ (audited)
Assets			
Current assets:			
Cash and cash equivalents		2,756,056	2,627,410
Accounts receivable, net		770,776	676,278
Inventories, net	5	502,867	494,986
Prepaid expenses and other current assets	9	280,522	192,919
Total current assets		4,310,221	3,991,593
Property, plant and equipment, net	6	1,615,792	1,578,423
Operating lease right-of-use assets		145,769	139,309
Intangible assets, net	7	64,890	51,095
Other non-current assets	9	161,722	160,490
Total non-current assets		1,988,173	1,929,317
Total assets		6,298,394	5,920,910
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		360,783	404,997
Accrued expenses and other payables	9	908,882	803,713
Tax payable	8	5,536	25,930
Operating lease liabilities, current portion		17,250	17,576
Research and development cost share liability, current portion	3	108,992	111,154
Short-term debt	10	808,394	851,529
Total current liabilities		2,209,837	2,214,899
Non-current liabilities:			
Long-term debt	10	146,091	166,484
Operating lease liabilities, non-current portion		53,940	44,277
Deferred tax liabilities	8	44,093	42,007
Research and development cost share liability, non-current portion	3	10,879	54,286
Other long-term liabilities	9	63,079	66,735
Total non-current liabilities		318,082	373,789
Total liabilities		2,527,919	2,588,688
Commitments and contingencies	16		
Shareholders' equity:			
Ordinary shares, $0.0001 par value per share; 1,540,975,898 and 1,387,367,704 shares issued and 1,428,203,304 and 1,387,367,704 shares outstanding as of June 30, 2025 and December 31, 2024, respectively		143	138
Additional paid-in capital		12,395,276	12,087,908
Accumulated other comprehensive loss	14	(113,698)	(148,988)
Accumulated deficit		(8,511,246)	(8,606,836)
Total shareholders' equity		3,770,475	3,332,222
Total liabilities and shareholders' equity		6,298,394	5,920,910

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

BEONE MEDICINES LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of U.S. Dollars ("$"))
(Unaudited)

	Note	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024
		$	$
Operating activities:			
Net income (loss)		95,590	(371,555)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization expense		68,418	50,224
Share-based compensation expenses	13	246,287	219,304
Acquired in-process research and development		500	—
Gain on deconsolidation of a subsidiary		—	(3,735)
Amortization of research and development cost share liability	3	(45,569)	(35,039)
Other items, net		15,128	5,413
Changes in operating assets and liabilities:			
Accounts receivable		(73,369)	(173,896)
Inventories		6,174	(35,949)
Other assets		(45,316)	(32,233)
Accounts payable		(35,852)	2,192
Accrued expenses and other payables		75,625	(28,256)
Other liabilities		64	(630)
Net cash provided by (used in) operating activities		307,680	(404,160)
Investing activities:			
Purchases of property, plant and equipment		(100,233)	(266,528)
Purchase of intangible asset		(20,000)	(4,674)
Proceeds from sale or maturity of investments		1,800	2,655
Purchase of in-process research and development		(60,000)	(31,800)
Other investing activities		(10,113)	(20,516)
Net cash used in investing activities		(188,546)	(320,863)
Financing activities:			
Proceeds from long-term loan	10	—	9,053
Repayment of long-term loan	10	(16,799)	(14,020)
Proceeds from short-term loans	10	221,521	324,412
Repayment of short-term loans	10	(275,782)	(157,490)
Payments of withholding taxes from share-based awards		(24,195)	—
Proceeds from option exercises and employee share purchase plan		96,503	20,355
Other financing activities		—	3,000
Net cash provided by financing activities		1,248	185,310
Effect of foreign exchange rate changes, net		26,957	(28,340)
Net increase (decrease) in cash, cash equivalents, and restricted cash		147,339	(568,053)
Cash, cash equivalents, and restricted cash at beginning of period		2,638,747	3,185,984
Cash, cash equivalents, and restricted cash at end of period		2,786,086	2,617,931
Supplemental cash flow information:			
Cash and cash equivalents		2,756,056	2,592,655
Short-term restricted cash		15,802	23,155
Long-term restricted cash		14,228	2,121
Income taxes paid		77,033	45,636
Interest expense paid		24,018	24,148
Supplemental non-cash information:			
Capital expenditures included in accounts payable and accrued expenses		57,923	115,564
ROU assets obtained in exchange for new operating lease liabilities		18,141	27,267
Increase in equity investment from deconsolidation of a subsidiary		—	40,798

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

BEONE MEDICINES LTD.
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares)
(Unaudited)

	Ordinary Shares Issued	Effect of Redomiciliation[1]	Total Outstanding Shares	Ordinary Shares Issued	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
		Shares		$	$	$	$	$
Balance at December 31, 2024	1,387,367,704	—	1,387,367,704	138	12,087,908	(148,988)	(8,606,836)	3,332,222
Issuance of shares reserved for share option exercises	402,532	—	402,532	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	15,511,587	—	15,511,587	2	63,874	—	—	63,876
Share-based compensation	—	—	—	—	95,478	—	—	95,478
Other comprehensive income	—	—	—	—	—	6,667	—	6,667
Net income	—	—	—	—	—	—	1,270	1,270
Balance at March 31, 2025	1,403,281,823	—	1,403,281,823	140	12,247,260	(142,321)	(8,605,566)	3,499,513
Issuance of shares reserved for share option exercises[1]	109,306,902	(112,772,594	(3,465,692)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	28,387,173	—	28,387,173	3	32,730	—	—	32,733
Share-based compensation	—	—	—	—	150,809		—	150,809
Withholding taxes from share-based awards	—	—	—	—	(35,523)	—	—	(35,523)
Other comprehensive income	—	—	—	—	—	28,623	—	28,623
Net income	—	—	—	—	—	—	94,320	94,320
Balance at June 30, 2025	1,540,975,898	(112,772,594	1,428,203,304	143	12,395,276	(113,698)	(8,511,246)	3,770,475
Balance at December 31, 2023	1,359,513,224	—	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)	—	(3,634,952)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	3,646,097	—	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	—	1,359,524,369	136	11,705,069	(131,644)	(8,213,200)	3,360,361
Issuance of shares reserved for share option exercises	2,418,936	—	2,418,936	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	17,158,596	—	17,158,596	1	4,491	—	—	4,492
Share-based compensation	—	—	—	—	130,637	—	—	130,637
Other comprehensive loss	—	—	—	—	—	(8,830)	—	(8,830)
Net loss	—	—	—	—	—	—	(120,405)	(120,405)
Balance at June 30, 2024	1,379,101,901	—	1,379,101,901	137	11,840,197	(140,474)	(8,333,605)	3,366,255

1. Upon effectiveness of the redomiciliation to Switzerland, ordinary shares (including in the form of ADS) held by the Company or one of its controlled subsidiaries immediately prior to the effective date of the redomiciliation became part of the Company's issued but not outstanding share capital and are considered own ordinary shares of the Company, or "treasury shares," under Swiss law. The Company expects to use these treasury shares in the future to satisfy obligations to deliver shares in connection with awards granted under the Company's equity incentive plans and agreements.

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

BEONE MEDICINES 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

BeOne Medicines Ltd. (the "Company", "BeOne", "it", "its"), formerly known as BeiGene, Ltd., is a global oncology company redomiciled in Switzerland during the second quarter of 2025, that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide.

The redomiciliation to Switzerland did not change the accounting basis under U.S. generally accepted accounting principles ("GAAP") of any of the Company's consolidated assets, liabilities, equity, or any previous results of operations or cash flows.

In connection with the redomiciliation, ordinary shares held by the Company or one of its controlled subsidiaries immediately prior to the effective date of the redomiciliation will be part of the Company's issued share capital and be considered own ordinary shares of the Company, or "treasury shares", under Swiss law. See BeiGene, Ltd.'s final prospectus filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(3) on March 10, 2025 for a full description of the changes related to the Company's ordinary shares resulting from the redomiciliation to Switzerland.

Since its inception in 2010, the Company has become a fully integrated global organization with more than 11,000 employees worldwide.

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of June 30, 2025, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024, the condensed consolidated statements of cash flows for the six months ended June 30, 2025 and 2024, and the condensed consolidated statements of shareholders' equity for the three and six months ended June 30, 2025 and 2024, and the related footnote disclosures are unaudited. The accompanying unaudited interim condensed consolidated financial statements were prepared in accordance with U.S. 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, 2024 (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 and six months ended June 30, 2025 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 performance obligations 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, 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 2024, the FASB issued Accounting Standards Update ("ASU") 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses. This update requires that at each interim and annual reporting period public entities disclose (1) the amounts of purchases of inventory, employee compensation, depreciation, amortization, and depletion in commonly presented expense captions; (2) certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; (3) a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively; and (4) the total amount of selling expenses and, in annual reporting periods, the definition of selling expenses. In January 2025, the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Clarifying the Effective Date. This update clarifies that ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. 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 does not expect that the adoption of ASU 2023-09 will have a significant impact on the Company's consolidated financial statements as the standard does not change the recognition or measurement of current and deferred income taxes and is currently evaluating the impact on the income tax disclosures.

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, 2024.

There have been no material changes to the Company's significant accounting policies as of and for the six months ended June 30, 2025, 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 June 30, 2025 and December 31, 2024:

As of June 30, 2025	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	863,314	—	—
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	218	—	—
Convertible debt instrument	—	—	8,792
Total	863,532	—	8,792

As of December 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	950,704	—	—
Prepaid expenses and other current assets:			
Convertible debt instrument	—	—	618
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	2,113	168	—
Convertible debt instrument	—	—	4,616
Total	952,817	168	5,234

The Company's cash equivalents are highly liquid investments with original maturities of 3 months or less. The Company determines the fair value of cash equivalents 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 elected the fair value option method of accounting for the convertible notes. Accordingly, the convertible notes are remeasured at fair value on a recurring basis using Level 3 inputs, with any changes in the fair value option recorded in other income (expense), net. The Company recorded net gains on fair value adjustment of $75 and $1,211 for the three and six months ended June 30, 2025, respectively, and $138 for the three and six months ended June 30, 2024, respectively.

As of June 30, 2025 and December 31, 2024, 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 debt 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 enters into collaborative arrangements for the research and development, manufacture and/or commercialization of drug products and drug candidates. To date, these collaborative arrangements have included out-licenses of 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 Annual Report for the year ended December 31, 2024 filed with the U.S. Securities and Exchange Commission on February 27, 2025.

For the three and six months ended June 30, 2025, the Company's collaboration revenue consisted primarily of royalty revenue from Imdelltra sales outside of China under the Amgen collaboration agreement and revenue generated under the Novartis broad markets agreement. For the three and six months ended June 30, 2024, collaboration revenue consisted primarily of revenue generated under the Novartis broad markets agreement.

The following table summarizes total collaboration revenue recognized for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue from collaborators	$	$	$	$
Amgen royalty revenue	9,033	836	14,552	836
Novartis broad markets revenue	3,320	4,154	6,842	8,501
Other	871	3,030	579	3,417
Revenue from collaborators	13,224	8,020	21,973	12,754

In-Licensing Arrangements - Commercial

Amgen

During the three and six months ended June 30, 2025 and 2024, the Company recorded the following amounts related to its collaboration arrangement with Amgen. For a detailed description of the arrangement and related rights and obligations, see the Company's Annual Report for the year ended December 31, 2024 filed on February 27, 2025. The Company is still in the commercialization period for XGEVA, KYPROLIS and BLINCYTO in China.

Amounts recorded related to the Company's portion of the co-development funding on the pipeline assets for the three and six months ended June 30, 2025 and 2024 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
BeOne's portion of the development funding	52,196	44,385	92,715	71,005
Less: Amortization of research and development cost share liability	25,757	21,903	45,569	35,039
Research and development expense	26,439	22,482	47,146	35,966

	As of June 30, 2025
	$
Remaining portion of development funding cap	242,916

As of June 30, 2025 and December 31, 2024, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of	
	June 30, 2025	December 31, 2024
	$	$
Research and development cost share liability, current portion	108,992	111,154
Research and development cost share liability, non-current portion	10,879	54,286
Total research and development cost share liability	119,871	165,440

The total reimbursement paid under the commercial profit-sharing agreement for product sales is classified in the income statement for the three and six months ended June 30, 2025 and 2024 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Cost of sales - product	9,533	9,590	17,027	18,159
Research and development	(1,597)	(439)	(2,109)	(1,144)
Selling, general and administrative	(25,037)	(21,100)	(48,985)	(39,253)
Total	(17,101)	(11,949)	(34,067)	(22,238)

The Company purchases commercial inventory from Amgen to distribute in China. Inventory purchases amounted to $73,288 and $136,032 during the three and six months ended June 30, 2025, respectively, and $47,653 and $109,879 during the three and six months ended June 30, 2024, respectively. Net amounts payable to Amgen was $110,065 and $116,563 as of June 30, 2025 and December 31, 2024, 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 and six months ended June 30, 2025 and 2024 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 term of the commercialization agreements.

		Three Months Ended June 30,		Six Months Ended June 30,	
		2025	2024	2025	2024
Payments due to collaboration partners	**Classification**	**$**	**$**	**$**	**$**
Upfront payments	Research and development expense	500	—	500	27
Development milestones incurred	Research and development expense	—	11,500	—	46,500
Regulatory and commercial milestone payments	Intangible asset	20,000	—	20,000	—
Total		20,500	11,500	20,500	46,527

4. Restricted Cash and Investments

Restricted Cash

The Company's restricted cash primarily consists of RMB-denominated cash deposits held in designated bank accounts as 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 June 30, 2025 and December 31, 2024 was as follows:

	As of	
	June 30, 2025	December 31, 2024
	$	$
Short-term restricted cash	15,802	9,312
Long-term restricted cash	14,228	2,025
Total	30,030	11,337

In addition to the restricted cash balances above, the Company is required by the PRC securities law to use the proceeds from its 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 offering prospectus as well as those disclosed in the Company's proceeds management policy approved by the board of directors. As of June 30, 2025, the Company had cash remaining related to the STAR Offering proceeds of $359,544.

Investments in Equity Securities

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

	As of	
	June 30, 2025	December 31, 2024
	$	$
Equity securities with readily determinable fair values [1]		
Fair value of Leap common stock	218	2,113
Fair value of Leap warrants	—	168
Equity securities without readily determinable fair values		
Pi Health, Inc. [2]	40,798	40,798
Other	47,378	48,157
Equity-method investments [3]	22,289	33,081
Total	110,683	124,317

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

[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 (expense), net during the six months ended June 30, 2024. The Company accounts for its investment as a private equity security without a readily determinable fair value, and the divestiture was 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.

[3] In the first quarter of 2025, in connection with the wind-down of the operations and related financial obligations of one of the Company's equity-method investments, the investment's fair value was assessed to be zero. The Company recognized an other-than-temporary impairment loss of $12,376 during the six months ended June 30, 2025, within unrealized losses from equity-method investments.

The following table summarizes unrealized losses related to investments in equity securities recorded in other income (expense), net for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Equity securities with readily determinable fair values	(7)	(621)	(2,063)	(2,033)
Equity securities without readily determinable fair values	(3,118)	—	(3,118)	(797)
Equity-method investments	(1,899)	(4,017)	(15,274)	(4,873)

5. Inventories, Net

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

	As of	
	June 30, 2025	December 31, 2024
	$	$
Raw materials	180,969	170,584
Work in process	98,922	60,118
Finished goods	222,976	264,284
Total inventories, net	502,867	494,986

6. Property, Plant and Equipment, Net

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

	As of	
	June 30, 2025	December 31, 2024
	$	$
Land	71,434	65,485
Building	932,950	607,857
Manufacturing equipment	258,737	244,255
Laboratory equipment	270,224	240,885
Leasehold improvement	74,476	64,680
Software, electronics and office equipment	107,340	100,348
Property, plant and equipment, at cost	1,715,161	1,323,510
Less: accumulated depreciation	(453,031)	(399,105)
Construction in progress	353,662	654,018
Property, plant and equipment, net	1,615,792	1,578,423

The Company has made a significant investment in its newly opened manufacturing and R&D center in Hopewell, New Jersey. In the six months ended June 30, 2025, $334,635 of assets were placed into service. As of June 30, 2025, the Company had construction in progress of $189,674 related to the Hopewell facility, the majority of which will be put into service in 2025.

Depreciation expense was $29,854 and $61,468 for the three and six months ended June 30, 2025, respectively, and $23,754 and $47,864 for the three and six months ended June 30, 2024, respectively.

7. Intangible Assets

Intangible assets as of June 30, 2025 and December 31, 2024 are summarized as follows:

	As of					
	June 30, 2025			December 31, 2024		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
	$	$	$	$	$	$
Finite-lived intangible assets:						
Developed products	76,294	(11,953)	64,341	62,889	(12,370)	50,519
Other	8,987	(8,438)	549	8,987	(8,411)	576
Total finite-lived intangible assets	85,281	(20,391)	64,890	71,876	(20,781)	51,095

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 selling, general and administrative expense in the accompanying consolidated statements of operations.

The weighted-average life for each finite-lived intangible assets is approximately 11 years. Amortization expense was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Amortization expense - Cost of sales - product	5,749	1,177	6,922	2,360
Amortization expense - Selling, general and administrative	11	—	28	—
Total	5,760	1,177	6,950	2,360

As of June 30, 2025, estimated amortization expense for each of the five succeeding years and thereafter was as follows:

Year Ending December 31,	Cost of Sales - Product	Selling, General and Administrative	Total
	$	$	$
2025 (remainder of year)	3,082	39	3,121
2026	6,164	67	6,231
2027	6,164	67	6,231
2028	6,164	67	6,231
2029	6,164	67	6,231
2030 and thereafter	36,603	242	36,845
Total	64,341	549	64,890

8. Income Taxes

Income tax expense was $5,229 and $24,859 for the three and six months ended June 30, 2025 and $14,485 and $22,209 for the three and six months ended June 30, 2024, respectively. The income tax expense for the three and six months ended June 30, 2025 was primarily attributable to current Switzerland tax expense based on year to date earnings, current China tax expense due to certain non-deductible expenses, offset with a net U.S. tax benefit mainly driven by changes to the Company's estimate of U.S. R&D credits to be taken for prior periods and are reflected as a discrete item in Q2 2025. The income tax expense for the three and six months ended June 30, 2024 was primarily attributable to current U.S. tax expense determined after other special tax deductions and research and development tax credits, current Switzerland tax expense based on year to date earnings, 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 June 30, 2025, the Company will maintain a full valuation allowance against its net deferred tax assets.

As of June 30, 2025, the Company had gross unrecognized tax benefits of $21,488. 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 $3,913 and $4,249 in the three and six months ended June 30, 2025, 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	
	June 30, 2025	December 31, 2024
	$	$
Prepaid research and development costs	76,231	64,277
Payroll tax receivable	69,987	14,569
Other receivables	39,367	18,259
Prepaid taxes	27,058	23,792
Prepaid general and administrative expenses	16,967	21,253
Short-term restricted cash	15,802	9,312
Prepaid insurance	8,486	6,242
Prepaid manufacturing cost	6,157	19,333
Other current assets	20,467	15,882
Total	280,522	192,919

Other non-current assets consist of the following:

	As of	
	June 30, 2025	December 31, 2024
	$	$
Long-term investments	119,475	128,933
Long-term restricted cash	14,228	2,025
Prepaid supply cost	12,321	12,249
Rental deposits and other	7,733	8,481
Prepayment of property and equipment	4,847	5,927
Prepaid VAT	3,118	2,875
Total	161,722	160,490

Accrued expenses and other payables consist of the following:

	As of	
	June 30, 2025	December 31, 2024
	$	$
Revenue rebates and returns related	297,317	235,600
Compensation related	233,246	248,348
Individual income tax and other taxes	109,376	34,904
External research and development activities related	106,185	154,269
Commercial activities	99,749	77,530
Accrued general and administrative expenses	46,091	31,106
Other	16,918	21,956
Total	908,882	803,713

Other long-term liabilities consist of the following:

	As of	
	June 30, 2025	December 31, 2024
	$	$
Deferred government grant income	29,569	30,324
Pension liability	17,329	16,405
Asset retirement obligation	3,573	3,794
Other	12,608	16,212
Total	63,079	66,735

10. Debt

The following table summarizes the Company's short-term and long-term debt obligations as of June 30, 2025 and December 31, 2024:

Lender	Borrower	Term	Maturity Date	Note	As of June 30, 2025	As of December 31, 2024
					$	$
China Construction Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	June 11, 2027	1	18,845	16,440
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	January 20, 2029	2	8,774	8,611
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	November 8, 2029	3	8,294	8,148
China CITIC Bank	BeOne Pharmaceutical (Suzhou) Co., Ltd.	10-year	July 28, 2032	4	5,947	1,384
China Merchants Bank	BeOne Medicines Ltd.	1-year	January 21, 2026	5	380,000	380,000
China Minsheng Bank	BeOne Medicines Ltd.	1-year	December 16, 2025	6	150,000	150,000
China Industrial Bank	BeOne Medicines USA, Inc.	364-day	June 28, 2026	7	94,223	—
China Industrial Bank	BeOne Medicines Ltd.	364-day	March 27, 2025	8	—	92,475
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	1-year	June 5, 2025	9	—	54,800
HSBC Bank	BeOne Medicines Ltd.	1-year	June 17, 2026	10	47,461	46,580
Shanghai Pudong Development Bank	BeOne Medicines Ltd.	1-year	November 24, 2025	11	94,850	93,091
Total short-term debt					808,394	851,529
China Construction Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	June 11, 2027	1	31,408	41,100
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	January 20, 2029	2	24,129	27,987
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	November 8, 2029	3	29,497	33,020
China CITIC Bank	BeOne Pharmaceutical (Suzhou) Co., Ltd.	10-year	July 28, 2032	4	61,057	64,377
Total long-term debt					146,091	166,484

1 The credit facility offers a borrowing capacity of RMB 580,000, denominated in RMB, and bears floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.8% as of June 30, 2025. The outstanding principal balance is payable in semi-annual installments. The Company repaid $8,358 (RMB60,000) during the six months ended June 30, 2025. The loan is secured by BeOne Guangzhou Biologics Manufacturing Co., Ltd.'s property ownership certificate and fixed assets.

2 The credit facility offers a borrowing capacity of RMB 350,000, denominated in RMB, and bears floating interest rates benchmarking against prevailing interest rates of financial institutions in the PRC. The loan interest rate was 3.4% as of June 30, 2025. The outstanding principal balance is payable in quarterly installments. The Company repaid $4,323 (RMB31,429) during the six months ended June 30, 2025. The loan is secured by Guangzhou Factory's second land use right and certain fixed assets.

3 The credit facility offers a borrowing capacity of RMB 378,000, denominated in RMB, and bears floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.3% as of June 30, 2025. The outstanding principal balance is payable in quarterly installments. The Company repaid $4,118 (RMB29,765) during the six months ended June 30, 2025. The loan is secured by fixed assets placed into service in the third phase of the Guangzhou manufacturing facility's buildout.

4 The credit facility offers a borrowing capacity of RMB 480,000, denominated in RMB, and bears floating interest rate benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.4% as of June 30, 2025. The outstanding principal balance is payable in semi-annual installments. The loan is secured by BeOne Pharmaceutical (Suzhou) Co., Ltd.'s property ownership certificate of the small molecule manufacturing campus in Suzhou, China.

5 The working capital loan facility offers a borrowing capacity of up to $380,000, denominated in USD, and bears floating interest rates benchmarking the secured overnight financing rate. The loan interest rate was 6.2% as of June 30, 2025. $300,000 of the borrowings matures on December 17, 2025, and $80,000 matures on January 21, 2026.

6 The working capital loan facility offers a borrowing capacity of up to $150,000, denominated in USD. The loan interest rate was 6.8% as of June 30, 2025.

7 The working capital loan facility offers a borrowing capacity of up to RMB 675,000, denominated in RMB. The loan interest rate was 3.0% as of June 30, 2025.

8 The working capital loan facility offered a borrowing capacity of up to RMB 675,000, denominated in RMB. The Company repaid the principal during the six months ended June 30, 2025.

9 The working capital loan facility offers a borrowing capacity of up to of RMB 400,000, denominated in RMB. The Company repaid the principal during the six months ended June 30, 2025.

10 The working capital loan facility offers a borrowing capacity of up to RMB 340,000, denominated in RMB, and bears floating interest rates benchmarking Hong Kong interbank market rate for RMB. The loan interest rate was 5.2% as of June 30, 2025.

11 The working capital loan facility offers a borrowing capacity of up to RMB 700,000, denominated in RMB. The loan interest rate was 2.9% as of June 30, 2025.

The Company has numerous financial and non-financial covenants on its debt obligations with various banks and other lenders. Some of these covenants include default and/or 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 June 30, 2025, the Company was in compliance with all covenants of its material debt agreements.

Interest Expense

Interest expense recognized for the three and six months ended June 30, 2025 was $12,048 and $25,009, respectively, among which, $4,054 and $10,013 was capitalized, respectively. Interest expense recognized for the three and six months ended June 30, 2024 was $13,233 and $25,637, respectively, among which, $8,312 and $17,521 was capitalized, respectively. Interest paid for the six months ended June 30, 2025 and 2024, net of amounts capitalized, amounted to $14,006 and $6,628, respectively.

11. Product Revenue

The Company's product revenue is primarily derived from the sale of its internally developed products BRUKINSA® and TEVIMBRA® in the U.S., China, EU, and other regions; 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 revenue for the three and six months ended June 30, 2025 and 2024.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Product revenue – gross	1,657,838	1,167,155	3,057,904	2,111,619
Less: Rebates and sales returns	(355,762)	(246,009)	(647,298)	(443,555)
Product revenue – net	1,302,076	921,146	2,410,606	1,668,064

The following table disaggregates net product revenue by product for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
BRUKINSA®	949,840	637,399	1,741,504	1,125,914
TEVIMBRA®	193,524	158,410	364,688	303,687
XGEVA®	81,318	55,054	151,741	98,435
BLINCYTO®	25,587	19,131	49,493	33,497
KYPROLIS®	19,416	15,936	39,144	30,047
POBEVCY®	11,242	11,572	24,987	28,205
Other	21,149	23,644	39,049	48,279
Total product revenue – net	1,302,076	921,146	2,410,606	1,668,064

The following table presents the roll-forward of accrued revenue rebates and returns for the six months ended June 30, 2025 and 2024:

	Rebates, Returns and Other Deductions	Contra AR Accruals	Total
	$	$	
Balance at December 31, 2024	235,600	50,699	286,299
Accrual	283,525	363,773	647,298
Payments	(221,808)	(361,633)	(583,441)
Balance at June 30, 2025	297,317	52,839	350,156
Balance at December 31, 2023	139,936	30,435	170,371
Accrual	222,179	221,376	443,555
Payments	(188,852)	(209,450)	(398,302)
Balance at June 30, 2024	173,263	42,361	215,624

12. Earnings (Loss) Per Share/ADS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Numerator:				
Net income (loss)	94,320	(120,405)	95,590	(371,555)
Denominator:				
Weighted-average shares outstanding—basic	1,408,166,754	1,361,082,567	1,399,159,898	1,358,315,145
Dilutive common share equivalents	55,110,647	—	55,136,577	—
Weighted-average shares outstanding—diluted	1,463,277,401	1,361,082,567	1,454,296,475	1,358,315,145
Antidilutive common share equivalents excluded from above	1,317,291	—	1,496,899	—
Earnings (loss) per share:				
Basic	0.07	(0.09)	0.07	(0.27)
Diluted	0.06	(0.09)	0.07	(0.27)
Earnings (loss) per ADS:				
Basic	0.87	(1.15)	0.89	(3.56)
Diluted	0.84	(1.15)	0.85	(3.56)

For the three and six months ended June 30, 2025, diluted earnings per share was computed using the weighted-average number of ordinary shares and the effect of potentially dilutive shares outstanding during the periods. Potentially dilutive shares consist of stock options, restricted stock units and ESPP shares. The dilutive effect of outstanding stock options, restricted stock units and ESPP shares is reflected in diluted net earnings per share using the treasury stock method.

For the three and six months ended June 30, 2024, the Company was in a net loss position and the effects of all share options, restricted share units and ESPP shares were excluded from the calculation of diluted loss per share, as their effect would have been anti-dilutive.

Each ADS represents 13 ordinary shares. Basic and diluted earnings (loss) per ADS was derived from the basic and diluted earnings (loss) per share, respectively.

13. Share-Based Compensation Expense

Share Option, Restricted Share Units and Performance Share Units

During the six months ended June 30, 2025, the Company granted options for 2,527,499 ordinary shares, restricted share units for 26,510,263 ordinary shares, and performance share units for 1,837,901 ordinary shares under the Company's share option and incentive plan. As of June 30, 2025, options, restricted share units, and performance share units for ordinary shares outstanding totaled 56,870,418, 82,357,691, and 3,896,477, respectively. As of June 30, 2025, share-based awards to acquire 58,818,941 ordinary shares were available for future grant under the Company's share option and incentive plan.

Employee Share Purchase Plan

The Company's employee share purchase plan (the "ESPP") allows eligible employees to purchase the Company's ordinary shares (including in the form of ADSs) at the end of each offering period, which will generally be six months, at a 15% discount to the market price of the Company's ADSs at the beginning or the end of each offering period, whichever is lower, using funds deducted from their payroll during the offering period. Eligible employees are able to authorize payroll deductions of up to 10% of their eligible earnings, subject to applicable limitations.

As of June 30, 2025, 3,998,286 ordinary shares were available for future issuance under the ESPP.

The following table summarizes the shares issued under the ESPP:

Issuance Date	Number of Ordinary Shares Issued	Market Price[1]		Purchase Price[2]		Proceeds
		ADS	Ordinary	ADS	Ordinary	
February 28, 2025	955,396	$ 188.26	$ 14.48	$ 160.02	$ 12.31	$ 11,760
August 31, 2024	1,035,996	$ 165.02	$ 12.69	$ 140.27	$ 10.78	$ 11,178
February 29, 2024	1,021,397	$ 165.65	$ 12.74	$ 140.80	$ 10.83	$ 11,063

[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 and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
Research and development	64,392	55,406	106,159	93,451
Selling, general and administrative	86,161	75,288	139,845	125,957
Total	150,553	130,694	246,004	219,408

14. Accumulated Other Comprehensive Loss

The movement of accumulated other comprehensive loss was as follows:

	Foreign Currency Translation Adjustments	Pension Liability Adjustments	Total
	$	$	$
Balance as of December 31, 2024	(135,552)	(13,436)	(148,988)
Other comprehensive income before reclassifications	34,988	(205)	34,783
Amounts reclassified from accumulated other comprehensive loss	—	507	507
Net-current period other comprehensive income	34,988	302	35,290
Balance as of June 30, 2025	(100,564)	(13,134)	(113,698)

15. 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 June 30, 2025 and December 31, 2024, amounts restricted were the net assets of the Company's PRC subsidiaries, which, after intercompany eliminations, amounted to $1,915,949 and $1,709,961, respectively.

16. Commitments and Contingencies

Purchase Commitments

As of June 30, 2025, the Company had non-cancellable purchase commitments amounting to $130,087, of which $32,591 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $97,496 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 $62,029 for the acquisition of property, plant and equipment as of June 30, 2025, related to various facilities across the globe, including the manufacturing and clinical R&D campus in Hopewell, New Jersey.

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/or development services. As of June 30, 2025, the Company's remaining co-development funding commitment was $242,916.

Funding Commitment

The Company had committed capital related to equity investments in the amount of $15,890. As of June 30, 2025, the remaining capital commitment was $6,740 and is expected to be paid from time to time over the investment period.

17. 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 primary measure of segment profitability for the Company's operating segment is considered to be consolidated net income (loss). Significant segment expenses reviewed by the CODM on a regular basis included within net income (loss) include cost of product sales, research and development expenses and selling, general and administrative expenses which are separately presented on the Company's consolidated statements of operations. Other segment items within net income (loss) include interest income, net, other income (expense), net and income tax expense.

The Company's long-lived assets are primarily located in the U.S. and China.

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	$	$	$	$
U.S. - total revenue	**694,427**	**481,430**	**1,261,638**	**832,886**
Product revenue	685,395	479,365	1,248,743	830,821
Collaboration revenue	9,032	2,065	12,895	2,065
China - total revenue	**432,924**	**352,070**	**832,516**	**672,446**
Product revenue	428,802	347,112	825,164	662,774
Collaboration revenue	4,122	4,958	7,352	9,672
Europe - total revenue	**152,384**	**82,389**	**270,938**	**149,249**
Product revenue	152,314	81,392	269,212	148,232
Collaboration revenue	70	997	1,726	1,017
Rest of world - total revenue	**35,565**	**13,277**	**67,487**	**26,237**
Product revenue	35,565	13,277	67,487	26,237
Total Revenue	**1,315,300**	**929,166**	**2,432,579**	**1,680,818**

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 ("U.S."), 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.

Effective May 27, 2025, we changed our jurisdiction of incorporation from the Cayman Islands to Switzerland through a transaction known as a continuation under Section 206 of the Companies Act (as amended) of the Cayman Islands and Article 161 of the Swiss Federal Act on Private International Law (the "Continuation") and changed our legal English name from BeiGene, Ltd. to BeOne Medicines Ltd. This Quarterly Report includes the results of BeiGene, Ltd. prior to the Continuation and BeOne Medicines Ltd. following the Continuation.

Unless the context requires otherwise, in this Quarterly Report, the terms "BeOne," the "Company," "we," "us" and "our" refer to (i) BeOne Medicines Ltd., a Switzerland holding company with operations conducted by its subsidiaries, and its subsidiaries, on a consolidated basis, following the Continuation and (ii) BeiGene, Ltd., a Cayman Islands holding company with operations conducted by its subsidiaries, and its subsidiaries, on a consolidated basis, prior to the Continuation.

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, Adjusted Income (Loss) from Operations, Adjusted Net Income (Loss), Adjusted Earnings Per Share, Free Cash Flow 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. Non-GAAP adjustments are tax effected to the extent there is US GAAP current tax expense. The Company currently records a valuation allowance on its net deferred tax assets, so there is no net impact recorded for deferred tax effects. 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 BeOne'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 BeOne may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

Overview

Our second quarter performance reinforces us as a global oncology leader and proves our ability to deliver sustainable, long-term growth. BRUKINSA continues as the BTK inhibitor market leader in the US across five indications. Our two additional Phase 3 hematology assets, BCL2 inhibitor sonrotoclax and BTK CDAC BGB-16673, have the potential to expand our franchise with pivotal data readouts and new trial initiations anticipated in the near-term. At our recent Investor R&D Day, we outlined more than 20 expected R&D milestones in the next 18 months. This includes advances across our solid tumor pipeline, where we are building future global franchises targeting a range of highly prevalent cancers.

Key highlights for the second quarter of 2025 are as follows:

- Second quarter 2025 total revenues increased 42% to $1.3 billion versus second quarter 2024
- Global BRUKINSA® (zanubrutinib) revenues increased 49% to $950 million versus second quarter 2024
- Reported GAAP diluted Earnings per American Depositary Share (ADS) of $0.84, non-GAAP diluted Earnings per ADS of $2.25
- Anticipate 20+ near-term milestones in next 18 months across hematology and solid tumor pipeline

Recent Developments

Recent Business Developments

On July 31, 2025, we announced that the European Medicines Agency ("EMA") has granted PRIority MEdicines (PRIME) designation to the Company's investigational Bruton's tyrosine kinase (BTK) degrader, BGB-16673, for the treatment of patients with Waldenstrom's macroglobulinemia (WM) previously treated with a BTK inhibitor.

On July 28, 2025, we announced that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency issued a positive opinion recommending approval of TEVIMBRA® (tislelizumab), in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, for the treatment of adult patients with resectable non-small cell lung cancer (NSCLC) at high risk of recurrence.

On July 10, 2025, we announced that the European Commission has approved TEVIMBRA, in combination with gemcitabine and cisplatin, for the first-line treatment of adult patients with metastatic or recurrent nasopharyngeal carcinoma, not amenable to curative surgery or radiotherapy.

On June 26, 2025, we announced major advancements to our industry-leading oncology pipeline during our investor R&D Day.

On June 25, 2025, we announced that the CHMP of the European Medicines Agency issued a positive opinion recommending approval of a new film-coated tablet formulation of BRUKINSA® (zanubrutinib) for all approved indications. The CHMP positive opinion will now be reviewed by the European Commission, which will grant the marketing authorization for the tablet formulation in the European Union and in the European Economic Area countries Norway and Iceland.

On June 11, 2025, we announced that the U.S. Food and Drug Administration approved a new tablet formulation of BRUKINSA for all five approved indications.

On May 27, 2025, we announced our new name and completed the redomiciliation to Switzerland, marking a significant milestone in the Company's evolution.

Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	$	%	2025	2024	$	%
	(dollars in thousands)							
Revenues								
Product revenue, net	$1,302,076	$ 921,146	$ 380,930	41.4 %	$2,410,606	$1,668,064	$ 742,542	44.5 %
Collaboration revenue	13,224	8,020	5,204	64.9 %	21,973	12,754	9,219	72.3 %
Total revenues	1,315,300	929,166	386,134	41.6 %	2,432,579	1,680,818	751,761	44.7 %
Cost of sales - product	164,606	138,132	26,474	19.2 %	329,608	263,067	66,541	25.3 %
Gross profit	1,150,694	791,034	359,660	45.5 %	2,102,971	1,417,751	685,220	48.3 %
Operating expenses								
Research and development	524,896	454,466	70,430	15.5 %	1,006,783	915,104	91,679	10.0 %
Selling, general and administrative	537,913	443,729	94,184	21.2 %	997,201	871,156	126,045	14.5 %
Total operating expenses	1,062,809	898,195	164,614	18.3 %	2,003,984	1,786,260	217,724	12.2 %
Income (loss) from operations	87,885	(107,161)	195,046	(182.0)%	98,987	(368,509)	467,496	(126.9)%
Interest income, net	3,497	13,225	(9,728)	(73.6)%	9,345	29,385	(20,040)	(68.2)%
Other income (expense), net	8,167	(11,984)	20,151	(168.1)%	12,117	(10,222)	22,339	(218.5)%
Income (loss) before income taxes	99,549	(105,920)	205,469	(194.0)%	120,449	(349,346)	469,795	(134.5)%
Income tax expense	5,229	14,485	(9,256)	(63.9)%	24,859	22,209	2,650	11.9 %
Net income (loss)	$ 94,320	$(120,405)	$ 214,725	(178.3)%	$ 95,590	$(371,555)	$ 467,145	(125.7)%

Comparison of the Three Months Ended June 30, 2025 and 2024

Revenue

Total revenue increased to $1,315.3 million for the three months ended June 30, 2025, from $929.2 million for the three months ended June 30, 2024, due to increased sales of BRUKINSA, TEVIMBRA, and our in-licensed products from Amgen.

Net product revenue consisted of the following:

	Three Months Ended June 30,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
BRUKINSA®	$ 949,840	$ 637,399	$ 312,441	49.0 %
TEVIMBRA®	193,524	158,410	35,114	22.2 %
XGEVA®	81,318	55,054	26,264	47.7 %
BLINCYTO®	25,587	19,131	6,456	33.7 %
KYPROLIS®	19,416	15,936	3,480	21.8 %
POBEVCY®	11,242	11,572	(330)	(2.9)%
Other	21,149	23,644	(2,495)	(10.6)%
Total product revenue	$ 1,302,076	$ 921,146	$ 380,930	41.4 %

Net product revenue increased 41.4% to $1,302.1 million for the three months ended June 30, 2025, compared to $921.1 million in the prior-year period, primarily due to increased sales of BRUKINSA globally, driven by continued growth in the U.S. and Europe. In addition, product revenues in the second quarter of 2025 were positively impacted by sales of TEVIMBRA and in-licensed products from Amgen, primarily XGEVA®.

Global revenue for BRUKINSA totaled $949.8 million in the second quarter, representing a 49.0% increase compared to the prior-year period; U.S. revenue for BRUKINSA totaled $683.7 million in the second quarter, compared to $479.4 million in the prior-year period, representing growth of 42.6%, driven primarily by robust demand growth across all indications and modest benefit due to net pricing. BRUKINSA continues to maintain its leading new patient share across the BTKi class due to its differentiated, best-in-class clinical profile. BRUKINSA revenue in Europe totaled $150.5 million in the second quarter, compared to $81.4 million in the prior-year period, representing growth of 84.9%, driven by increased market share across all major European markets, including Germany, Italy, Spain, France and the UK. BRUKINSA revenue in China totaled $83.2 million, representing growth of 30.8%. BRUKINSA rest of world revenue totaled $32.5 million in the second quarter, representing growth of 149.0% compared to the prior-year period.

Revenue for TEVIMBRA totaled $193.5 million in the second quarter, compared to $158.4 million in the prior-year period, representing a 22.2% increase.

Revenue for Amgen products in China totaled $126.3 million in the second quarter, compared to $90.1 million in the prior-year period, representing a 40.2% increase, driven primarily by increased XGEVA® sales volume.

Collaboration revenue totaled $13.2 million and $8.0 million for the three months ended June 30, 2025 and 2024, respectively, primarily related to revenue generated under the Novartis broad markets marketing and promotion agreement and royalty revenue under the Amgen collaboration.

Gross Margin

Gross margin on global product sales increased to $1,137.5 million for the three months ended June 30, 2025, compared to $783.0 million in the prior-year period, primarily due to increased product sales in the current year period. Gross margin as a percentage of product sales increased to 87.4% for the three months ended June 30, 2025, from 85.0% in the comparable period of the prior year. The gross margin percentage increased due to a proportionally higher sales mix of global BRUKINSA compared to other products in our portfolio. Gross margin also benefited from cost of sales productivity improvements for both BRUKINSA and TEVIMBRA. On an adjusted basis, which does not include depreciation and amortization, gross margin as a percentage of product sales increased to 88.1%, from 85.4% in the comparable period of the prior year.

Research and Development Expense

Research and development expense increased by $70.4 million, or 15.5%, to $524.9 million for the three months ended June 30, 2025 from $454.5 million for the three months ended June 30, 2024. The following table summarizes external clinical, external non-clinical and internal research and development expense for the three months ended June 30, 2025 and 2024, respectively:

	Three Months Ended June 30,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 182,567	$ 124,762	$ 57,805	46.3 %
Upfront license and development milestone fees	500	11,500	(11,000)	(95.7)%
Amgen co-development expense[1]	26,439	22,482	3,957	17.6 %
Total external research and development expenses	209,506	158,744	50,762	32.0 %
Internal research and development expenses	315,390	295,722	19,668	6.7 %
Total research and development expenses	$ 524,896	$ 454,466	$ 70,430	15.5 %
Adjusted research and development expenses[2]	$ 444,057	$ 382,509	$ 61,548	16.1 %

1. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended June 30, 2025 totaled $52.2 million, of which $26.4 million was recorded as R&D expense. The remaining $25.8 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 second quarter was primarily attributable to an increase in external costs of development programs primarily due to advancing preclinical programs into the clinic and early clinical programs into late stage, including Sonrotoclax (BCL2i), offset by lower development upfront and milestone fees.

Internal research and development expense increased by $19.7 million, or 6.7%, to $315.4 million, and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, as well as our continued efforts to internalize research and clinical trial activities and control spend.

Selling, General and Administrative Expense

	Three Months Ended June 30,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
Selling, general and administrative expenses	$ 537,913	$ 443,729	$ 94,184	21.2 %
Adjusted selling, general and administrative expenses[1]	$ 441,655	$ 363,922	$ 77,733	21.4 %

1. Adjusted selling, general and administrative 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 $94.2 million, or 21.2%, to $537.9 million for the three months ended June 30, 2025, from $443.7 million for the three months ended June 30, 2024. The increase was primarily attributable to continued investment in global commercial expansion primarily in the U.S. and Europe. Selling, general and administrative expenses as a percentage of product sales were 41.3% in the second quarter of 2025 compared to 48.2% in the prior-year period. We expect continued investment in selling and marketing activities as our product sales increase.

Interest Income, Net

Interest income, net decreased by $9.7 million, or 73.6%, to $3.5 million for the three months ended June 30, 2025, from $13.2 million for three months ended June 30, 2024. The decrease in interest income, net, was primarily attributable to decreased interest income resulting from lower interest rates on our cash and cash equivalents balance. Interest expense increased resulting from higher interest rates on debt balance and lower interest capitalized related to completion of certain phases of our Hopewell facility.

Other Income (Expense), Net

Other income, net was $8.2 million for the three months ended June 30, 2025, primarily due to foreign exchange gains and government subsidy income, partially offset by unrealized losses on our equity investments. For the three months ended June 30, 2024, other expense, net was $12.0 million, primarily due to foreign exchange losses.

Income Tax Expense

Income tax expense was $5.2 million for the three months ended June 30, 2025 as compared to $14.5 million for the three months ended June 30, 2024. The income tax expense for the three months ended June 30, 2025 was primarily attributable to current Switzerland tax expense based on year to date earnings, current China tax expense due to certain non-deductible expenses, offset by discrete adjustments of approximately $14.2 million, primarily related to updated provision estimates for R&D tax credits. The income tax expense for the three months ended June 30, 2024 was primarily attributable to current U.S. tax expense determined after other special tax deductions and research and development tax credits, current Switzerland tax expense based on year to date earnings, and current China tax expense due to certain non-deductible expenses.

On July 4, 2025, the reconciliation bill (H.R. 1), commonly referred to as the One Big Beautiful Bill Act (“OBBBA”), was signed into law and includes a broad range of tax reform provisions that may affect our financial results. The OBBBA allows an elective deduction for domestic research and development expenses, a reinstatement of elective 100% first-year bonus depreciation, and a more favorable tax rate on foreign-derived deduction eligible Income. We are in the process of evaluating the impact of the OBBBA on our consolidated financial statements.

Net Income (Loss) and Earnings Per Share

GAAP net income improved for the second quarter of 2025, as compared to the prior-year period loss, primarily attributable to revenue growth and improved operating leverage.

For the second quarter of 2025, basic and diluted earnings per share was $0.07 and $0.06 per share and $0.87 and $0.84 per American Depositary Share ("ADS"), respectively, compared to basic loss of $0.09 per share and $1.15 per ADS in the prior-year period.

Comparison of the Six Months Ended June 30, 2025 and 2024

Revenue

Total revenue increased to $2,432.6 million, or 44.7%, for the six months ended June 30, 2025, from $1,680.8 million for the six months ended June 30, 2024, primarily due to increased sales of our internally developed products, BRUKINSA and tislelizumab, as well as increased sales of in-licensed products, most notably from the Amgen products.

Net product revenues consisted of the following:

	Six Months Ended June 30,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
BRUKINSA®	1,741,504	1,125,914	$ 615,590	54.7 %
TEVIMBRA®	364,688	303,687	61,001	20.1 %
XGEVA®	151,741	98,435	53,306	54.2 %
BLINCYTO®	49,493	33,497	15,996	47.8 %
KYPROLIS®	39,144	30,047	9,097	30.3 %
POBEVCY®	24,987	28,205	(3,218)	(11.4)%
Other	39,049	48,279	(9,230)	(19.1)%
Total product revenue	2,410,606	1,668,064	742,542	44.5 %

Net product revenue increased 44.5% to $2,410.6 million for the six months ended June 30, 2025, compared to $1,668.1 million in the prior-year period, primarily due to increased sales of BRUKINSA globally, driven by continued growth in the U.S. and Europe. In addition, product revenues in the six months ended June 30, 2025 were positively impacted by sales of TEVIMBRA and in-licensed products from Amgen, primarily XGEVA®.

Global sales of BRUKINSA totaled $1,741.5 million in the six months ended June 30, 2025, representing a 54.7% increase compared to the prior-year period. U.S. sales of BRUKINSA totaled $1,246.9 million in the six months ended June 30, 2025, compared to $830.8 million in the prior-year period, representing growth of 50.1%, driven primarily by robust demand growth across all indications and modest benefit due to net pricing. BRUKINSA continues to maintain its leading new patient share across the BTKi class due to its differentiated, best-in-class clinical profile. BRUKINSA sales in Europe totaled $266.4 million in the six months ended June 30, 2025, representing growth of 79.7% driven by increased market share across all major European markets, including Germany, Italy, Spain, France and the UK. BRUKINSA revenue in China totaled $164.4 million, representing growth of 35.8%. BRUKINSA rest of world revenue totaled $63.9 million in the six months ended June 30, 2025, representing growth of 147.2% compared to the prior-year period.

Revenue for TEVIMBRA totaled $364.7 million in the six months ended June 30, 2025, compared to $303.7 million in the prior-year period, representing a 20.1% increase.

Revenue for Amgen products in China totaled $240.4 million in the six months ended June 30, 2025, compared to $162.0 million in the prior-year period, driven primarily by increased XGEVA® sales volume.

Collaboration revenue totaled $22.0 million and $12.8 million for the six months ended June 30, 2025 and 2024, respectively, primarily related to revenue generated under the Novartis broad markets marketing and promotion agreement and royalty revenue under the Amgen collaboration.

Gross Margin

Gross margin on product sales increased to $2,081.0 million for the six months ended June 30, 2025, compared to $1,405.0 million in the prior-year period, primarily due to increased product revenue in the current year period. Gross margin as a percentage of product sales increased to 86.3% for the six months ended June 30, 2025, from 84.2% in the comparable period of the prior year. The gross margin percentage increased due to a proportionally higher sales mix of global BRUKINSA compared to other products in our portfolio. Gross margin also benefited from cost of sales productivity improvements for both BRUKINSA and TEVIMBRA. On an adjusted basis, which does not include depreciation and amortization, gross margin as a percentage of product sales increased to 86.9%, from 84.7% in the comparable period of the prior year.

Research and Development Expense

Research and development expense increased by $91.7 million, or 10.0%, to $1,006.8 million for the six months ended June 30, 2025 from $915.1 million for the six months ended June 30, 2024. The following table summarizes external clinical, external non-clinical and internal research and development expense for the six months ended June 30, 2025 and 2024, respectively:

	Six Months Ended June 30,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 352,613	$ 247,633	$ 104,980	42.4 %
Upfront license and development milestone fees	500	46,528	(46,028)	(98.9)%
Amgen co-development expense[1]	47,146	35,966	11,180	31.1 %
Total external research and development expenses	400,259	330,127	70,132	21.2 %
Internal research and development expenses	606,524	584,977	21,547	3.7 %
Total research and development expenses	$ 1,006,783	$ 915,104	$ 91,679	10.0 %
Adjusted research and development expenses[2]	$ 865,252	$ 787,949	$ 77,303	9.8 %

1. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the six months ended June 30, 2025 totaled $92.7 million, of which $47.1 million was recorded as R&D expense. The remaining $45.6 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 six months ended June 30, 2025 was primarily attributable to an increase in external costs of development programs primarily due to advancing preclinical programs into the clinic and early clinical programs into late stage, including Sonrotoclax (BCL2i), offset by lower development upfront and milestone fees.

Internal research and development expense increased $21.5 million, or 3.7%, to $606.5 million and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, as well as our continued efforts to internalize research and clinical trial activities and control spend.

Selling, General and Administrative Expense

	Six Months Ended June 30,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
Selling, general and administrative expenses	$ 997,201	$ 871,156	$ 126,045	14.5 %
Adjusted selling, general and administrative expenses[1]	$ 837,166	$ 736,068	$ 101,098	13.7 %

1. Adjusted selling, general and administrative 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 $126.0 million, or 14.5%, to $997.2 million, for the six months ended June 30, 2025, from $871.2 million for the six months ended June 30, 2024. The increase was primarily attributable to continued investment in global commercial expansion primarily in the U.S. and Europe. Selling, general and administrative expenses as a percentage of product sales were 41.4% for the six months ended June 30, 2025 compared to 52.2% in the prior-year period. We expect continued investment in selling and marketing activities as our product sales increase.

Interest Income, Net

Interest income, net decreased by $20.0 million, or 68.2%, to $9.3 million for the six months ended June 30, 2025, from $29.4 million for the six months ended June 30, 2024. The decrease in interest income was primarily attributable to lower interest rates earned on our cash and cash equivalents. Interest expense increased resulting from higher interest rates on debt balance and lower interest capitalized related to completion of certain phases of our Hopewell facility.

Other Income (Expense), Net

Other income, net was $12.1 million for the six months ended June 30, 2025, primarily due to foreign exchange gains and government subsidy income, partially offset by unrealized losses on our equity investments. For the six months ended June 30, 2024, other expense, net was $10.2 million, primarily due to foreign exchanges losses resulting from the strengthening of the U.S. dollar compared to the RMB and the revaluation impact of RMB-denominated deposits held in U.S. functional currency subsidiaries.

Income Tax Expense

Income tax expense increased to $24.9 million for the six months ended June 30, 2025, from $22.2 million for the six months ended June 30, 2024. The income tax expense for the six months ended June 30, 2025 was primarily attributable to current Switzerland tax expense based on year to date earnings, current China tax expense due to certain non-deductible expenses, offset by net discrete adjustments of approximately $8.7 million, primarily related to updated provision estimates for R&D tax credits. The income tax expense for the six months ended June 30, 2024 was primarily attributable to current U.S. tax expense determined after other special tax deductions and research and development tax credits, current Switzerland tax expense based on year to date earnings, and current China tax expense due to certain non-deductible expenses.

On July 4, 2025, the reconciliation bill (H.R. 1), commonly referred to as the One Big Beautiful Bill Act (“OBBBA”), was signed into law and includes a broad range of tax reform provisions that may affect our financial results. The OBBBA allows an elective deduction for domestic research and development expenses, a reinstatement of elective 100% first-year bonus depreciation, and a more favorable tax rate on foreign-derived deduction eligible Income. We are in the process of evaluating the impact of the OBBBA on our consolidated financial statements.

Net Income (Loss) and Earnings Per Share

GAAP net income improved for the six months ended June 30, 2025, as compared to the prior-year period loss, primarily attributable to revenue growth and improved operating leverage.

For the six months ended June 30, 2025, basic and diluted earnings per share was $0.07 per share and $0.89 and $0.85 per ADS, respectively, compared to basic loss of $0.27 per share and $3.56 per ADS in the prior-year period.

Non-GAAP Reconciliation

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	(in thousands)			
Reconciliation of GAAP to adjusted cost of sales - products:				
GAAP cost of sales - products	$ 164,606	$ 138,132	$ 329,608	$ 263,067
Less: Depreciation	3,321	2,684	5,934	5,029
Less: Amortization of intangibles	5,749	1,177	6,922	2,360
Less: Other	893	—	893	—
Adjusted cost of sales - products	$ 154,643	$ 134,271	$ 315,859	$ 255,678
Reconciliation of GAAP to adjusted research and development:				
GAAP research and development	$ 524,896	$ 454,466	$ 1,006,783	$ 915,104
Less: Share-based compensation expenses	64,392	55,406	106,159	93,451
Less: Depreciation	16,447	16,551	35,372	33,704
Adjusted research and development	$ 444,057	$ 382,509	$ 865,252	$ 787,949
Reconciliation of GAAP to adjusted selling, general and administrative:				
GAAP selling, general and administrative	$ 537,913	$ 443,729	$ 997,201	$ 871,156
Less: Share-based compensation expenses	86,161	75,288	139,845	125,957
Less: Depreciation	10,086	4,519	20,162	9,131
Less: Amortization of intangibles	11	—	28	—
Adjusted selling, general and administrative	$ 441,655	$ 363,922	$ 837,166	$ 736,068
Reconciliation of GAAP to adjusted operating expenses				
GAAP operating expenses	$ 1,062,809	$ 898,195	$ 2,003,984	$ 1,786,260
Less: Share-based compensation expenses	150,553	130,694	246,004	219,408
Less: Depreciation	26,533	21,070	55,534	42,835
Less: Amortization of intangibles	11	—	28	—
Adjusted operating expenses	$ 885,712	$ 746,431	$ 1,702,418	$ 1,524,017
Reconciliation of GAAP to adjusted income (loss) from operations:				
GAAP income (loss) from operations	$ 87,885	$ (107,161)	$ 98,987	$ (368,509)
Plus: Share-based compensation expenses	150,553	130,694	246,004	219,408
Plus: Depreciation	29,854	23,754	61,468	47,864
Plus: Amortization of intangibles	5,760	1,177	6,950	2,360
Plus: Other	893	—	893	—
Adjusted income (loss) from operations	$ 274,945	$ 48,464	$ 414,302	$ (98,877)
Reconciliation of GAAP to adjusted net income (loss):				
GAAP net income (loss)	$ 94,320	$ (120,405)	$ 95,590	$ (371,555)
Plus: Share-based compensation expenses	150,553	130,694	246,004	219,408
Plus: Depreciation	29,854	23,754	61,468	47,864
Plus: Amortization of intangibles	5,760	1,177	6,950	2,360
Plus: Other	893	—	893	—
Plus: Impairment of equity investments	3,118	—	15,494	—
Plus: Discrete tax items	(14,210)	1,513	(8,737)	2,403
Plus: Income tax effect of non-GAAP adjustments	(17,466)	(13,439)	(28,703)	(23,082)
Adjusted net income (loss)	$ 252,822	$ 23,294	$ 388,959	$ (122,602)

Reconciliation of GAAP to adjusted EPS - basic				
GAAP earnings (loss) per share - basic	$ 0.07	$ (0.09)	$ 0.07	$ (0.27)
Plus: Share-based compensation expenses	0.11	0.10	0.18	0.16
Plus: Depreciation	0.02	0.02	0.04	0.04
Plus: Amortization of intangibles	0.00	0.00	0.00	0.00
Plus: Other	0.00	0.00	0.00	0.00
Plus: Impairment of equity investments	0.00	0.00	0.01	0.00
Plus: Discrete tax items	(0.01)	0.00	(0.01)	0.00
Plus: Income tax effect of non-GAAP adjustments	(0.01)	(0.01)	(0.02)	(0.02)
Adjusted earnings (loss) per share - basic	$ 0.18	$ 0.02	$ 0.28	$ (0.09)
Reconciliation of GAAP to adjusted EPS - diluted				
GAAP earnings (loss) per share - diluted	$ 0.06	$ (0.09)	$ 0.07	$ (0.27)
Plus: Share-based compensation expenses	0.10	0.09	0.17	0.16
Plus: Depreciation	0.02	0.02	0.04	0.04
Plus: Amortization of intangibles	0.00	0.00	0.00	0.00
Plus: Other	0.00	0.00	0.00	0.00
Plus: Impairment of equity investments	0.00	0.00	0.01	0.00
Plus: Discrete tax items	(0.01)	0.00	(0.01)	0.00
Plus: Income tax effect of non-GAAP adjustments	(0.01)	(0.01)	(0.02)	(0.02)
Adjusted earnings (loss) per share - diluted	$ 0.17	$ 0.02	$ 0.27	$ (0.09)
Reconciliation of GAAP to adjusted earnings (loss) per ADS - basic				
GAAP earnings (loss) per ADS - basic	$ 0.87	$ (1.15)	$ 0.89	$ (3.56)
Plus: Share-based compensation expenses	1.39	1.25	2.29	2.10
Plus: Depreciation	0.28	0.23	0.57	0.46
Plus: Amortization of intangibles	0.05	0.01	0.06	0.02
Plus: Other	0.01	0.00	0.01	0.00
Plus: Impairment of equity investments	0.03	0.00	0.14	0.00
Plus: Discrete tax items	(0.13)	0.01	(0.08)	0.02
Plus: Income tax effect of non-GAAP adjustments	(0.16)	(0.13)	(0.27)	(0.22)
Adjusted earnings (loss) per ADS - basic	$ 2.33	$ 0.22	$ 3.61	$ (1.17)
Reconciliation of GAAP to adjusted earnings (loss) per ADS - diluted				
GAAP earnings (loss) per ADS - diluted[1]	$ 0.84	$ (1.13)	$ 0.85	$ (3.56)
Plus: Share-based compensation expenses	1.34	1.23	2.20	2.10
Plus: Depreciation	0.27	0.22	0.55	0.46
Plus: Amortization of intangibles	0.05	0.01	0.06	0.02
Plus: Other	0.01	0.00	0.01	0.00
Plus: Impairment of equity investments	0.03	0.00	0.14	0.00
Plus: Discrete tax items	(0.13)	0.01	(0.08)	0.02
Plus: Income tax effect of non-GAAP adjustments	(0.16)	(0.13)	(0.26)	(0.22)
Adjusted earnings (loss) per ADS - diluted	$ 2.25	$ 0.22	$ 3.48	$ (1.17)

1. For the second quarter of 2024, GAAP diluted loss per ADS includes $0.02 loss per ADS attributable to the dilutive ADS outstanding for purposes of this reconciliation. As the Company was in a GAAP net loss position no diluted weighted average shares outstanding were calculated for US GAAP purposes.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Free Cash Flow (Non-GAAP):				
Net cash provided by (used in) operating activities (GAAP)	$ 263,598	$ (95,588)	$ 307,680	$ (404,160)
Less: Purchases of property, plant and equipment	(43,826)	(109,950)	(100,233)	(266,528)
Free Cash Flow (Non-GAAP)	$ 219,772	$ (205,538)	$ 207,447	$ (670,688)

Liquidity and Capital Resources

The following table represents our cash and debt balances as of June 30, 2025 and December 31, 2024:

	As of	
	June 30, 2025	December 31, 2024
	(dollars in thousands)	
Cash, cash equivalents and restricted cash	$ 2,786,086	$ 2,638,747
Total debt	$ 954,485	$ 1,018,013

To date, we have financed our operations and investments in long-term assets principally through proceeds from public and private offerings of our securities, proceeds from debt and our collaborations, and since the third quarter of 2024 cash flow from operations. Based on our current operating plan, we expect that our operating cash flows and existing cash and cash equivalents will enable us to fund our operating expenses and planned long-term investments 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 primarily incurred through various banks by both our subsidiaries and the Parent Company of $954.5 million as of June 30, 2025. We paid down $71.1 million of the debt in the six months ended June 30, 2025 using existing cash. The majority of those debt obligations, or approximately $672.3 million, owed by BeOne Medicines Ltd. mature 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 a consolidated basis.

On December 15, 2021, we completed our initial public offering on the STAR Market of the Shanghai Stock Exchange (the "STAR Offering"). 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 June 30, 2025, we had cash remaining related to the STAR Offering proceeds of $359.5 million.

The following table provides information regarding our cash flows for the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,	
	2025	2024
	(dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 2,638,747	$ 3,185,984
Net cash provided by (used in) operating activities	307,680	(404,160)
Net cash used in investing activities	(188,546)	(320,863)
Net cash provided by financing activities	1,248	185,310
Net effect of foreign exchange rate changes	26,957	(28,340)
Net increase (decrease) in cash, cash equivalents, and restricted cash	147,339	(568,053)
Cash, cash equivalents and restricted cash at end of period	$ 2,786,086	$ 2,617,931

Operating Activities

Cash provided by operating activities improved $711.8 million in the six months ended June 30, 2025, versus the prior year period due to our significantly improved revenue and $359.7 million of increase in gross margin in the current year period, offset by continued funding of our development pipeline and commercial operations, and increasing working capital to support our global expansion.

Investing Activities

Investing activities used $188.5 million of cash in the six months ended June 30, 2025, compared to $320.9 million in the prior year period due primarily to a decrease in capital expenditures, partially offset by an increase in acquired in-process research and development and regulatory milestone payments.

Financing Activities

Financing activities provided $1.2 million of cash in the six months ended June 30, 2025, compared to $185.3 million in the prior year period due primarily to a net reduction in debt borrowings in the current year period and higher payroll tax payments upon vesting of share-based compensation awards, partially offset by higher proceeds from option exercises and employee share purchase plan.

Our borrowing and repayment cycle is dictated by the short-term maturities of our debt and the ability to increase our borrowings, if necessary, is dependent on interest rates, credit spreads, bank lending capacity and other factors. We expect to repay approximately $808.4 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.

Effects of Exchange Rates on Cash

As noted above, we hold RMB denominated cash in our Parent Company (largely arising from the STAR Offering) and incur foreign currency gains or losses when remeasuring such cash to the U.S. dollar. In the six months ended June 30, 2025, we incurred realized gains on cash of $6.5 million that is included in the reconciling items between net income and net cash provided by operating activities on the consolidated statements of cash flows primarily related to the remeasurement of RMB denominated cash to USD. The RMB denominated cash in our Parent Company, however, is required to be used to fund RMB denominated expenditures and thus foreign currency gains or losses on such cash does not affect our ability to fund those expenditures.

We also have substantial operations in China and Europe, where the functional currency is the RMB and Euro, and as such the net cash flows are translated to the U.S. dollar for financial reporting. This process generates translation gains and losses primarily on RMB-denominated cash held in China and Euro-denominated cash held in Europe that are included in the effects of foreign exchange rate changes on the consolidated statements of cash flows, as such translation gains and losses are excluded from cash flows from operating, investing and financing activities.

Future Liquidity and Material Cash Requirements

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 cash on hand.

Contractual and Other Obligations

The following table summarizes our significant contractual obligations as of the payment due date by period as of June 30, 2025:

	Payments Due by Period		
	Total	Short Term	Long Term
	(dollars in thousands)		
Contractual obligations			
Operating lease commitments	$ 79,054	$ 10,608	$ 68,446
Purchase commitments	130,087	105,910	24,177
Debt obligations	954,485	808,394	146,091
Interest on debt	39,869	28,533	11,336
Co-development funding commitment	242,916	220,869	22,047
Funding commitment	6,740	2,298	4,442
Capital commitments	62,029	62,029	—
Total	$ 1,515,180	$ 1,238,641	$ 276,539

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 June 30, 2025, non-cancellable purchase commitments amounted to $130.1 million, of which $32.6 million related to minimum purchase requirements for supply purchased from contract manufacturers and $97.5 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 are $808.4 million. Total long-term debt obligations are $146.1 million. We have numerous financial and non-financial covenants on our debt obligations with various banks and other lenders. Some of these covenants include default and/or 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 June 30, 2025, we were in compliance with all covenants of our material debt agreements. See above regarding Liquidity and Capital Resources and Note 10 in the Notes to the Condensed Consolidated Financial Statements for further detail of our debt obligations.

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

Co-Development Funding Commitment

Under the Amgen collaboration, we are responsible for co-funding global development costs for the licensed Amgen oncology pipeline assets up to a total cap of $1.25 billion. We are funding our portion of the co-development costs by contributing cash and development services. As of June 30, 2025, our remaining co-development funding commitment was $242.9 million.

Funding Commitment

Funding commitment represents our committed capital related to equity investments. As of June 30, 2025, our remaining capital commitment was $6.7 million and is expected to be paid from time to time over the investment period.

Capital Commitments

We had capital commitments amounting to $62.0 million for the acquisition of property, plant and equipment as of June 30, 2025, related to various facilities across the globe, including the manufacturing and clinical R&D campus in Hopewell, New Jersey.

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies as of and for the three and six months ended June 30, 2025, as compared to those described in the section titled "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2024.

For new accounting policies adopted during the three and six months ended June 30, 2025, 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 $615.4 million of outstanding floating rate debt as of June 30, 2025. A 100-basis point increase in interest rates as of June 30, 2025 would increase our annual pre-tax interest expense by approximately $6.2 million.

Foreign Currency Exchange Rate Risk

China Exchange Rate Regime

RMB is not freely convertible into foreign currencies for capital account transactions. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. 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 appreciated approximately 1.9% in the six months ended June 30, 2025 and depreciated approximately 2.8% in the year ended December 31, 2024, 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.

Transactional Risk

We are exposed to foreign exchange risk arising from various currency exposures when we enter into transactions denominated in foreign currencies. Our reporting currency is the U.S. dollar, and our most significant functional currencies are the U.S. dollar and the RMB. A portion of our operating transactions and monetary assets and liabilities are in currencies other than the U.S. dollar and RMB, primarily the U.S. dollar against the RMB, Euro, and Australian dollar. During the six months ended June 30, 2025 and 2024, we recognized $6.5 million of foreign exchange gains and $13.5 million of foreign exchange losses, respectively, resulting from changes in the value of the U.S. Dollar compared to the RMB and the revaluation impact of RMB-denominated deposits held in U.S. dollar functional currency entities, including the Parent Company. As of June 30, 2025, the Parent Company held RMB-denominated deposits of $128.9 million. A hypothetical 10% appreciation in the U.S. dollar exchange rate compared with the RMB as of June 30, 2025 would have resulted in an increase in foreign exchange loss of approximately $11.7 million.

Translational Risk

We also face foreign currency exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period, primarily the RMB against the U.S. dollar. 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 reduce the effect of fluctuating currency exchange rates.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the six months ended June 30, 2025.

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 June 30, 2025, 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 June 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims of a nature considered ordinary course in our business, including the intellectual property litigation described herein. Most of the issues raised by such claims are highly complex and subject to substantial uncertainties. For a description of risks relating to these legal proceedings, see "Part II—Item 1A—Risk Factors" of this Quarterly Report, including the discussion under the heading 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., which subsequently changed its name to BeOne Medicines 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 (the "USPTO") that was later filed by the Company on November 1, 2023. On May 1, 2024, the USPTO granted the Company's PGR petition. On April 29, 2025, the USPTO issued a Final Written Decision ("FWD") that invalidated all challenged claims of the '803 patent. On May 29, 2025, Pharmacyclics filed a request for Director Review of the USPTO's FWD. On July 17, 2025, the USPTO denied Pharmacyclics' request.

AbbVie Litigation

On September 6, 2024, AbbVie Inc. filed a complaint in the U.S. District Court for the Northern District of Illinois against the Company, one of its wholly-owned subsidiaries and an individual scientist, alleging misappropriation of trade secrets concerning the Company's Bruton's tyrosine kinase ("BTK") degrader program, including the lead compound, BGB-16673. The complaint seeks an unspecified amount of monetary damages, declaratory judgment, restitution and other equitable remedies. The Company is vigorously defending against the claims and filed a motion to dismiss the complaint in its entirety on December 19, 2024.

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 on Form 10-Q (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, and 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 on page 1 hereof.

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, 2024 (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 U.S., 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 historically incurred significant net losses and may incur net losses in the future.
- 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, we may lose market exclusivities in our medicines.
- 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 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 U.S. or other governments and the significant oversight and discretion the PRC government has over the conduct of the business operations of our PRC subsidiaries may materially and adversely affect our business, financial condition, and results of operations and may result in our inability to sustain our growth and expansion strategies.
- The PRC government may intervene or influence our operations at any time, and has the ability to exert significant oversight and control over any offering of securities conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and 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.
- There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, and rules and regulations in China can change quickly with little advance notice.
- Filing or other procedures with the China Securities Regulatory Commission ("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.
- The trading prices of our ordinary shares, ADSs, and/or RMB Shares can be volatile, which could result in substantial losses to you.
- Your rights as a shareholder changed as a result of the Continuation.
- As a result of increased shareholder voting requirements following the Continuation, we have less flexibility with respect to certain aspects of capital management than previously.
- The Continuation has resulted in and may continue to result in additional direct and indirect costs.

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—U.S. 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.

On April 15, 2025, the Trump Administration published Executive Order 14273 (90 Fed. Reg. 16441), "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the U.S. Department of Health and Human Services to take steps to reduce drug prices. On May 12, 2025, the Administration published Executive Order 14297 (90 Fed. Reg. 20749), "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs certain executive officials to "communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations" and directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries."

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards and similar entities.

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 in China.

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 bidders who can satisfy the quality and quantity requirements, with price being a significant factor in the procurement decisions. 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 in China.

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, including tariffs that have been or may in the future be imposed by the U.S. or other countries, 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, and protectionist or retaliatory measures taken by the U.S. or China;
- economic weakness;
- compliance with tax, employment, immigration and labor laws for employees traveling internationally;
- 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;
- economic and political instability; and
- international military conflicts and related sanctions.

For example, in April 2025, the U.S. imposed tariffs on imports on its trading partners, including Canada, Mexico, the EU and China. While certain tariffs have been subsequently suspended, modified or temporarily reduced, we cannot predict the results of the U.S. government's trade negotiations or the outcome of ongoing legal challenges to specific tariff policies. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Furthermore, increased tariffs may make certain products no longer commercially viable. 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.

Furthermore, on April 1, 2025, the Bureau of Industry and Security of the U.S. Department of Commerce ("BIS") initiated an investigation into whether imports of pharmaceutical products present a risk to the national security of the U.S. This investigation could result in BIS recommending additional tariffs on imports of pharmaceutical products into the U.S. The scope or scale of any resulting tariffs could adversely impact our business.

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. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. From time to time, laws may be passed that significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

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—U.S. 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.

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 may also 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 U.S., 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 public health crisis, government shutdown, resource shortages 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. In 2022, the FDA deferred action on the BLA for TEVIMBRA® 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. In 2024, the FDA deferred approval for tislelizumab in first-line unresectable, recurrent, locally advanced, or metastatic ESCC on account of a delay in scheduling clinical site inspections.

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. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted.

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 on-site 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 jurisdictions.

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 our Annual 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. For example, in August 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. The IRA includes several provisions that may impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our medicines and drug candidates. For additional information, please see the section of our Annual Report titled "*Part I – Item 1 – Business – Government Regulation – U.S. Regulation – Healthcare Reform*."

Furthermore, the Creating and Restoring Equal Access to Equivalent Samples Act, requires sponsors of approved new drug applications and biologics license applications to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs and biosimilar biological products. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to respond to such requests or any legal challenges under this law, our business could be adversely impacted.

In addition, proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. For example, by Executive Order, the FDA works with states and Indian Tribes that propose to develop importation programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In January 2024, the FDA issued to Florida the first approval for a state importation plan and several states have pending applications with the FDA. If successfully implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. 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—U.S. Regulation—Healthcare Reform."

Furthermore, changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. We cannot predict the initiatives or changes that may be adopted in the future or the impact, if any, they may have on our business. 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 historically incurred significant net losses and may incur net losses in the future.

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 June 30, 2025 and December 31, 2024, we had an accumulated deficit of $8.5 billion and $8.6 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.

Although we expect to achieve positive GAAP operating income for full year 2025 as product sales growth exceeds expense growth, we may incur losses in the future. 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 any 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. To the extent 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 $0.1 billion, $1.2 billion and $1.5 billion of net cash during the years ended December 31, 2024, 2023 and 2022, respectively. Our operating activities provided approximately $308 million of net cash during the six months ended June 30, 2025 and used approximately $404 million of net cash during the six months ended June 30, 2024, respectively. We recorded negative net cash flows from operating activities in 2024, 2023 and 2022 primarily due to our net losses of $0.6 billion, $0.9 billion and $2.0 billion, respectively. We cannot assure you that we will be able to continue 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 and cash equivalents to meet our projected operating requirements for at least the next 12 months. However, our existing cash and cash equivalents and potential future 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 negative net cash flows and our 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 possibly 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.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy proposed or adopted by the PRC, Australia and other governments. It is difficult to predict how market forces or PRC, Australia, other governments outside the U.S. and U.S. government policies may impact the exchange rate of the RMB and the U.S. dollar or any other currencies in the future. There remains significant international pressure on China to adopt a more flexible currency policy, including from the U.S. government, which has threatened to label China as a "currency manipulator," which could result in greater fluctuation of the RMB against the U.S. dollar.

Substantially all of our revenues are denominated in U.S. dollars and RMB, our costs are denominated in U.S. dollars, Australian dollars and RMB, and a large portion of our financial assets and a significant portion of our debt is denominated in U.S. dollars and RMB. To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount we would receive.

In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to obtain approval from or registration with appropriate government authorities or designated banks before converting significant sums of foreign currencies into RMB. All of these factors could materially and adversely affect our business, financial condition, results of operations, and prospects, and could reduce the value of, and any dividends payable on, our shares in foreign currency terms.

****Our business, profitability and liquidity may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers or by actual events or concerns involving the liquidity, default, or non-performance of financial institutions, including the U.S. government, and an impairment in the carrying value of any 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 of 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 June 30, 2025, we had approximately $863.3 million invested in government money market funds. 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 no short-term investments, cash and cash equivalents of $2.8 billion and restricted cash of $30.0 million as of June 30, 2025, 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 June 30, 2025, we held no short-term investments. To the extent we invest in U.S. Treasury securities as short-term investments 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 responsible business and sustainability expectations or standards or achieve our corporate strategy goals could adversely affect our business, results of operations, financial condition or stock price.

There has been focus from global regulators and stakeholders on responsible business and sustainability matters, including greenhouse gas emissions and climate-related risks; human capital management; responsible sourcing and supply chain; human rights and social responsibility; and corporate governance and oversight. As part of our long-term strategy and in-line with safeguarding sustainable value growth, we actively manage these issues. We have identified key strategic priorities and set goals that reflect our current plans and aspirations and cannot guarantee that we will be able to achieve them. Evolving stakeholder expectations and our efforts and ability to manage these issues and 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 sustainability laws and reporting requirements and the related costs to comply with the emerging regulations. Our failure, or perceived failure, to achieve our sustainability goals or comply with sustainability-related 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 these sustainability issues.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our medicines and drug candidates, we may lose market exclusivities in our medicines.

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 in all countries worldwide could be prohibitively expensive. As the patent laws of different countries vary, our patent applications may not be granted in all countries and the issued patents may vary in scope and enforceability. In addition, different countries may provide varying regulatory exclusivities to pharmaceutical drugs, and some countries provide no regulatory exclusivities. Consequently, we may not have the same patent protection or exclusivities to our medicines or drug candidates in all countries worldwide. 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 expiration, 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 but not limited to 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, unenforceable or not infringed by a court or government patent authorities.***

Third parties may infringe, 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. The third parties may also 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. 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.

The scope, validity or enforceability of our or our collaborators' patents may be challenged in court or other authorities, and we or they may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. As such, any issued patents may not protect us from generic or biosimilar competition for these medicines. 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 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 alleging 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.

For example, on June 13, 2023, Pharmacyclics LLC ("Pharmacyclics") filed a complaint in the U.S. District Court for the District of Delaware against us and one of our subsidiaries, alleging that BRUKINSA infringes a Pharmacyclics' patent issued on June 13, 2023. For additional information on this litigation, please see the section of this Quarterly Report titled "Legal Proceedings". Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities.

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.

Even in the absence of litigation, we may seek to obtain licenses from third parties to mitigate freedom to operate risks and as a result, could impose costly royalty and other fees and expenses on us.

****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 others.***

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 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 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 our best 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 misappropriated trade secrets or other proprietary information, of any such employees' former employers. For example, in September 2024, AbbVie filed a lawsuit alleging misappropriation of certain trade secrets concerning our Bruton's tyrosine kinase degrader program, including lead compound BGB-16673. Defending against such claims, regardless of their merit, could result in substantial costs and be a distraction to management. If we fail in defending any such claims, we may need to pay monetary damages and lose valuable intellectual property rights and suffer reputational harm.

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 recently opened 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. In December 2024, we entered into a global licensing agreement with CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd. for a methionine adenosyltransferase 2A (MAT2A)-inhibitor being explored for solid tumors.

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 approved 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 BeOne. 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. 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 2024, we had approximately 10,500 employees, and we ended the year with over 11,000 employees, an increase of approximately 5%. As of the date of this Quarterly Report, we had over 11,000 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 have invested, and 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 and Chief Operating Officer; Aaron Rosenberg, our Chief Financial Officer; and the other principal members of our management and scientific teams play a critical role in the Company's operations 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 options, restricted share units and restricted shares that vest over time or are 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 Information Security Technology – Guideline for Identification of Critical Data, 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. The PRC Biosecurity Law establishes an integrated system to regulate biosecurity-related activities in China, including the security regulation of HGR and biological resources. The PRC Biosecurity Law for the first time expressly declared that China has sovereignty over its HGR and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese HGR by foreign entities in China. Although the Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives the National Health Commission, 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 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 recently opened our commercial-stage biologics manufacturing and clinical R&D center in New Jersey and a new small molecule manufacturing campus in Suzhou, China. These facilities may encounter unanticipated delays and expenses in startup operations due to a number of factors, including regulatory requirements. If 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, 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 cyberattacks, computer viruses, unauthorized access to systems and data, malicious internet-based activity, online and offline fraud, wrongful conduct by insider employees and vendors, denial-of-service attacks, ransomware attacks, business email compromises, social engineering (including phishing attacks), computer malware, malicious codes, wrongful intrusions, and other similar activities, as well as natural disasters, terrorism, war, and telecommunication and electrical failures, which can compromise the confidentiality, integrity and availability of the systems. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources. Although, to our knowledge, we have not experienced any material cyber incidents or data breaches 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, business email compromises, social engineering (including phishing attacks), 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. Like other companies in our industry, we, and our contractors and collaborators, have experienced and will continue to experience cybersecurity threats and incidents relating to our information technology systems and infrastructure, including malicious codes and viruses, phishing, email compromise attacks, ransomware, or other cyber-attacks. Such threats could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information and expose our confidential data. 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. 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.

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. 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 provide legal notifications and disclosures, as well as 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, data 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. Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

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.

A growing number of laws and regulations are being adopted which focus on enforcement efforts surrounding artificial intelligence and the use of such technologies in compliance with ethical standards and societal expectations. For example, the EU's Artificial Intelligence Act imposes significant obligations on providers and deployers of artificial intelligence systems, and encourages ethical principles in the development and use of these systems. Likewise, in the U.S., several states passed laws to regulate various uses of artificial intelligence. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of artificial intelligence in regulated sectors. The FDA, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. We currently use systems that incorporate artificial intelligence, and if we develop or continue to use artificial intelligence systems governed by these laws or regulations, we will need to apply significant resources to design, develop, test and maintain such systems in accordance with applicable law and regulation, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Additionally, our vendors may incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet regulatory standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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 privacy and 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), 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 transfer of, or access to, 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. For example, the U.S. Department of Justice ("the DOJ") issued regulations implementing Executive Order ("EO") 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," which became effective in April 2025 and prohibit certain transactions involving access to bulk sensitive data by countries of concern, such as China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela. For instance, the DOJ's regulations prohibit transactions involving human genomic data and biospecimens of more than 100 U.S. individuals, except where necessary for specified exempt activities, such as for regulatory approvals, clinical investigations in support of FDA applications, and post-marketing surveillance. 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 and corporate structures; 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; changes to vendors and other third parties that we work with; 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 and our ability to participate in certain government-supported programs. 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 collect and maintain de-identified or pseudonymized health data for clinical trials in compliance that 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. 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. Chinese authorities have issued guidance, regulations, and amendments that continue to evolve the required standard of security and potential liabilities for violations. For example, the Network Data Security Management Regulations issued in September 2024 impose detailed and prescriptive requirements for protecting network security. 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 (effective September 2022) and the Provisions on Promoting and Standardizing Cross-Border Data Flows (effective March 2024), which provide certain clarification and relaxation to the compliance mechanisms for cross-border transfer of personal information, and provide several exemptions from undergoing security assessment, obtaining personal information protection certification, or entering into prescribed agreement for cross-border transfer of personal information for businesses. The provisions also explicitly state that data processors are not required to conduct data security assessment for cross-border important data transfers if the concerning data has not been notified or published as important data by relevant departments or regions. 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; (iii) non-sensitive personal data of more than 1 million persons or sensitive personal data of more than 10,000 persons transferred overseas since January 1 of the current 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 as of February 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 State Council published the Administrative Regulations on Cyber Data Security ("Cyber Data Security Regulations", effective January 1, 2025), pursuant to which data processors are required to identify and report important data. Important data processors shall further adopt specific measures to secure the important data, such as designing the personnel and management institution responsible for the network data security, conducting risk assessment for the sharing, entrusted processing and joint processing of important data, and submit the annual risk assessment reports to competent authorities. Furthermore, data processors shall be subject to national security review if their cyber data processing activities affect or may affect national security.

There remain uncertainties as to how widespread the cybersecurity or national security 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 Quarterly 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" requiring us to go through the cybersecurity review procedures pursuant to the Revised Cybersecurity Review Measures or national security review under the 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 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 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, political uncertainty, 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, or if staffing changes prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, 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. Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The Trump Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies.

Furthermore, 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 compliant 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, which 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 a 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 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 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 is 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.

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 U.S. or other governments and the significant oversight and discretion the PRC government has over the conduct of the business operations of our PRC subsidiaries may materially and adversely affect our business, financial condition, and results of operations and may result in our inability to sustain our growth and expansion strategies.

Due to our operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC or changes in government relations between China and the 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, regulation of foreign exchange and allocation of resources. 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 regulation over 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 may intervene or influence our operations at any time, and has the ability to exert significant oversight and control over any offering of securities conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and 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 Chinese government may intervene or influence our operations at any time, or may exert control over operations of our business, which could result in a material change in our operations and/or the value of our securities. Any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers 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 be worthless.

For example, the PRC government has indicated its intent to exert more oversight and control 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 control or influence 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 result in a material change in our operations, and could also 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.

Additionally, 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. Therefore, investors of our company face potential uncertainty from actions taken by the government authorities affecting our business. Any intervention by the PRC government in our operations could undermine our business plan and cause the value of an investment in the Company to significantly decline or become worthless.

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.

The Holding Foreign Companies Accountable Act (as amended, the "HFCAA") provides that if the SEC determines an issuer has filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for two consecutive years beginning in 2021, the SEC shall prohibit that issuer's 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.

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 those thereafter. 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 HFCAA. Given that Ernst and Young LLP (U.S.) has served as the principal accountant to audit our consolidated financial statements since 2022, we believe this should preclude the delisting of our ADSs from Nasdaq under HFCAA.

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, and rules and regulations in China can change quickly with little advance notice.

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 with little advance notice. 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 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 significant 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, 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 U.S. may not be efficient in the absence of a mutual and practical cooperation mechanism. For risks associated with investing in us as a Swiss company, see the risk factor titled *"As we are now a Swiss company, our shareholders have broader rights in certain aspects than they would have under Hong Kong law, Chinese law, U.S. law, or previously applicable Cayman Islands law. While these enhanced rights offer increased shareholder participation, our flexibility to swiftly implement certain initiatives or strategies may be limited, and situations may arise where greater flexibility could otherwise provide meaningful benefits to our shareholders."*

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 significant 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 and significant 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 there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, 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, requiring Chinese companies that have already directly or indirectly offered and listed securities in overseas markets to fulfill their filing obligations and report relevant information to the CSRC within three working days after conducting a follow-on offering of equity securities on the same overseas market. The Overseas Listing Trial Measures, the relevant guidelines and their implementation may continue to evolve. 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 Quarterly 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 Switzerland, 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 June 30, 2025 and December 31, 2024, these restricted assets totaled $1.9 billion and $1.7 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, 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 in 2016, 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 BeOne Medicines (Hong Kong) Co., Limited ("BeOne HK"), a company incorporated under the laws of Hong Kong on November 22, 2010 and a wholly-owned subsidiary of the Company. BeOne 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 BeOne Medicines 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 BeOne Medicines 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 Swiss 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 U.S., 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 “ONC”, 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/or reputational harm 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 August 1, 2025, 1,430,372,987 ordinary shares, par value $0.0001 per share, were outstanding, of which 709,335,614 ordinary shares were held in the form of 54,564,278 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, as amended by the Post-Effective Amendment No. 1 filed with the SEC on May 27, 2025, registering 183,209,748 ordinary shares, including 128,104,537 ordinary shares in the form of 9,854,195 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 ordinary shares maintained on our Swiss share register in Switzerland and Hong Kong share 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 securities from one or more of the stock exchanges where they are currently traded, subject to our shareholders' approval if required. We cannot predict the effect such delisting of our securities from one or more of the stock exchanges would have on the market price of our securities on the other stock exchanges. Additionally, the listing and trading of our equity securities in multiple jurisdictions and multiple markets have 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. In addition, we may be subject to securities litigation filed with the courts in China by investors with respect to RMB Shares traded on the STAR Market.

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

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

Any future distribution of dividends will be subject to approval by shareholders at a general meeting based on a proposal by the board of directors in accordance with Swiss law. The proposal by the board of directors to shareholders to approve a declaration of a dividend will depend, among other things, upon then existing conditions, including our financial condition, results of operations, contractual and other relevant legal or regulatory restrictions, capital requirements, business prospects and other factors deemed relevant by our board of directors.

Even if our board of directors decides to propose to shareholders to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend, among other things, on 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. In addition, payment of future dividends, if any, is subject to certain limitations pursuant to Swiss law or by our articles of association. Accordingly, the return on your investment in our ordinary shares, ADSs and/or RMB Shares will likely depend entirely upon any future price appreciation of our ordinary shares, ADSs and/or RMB Shares. There is no guarantee that our ordinary shares, ADSs and/or RMB Shares will appreciate in value or even maintain the price at which you purchased our ordinary shares, ADSs and/or RMB Shares. You may not realize a return on your investment in our ordinary shares, ADSs and/or RMB Shares and you may even lose your entire investment in our 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 our 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 our ordinary shares, ADSs and/or RMB Shares or publishes inaccurate or unfavorable research about our business, the market price for our 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 our ordinary shares, ADSs and/or RMB Shares to decline significantly.

****As we are now a Swiss company, our shareholders have broader rights in certain aspects than they would have under Hong Kong law, Chinese law, U.S. law, or previously applicable Cayman Islands law. While these enhanced rights offer increased shareholder participation, our flexibility to swiftly implement certain initiatives or strategies may be limited, and situations may arise where greater flexibility could otherwise provide meaningful benefits to our shareholders.***

We are now a corporation (*Aktiengesellschaft*) organized under Swiss law. Our corporate affairs are governed by our Swiss articles of association (as may be amended from time to time) (the "Swiss Articles"), our organizational regulations (as may be amended from time to time), and the laws of Switzerland, in particular the Swiss Code of Obligations (*Obligationenrecht*).

Under Swiss law, shareholder rights are broader than those under Cayman Islands law previously applicable to us before the Continuation. For example, shareholder approval is required for all dividend distributions, subject to the Company having sufficient distributable reserves. The board of directors cannot unilaterally declare dividends, unlike under Hong Kong, Delaware, or Cayman Islands law, which give the board of directors discretion to directly declare dividends, providing more flexibility.

Furthermore, under Swiss law, a staggered or classified board is not permitted and all directors are elected annually, which could increase board turnover and potentially reduce continuity and stability in management. Under Hong Kong, Delaware, and Cayman Islands law, staggered boards are allowed, which may provide greater stability. These and other Swiss law requirements could limit our flexibility to swiftly implement certain initiatives or strategies that could otherwise provide meaningful benefits to our shareholders.

****As we are a Swiss company, our shareholders may face difficulties in enforcing their interests.***

As we are a Swiss company, our shareholders 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 Swiss 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 Switzerland and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. Swiss courts may recognize judgments obtained in the U.S., Hong Kong, or mainland China under certain conditions, but may not fully enforce punitive damages awarded.

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 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 or an extraordinary general meeting is 21 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 Swiss Articles include provisions that could limit the ability of others to acquire control of our Company, which 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, in new share issuances, our board of directors has the authority, without further action by our shareholders, to limit or withdraw subscription rights of existing shareholders and allocate such rights to third parties, the Company, or its group companies for various reasons, including raising equity capital quickly, acquiring enterprises or products, expanding the shareholder base, or defending against a takeover bid.

Further, our Swiss Articles require a majority of all shares entitled to vote at the relevant general meeting of shareholders to pass resolutions on the removal of board members during their one-year term of office. This threshold makes it difficult for a potential acquirer to remove existing directors during their one-year term and replace them with their own nominees.

Our Swiss Articles designate specific courts as the exclusive forum for any disputes that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us, our directors, officers, or other employees.

Our Swiss Articles provide that our place of incorporation in Basel, Switzerland, will be the exclusive forum for any disputes arising under, out of, in connection with, or related to the corporate relationship. As a result, any derivative action or proceeding brought on behalf of us asserting a claim of breach of a fiduciary duty owed by any director or officer of us to the Company and our shareholders, can only be brought in the courts of Basel, Switzerland. Our Swiss Articles 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 bound by 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.

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, registration of ADS transfers, conversion of ADSs of one series for ADSs of another series, 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 37% of our outstanding ordinary shares as of August 1, 2025. 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" (a "PFIC") for any taxable year if either (1) 75% or more of its gross income consists of certain types of passive income or (2) 50% or more of the average quarterly value of its assets during such year produce or are held for the production of passive income. Based upon the composition of our income and assets, we believe that we were not a PFIC for the taxable year ended December 31, 2024. 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.

Risks Related to Our Continuation to Switzerland

****Your rights as a shareholder changed as a result of the Continuation.***

Effective May 27, 2025, we changed our jurisdiction of incorporation from the Cayman Islands to Switzerland through a transaction known as a continuation under Section 206 of the Companies Act (as amended) of the Cayman Islands and Article 161 of the Swiss Federal Code on Private International Law (such transaction, the "Continuation"). Because of differences in Swiss law and Cayman Islands law and certain changes that were made to our governing documents in connection with the Continuation, your rights as a shareholder have changed. For a description of these differences, see "Proposal No. 1: Approval of the Continuation — Comparison of Shareholder Rights" in the proxy statement/prospectus filed with the SEC on March 10, 2025.

As a result of increased shareholder voting requirements following the Continuation, we have less flexibility with respect to certain aspects of capital management than previously.

Under Cayman Islands law, our directors were permitted to issue, without shareholder approval, any ordinary shares authorized in our then-effective amended and restated articles of association that were not issued or reserved. In addition, our board of directors had the right, subject to statutory limitations, to declare and pay dividends on our ordinary shares without a shareholder vote.

Under our Swiss Articles, our shareholders pre-authorized our board of directors to issue new registered shares of the Company for general corporate purposes based on the capital band, and for convertible instruments and long-term incentive plan purposes based on conditional capital, in each case without additional shareholder approval. However, the shareholder authorization for general corporate purposes based on the capital band must be renewed by the shareholders at least every five years, and both the authorizations under the capital band and the conditional capital are limited to 50% of a company's stated capital. Swiss law also reserves for approval by shareholders many corporate actions over which our board of directors previously had authority under Cayman Islands Law. For example, dividends must be approved by shareholders. While we do not believe that the differences between Cayman Islands law and Swiss law relating to our capital management will have an adverse effect on our Company, we cannot assure you that situations will not arise where such flexibility would have provided substantial benefits to our shareholders.

The Continuation has resulted in and may continue to result in additional direct and indirect costs.

The Continuation has resulted in and may continue to result in additional direct costs. Following the Continuation, we expect to hold a large portion of meetings of our board of directors and management strategy meetings as well as our annual general meetings in Basel. We also plan to continue expanding our physical presence in Switzerland. With that, we will further strengthen our presence in Switzerland. We will incur additional costs and expenses, primarily Swiss tax and professional fees, to comply with Swiss corporate and tax laws. We may continue to experience indirect costs if management and employees' attention is diverted from our business or if the administrative complexity associated with the new structure leads to increased administrative costs and expenses.

If you fail to make a required tax filing, the Continuation could result in adverse tax consequences for you.

Depending on your circumstances, you may be required to make a filing with the U.S. Internal Revenue Service or your respective tax authority, as a result of the change of our place of incorporation. Failure to make this filing on a timely basis could result in your owing taxes because of the change, even though you will not have realized any income or liquidity as a result of the change. For a more detailed description of the tax consequences associated with this transaction, please read "Proposal No. 1: Approval of the Continuation — Material Tax Considerations — United States Tax Considerations" in the proxy statement/prospectus filed with the SEC on March 10, 2025.

You may be subject to Swiss withholding taxes on the payment of dividends.

Under current Swiss law, distributions made out of capital contribution reserves recognized by the Swiss Federal Tax Administration or made in the form of a par value reduction are not subject to Swiss withholding tax. We had qualifying capital contribution reserves in the amount of approximately US$11-12 billion available for distribution not subject to Swiss withholding tax as of the effective date of the Continuation. However, there can be no assurances that the Swiss withholding rules will not be changed in the future or that shareholders will approve a distribution out of qualifying capital contribution reserves recognized by the Swiss Federal Tax Administration. Further, over the long term, the amount of qualifying contribution reserves available may be limited. If we are unable to make a distribution out of qualifying capital contribution reserves, then any dividends paid will generally be subject to a Swiss withholding tax at a rate of 35%. The withholding tax must be withheld from the gross distribution and paid to the Swiss Federal Tax Administration. A U.S. holder that qualifies for benefits under the Convention between the U.S. and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, (the "U.S.-Swiss Treaty"), may apply for a refund of the tax withheld in excess of the 15% treaty rate (or for a full refund in case of qualified pension funds or a refund in excess of the 5% treaty rate if you are a corporate shareholder that directly holds at least 10% of our capital). A China Holder that qualifies for benefits under the Agreement between the Government of the People's Republic of China and the Swiss Federal Council for the Avoidance of Double Taxation with Respect to Taxes on Income and on Capital ("PRC-Swiss Treaty") may apply for a refund of the tax withheld in excess of the 10% or 5% treaty rate (as applicable). A Hong Kong shareholder that qualifies for benefits under the Agreement between the Government of the Hong Kong Special Administrative Region of the People's Republic of China and the Swiss Federal Council for the Avoidance of Double Taxation with respect to Taxes on Income ("Hong Kong-Swiss Treaty") may apply for a refund of the tax withheld in excess of the 10% treaty rate (or a full refund in case of specific qualified persons, including, a pension fund, or a corporate shareholder that directly holds at least 10% our capital). Subject to applicable laws and regulations, this may also apply to other shareholders that are entitled to a dividend withholding tax rate lower than the Swiss withholding tax rate under the tax treaties between the shareholders' own tax residency jurisdictions and Switzerland. Switzerland currently has concluded more than 100 tax treaties with the same treatment regarding the refund of Swiss withholding taxes.

Under current Swiss law, repurchases of shares for the purposes of capital reduction are treated as a partial liquidation subject to 35% Swiss withholding tax on the difference between the par value plus qualifying capital contributions reserves and the repurchase price, irrespective of the tax residency of the shareholder. The repurchase of shares for purposes other than capital reduction, such as to retain as treasury shares for use in connection with equity incentive plans, convertible debt, similar instruments or acquisitions, will not be subject to the 35% Swiss withholding tax, irrespective of the tax residency of the shareholder, provided the total treasury shares do not exceed 10% or 20% (as applicable) of the share capital. Any portion of the repurchase price attributable to par value or qualifying capital contribution reserves recognized by the Swiss Federal Tax Administration will not be subject to the 35% Swiss withholding tax. See "Proposal No. 1: Approval of the Continuation — Material Tax Considerations — Taxation of Shareholders Subsequent to the Continuation — Swiss Taxation" in the proxy statement/prospectus filed with the SEC on March 10, 2025.

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	Duration of Trading	Aggregate Number of Securities
Chan Lee *(Senior Vice President, General Counsel)*	Adoption *(May 14, 2025)*	Rule 10b5-1 trading arrangement	Sale	August 13, 2026	Up to 36,671 ADSs plus an additional number of ADSs subject to restricted share units ("RSUs") equal to the net number of ADSs resulting from applicable RSU vestings after sell-to-cover for withholding tax.
Dr. Xiaobin Wu *(President, Chief Operating Officer)*	Modification *(May 14, 2025)*	Rule 10b5-1 trading arrangement	Sale	August 13, 2026	Up to 89,794 ADSs.

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
3.1	Articles of Association of BeOne Medicines Ltd., effective May 27, 2025.		8-K12G3 (Exhibit 3.1)	5/27/2025	000-56752
3.2	Organizational Regulations of BeOne Medicines Ltd., effective May 27, 2025.		8-K12G3 (Exhibit 3.2)	5/27/2025	000-56752
4.1.1	Amended and Restated Deposit Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A., and the Form of American Depositary Receipt thereunder.		8-K12G3 (Exhibit 4.1.1)	5/27/2025	000-56752
.2	Form of American Depositary Receipt under the Amended and Restated Deposit Agreement (included in Exhibit 4.1.1)		8-K12G3 (Exhibit 4.1.2)	5/27/2025	000-56752
.3	Amended and Restated Restricted ADS Letter Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A.		8-K12G3 (Exhibit 4.1.3)	5/27/2025	000-56752
.4	Amended and Restated Letter Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A.		8-K12G3 (Exhibit 4.1.4)	5/27/2025	000-56752
.5	Amended and Restated Supplemental Letter Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A.		8-K12G3 (Exhibit 4.1.5)	5/27/2025	000-56752
10.1#	Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and John V. Oyler.		8-K12G3 (Exhibit 10.1)	5/27/2025	000-56752
10.2#	Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines (Beijing) Co., Ltd. and Xiaobin Wu.		8-K12G3 (Exhibit 10.2)	5/27/2025	000-56752
10.3#	Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and Aaron Rosenberg.		8-K12G3 (Exhibit 10.3)	5/27/2025	000-56752
10.4#	Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines (Shanghai) Co., Ltd. and Lai Wang.		8-K12G3 (Exhibit 10.4)	5/27/2025	000-56752
10.5#	Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and Chan Lee.		8-K12G3 (Exhibit 10.5)	5/27/2025	000-56752
10.6#	Form of Indemnification Agreement, entered into between the Company and its directors and officers.		8-K12G3 (Exhibit 10.6)	5/27/2025	000-56752
10.7#	Consulting Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and Xiaodong Wang.		8-K12G3 (Exhibit 10.7)	5/27/2025	000-56752

Exhibit No.	Exhibit Description	Filed/Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File / Reg. Number
10.8#	Independent Non-Executive Director Compensation Policy, as amended		POS AM No. 1 to Registration Statement on Form S-4 (Exhibit 10.10)	5/27/2025	333-281324
10.9#	2011 Option Plan, as amended and form of option agreement thereunder		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.1)	5/27/2025	333-279980
10.10#	Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.1)	5/27/2025	333-279980
10.11#	Form of Global Performance Share Unit Award Agreement for Employees under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.2)	5/27/2025	333-279980
10.12#	Form of Global Restricted Share Unit Award Agreement for Non-Employee Directors under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.3)	5/27/2025	333-279980
10.13#	Form of Global Restricted Share Unit Award Agreement for Employees under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.4)	5/27/2025	333-279980
10.14#	Form of Global Restricted Share Unit Award Agreement for Consultants under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.5)	5/27/2025	333-279980
10.15#	Form of Global Non-Qualified Share Option Agreement for Employees under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.6)	5/27/2025	333-279980
10.16#	Form of Global Non-Qualified Share Option Agreement for Non-Employee Directors under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.9)	8/2/2023	001-37686
10.17#	Form of Global Non-Qualified Share Option Agreement for Non-Employee Consultants under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.8)	5/27/2025	333-279980
10.18#	Fifth Amended and Restated 2018 Employee Share Purchase Plan	X			
10.19	Letter Agreement, dated May 9, 2025, Regarding the Collaboration Agreement, dated October 31, 2019, by and between BeiGene Switzerland GmbH and Amgen Inc.	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			

Exhibit No.	Exhibit Description	Filed/Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File / Reg. Number
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			

* Furnished herewith.

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

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.

BEONE MEDICINES LTD.

Date: August 6, 2025

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

Date: August 6, 2025

By: /s/ Aaron Rosenberg
Aaron Rosenberg
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.18

BEONE MEDICINES LTD.

FIFTH AMENDED AND RESTATED 2018 EMPLOYEE SHARE PURCHASE PLAN

The purpose of the BeOne Medicines Ltd. Fifth Amended and Restated 2018 Employee Share Purchase Plan (the "Plan") is to provide the Participants (as defined in Section 1) with opportunities to purchase Shares (either in the form of Ordinary Shares or ADSs).

The Plan includes two components: a Code Section 423 component (the "423 Component") and a non-Code Section 423 component (the "Non-423 Component"). The 423 Component is intended to constitute an "employee stock purchase plan" within the meaning of Section 423(b) of the United States Internal Revenue Code of 1986, as amended (the "Code"), and the 423 Component shall be interpreted in accordance with that intent. Under the Non-423 Component, which does not qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code, Options may be granted pursuant to any rules, procedures, agreements, appendices or sub-plans adopted by the Administrator in offering the Plan to eligible employees participating in the Non-423 Component. Except as otherwise provided herein or by the Administrator, the Non-423 Component will operate and be administered in the same manner as the 423 Component. For avoidance of doubt, up to the maximum number of Shares reserved under the Plan may be used to satisfy purchases of Shares under the 423 Component and any remaining portion of such maximum number of Shares may be used to satisfy purchases of Shares under the Non-423 Component.

Unless otherwise defined herein, capitalized terms in this Plan shall have the same meaning ascribed to them in Section 1.

1. Definitions.

The term "ADSs" means American depositary shares. Each ADS represents 13 Ordinary Shares.

The term "Change in Control" means (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding Shares immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding Shares or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Shares of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

The term "Compensation" means the amount of base pay (including overtime and commissions, to the extent determined by the Administrator), prior to salary reduction pursuant to Sections 125, 132(f) or 401(k) of the Code, but excluding incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances or travel expenses, income or gains on the exercise of Company share options, and similar items. The Administrator shall have the discretion to determine the application of this definition to Participants outside the United States.

The term "Designated Subsidiary" means any present or future Subsidiary (as defined below) that has been designated by the Administrator to participate in the Plan. The Administrator may so designate any Subsidiary, or revoke any such designation, at any time and from time to time, either before or after the Plan is approved by the shareholders and may further designate such Subsidiaries or Participants as participating in the 423 Component or Non-423 Component. The Administrator also may determine which Subsidiaries or eligible employees may be excluded from participation in the Plan, to the extent consistent with Section 423 of the Code and Section 16 below or as implemented under the Non-423 Component, and determine which Designated Subsidiary or Subsidiaries will participate in separate Offerings; provided, that unless otherwise specified by the Administrator, each Offering to the Eligible Employees of the Company or a Designated Subsidiary will be deemed a separate Offering for purposes of Section 423 of the Code (the terms of which Offering under the Non-423 Component need not be identical). With respect to Offerings under the 423 Component, the terms of separate Offerings need not be identical provided that all Eligible Employees granted Options in a particular Offering will have the same rights and privileges, except as otherwise may be permitted by Code Section 423; an Offering under the Non-423 Component need not satisfy such requirements. At any time, a Subsidiary that is a Designated Subsidiary under the 423 Component will not be a Designated Subsidiary under the Non-423 Component.

The term "Fair Market Value of the Shares" on any given date means the fair market value of the Shares determined in good faith by the Administrator; provided, however, that if the ADSs are admitted to quotation on the National Association of Securities Dealers Automated Quotation System ("NASDAQ"), NASDAQ Global Market or another national securities exchange, the determination shall be made by reference to the closing price on such date. If there is no closing price for such date, the determination shall be made by reference to the last date preceding such date for which there is a closing price.

The term "Hong Kong Listing Rules" means the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended from time to time.

The term "Ordinary Shares" means the ordinary registered shares of the Company (including Treasury Shares).

The term "Parent" means a "parent corporation" with respect to the Company, as defined in Section 424(e) of the Code.

The term "Participant" means an individual who is eligible as determined in Section 5 and who has complied with the provisions of Section 6.

The term "Shares" means the Ordinary Shares or ADSs, as the context so requires.

The term "Subsidiary" means a "subsidiary corporation" with respect to the Company, as defined in Section 424(f) of the Code.

The term "Treasury Shares" means Shares held by the Company or any of its Subsidiaries (or an agent or nominee on behalf of the Company or a Subsidiary, as the case may be) in treasury, including, but not limited to, as a result of a repurchase of Shares on the open market or the issuance by the Company of new Shares to a Subsidiary, agent or nominee to be held on behalf of the Company or a Subsidiary).

2. *Administration.* The Plan will be administered by the person or persons (the "Administrator") appointed by the Company's Board of Directors (the "Board") for such purpose. The Administrator has authority at any time to: (i) adopt, alter and repeal such rules, guidelines and practices for the administration of the Plan and for its own acts and proceedings as it shall deem advisable; (ii) interpret the terms and provisions of the Plan; (iii) make all determinations it deems advisable for the administration of the Plan; (iv) decide all disputes arising in connection with the Plan; (v) implement any procedures, steps, additional or different requirements as may be necessary to accommodate the specific requirements of local laws, regulations and procedures for jurisdictions in which the Plan is offered, including, without limitation, the laws of the People's Republic of China (the "PRC"), Switzerland and the other countries in which the Company operates, that may be applicable to this Plan, any Options or any related documents; and (vi) otherwise supervise the administration of the Plan, in its sole and absolute discretion and taking into account any matters in its sole and absolute discretion. All interpretations and decisions of the Administrator shall be binding on all persons, including the Company and the Participants. No member of the Board or individual exercising administrative authority with respect to the Plan shall be liable for any action or determination made in good faith with respect to the Plan or any Option granted hereunder.

3. *Scheme mandate limit.* The maximum number of Shares which may be issued pursuant to all Options to be granted under the Plan shall be 5,989,678 Shares (the "Scheme Mandate Limit"), being approximately 0.44% of the issued share capital of the Company (excluding Treasury Shares) as at June 5, 2024, being the effective date of the shareholder approval of the fourth amended and restated Plan (the "Amended Effective Date"). Over the lifetime of the Plan, a total of 12,425,315 ordinary shares have been authorized.

The total number of Shares which may be issued in respect of all Options and awards to be granted under the Plan under the Scheme Mandate Limit and any other plans of the Company shall not exceed 10% of the Shares in issue (excluding Treasury Shares) as at the Amended Effective Date.

4. *Offerings.* The Company will make one or more offerings to eligible employees to purchase Shares under the Plan ("Offerings"). Unless otherwise determined by the Administrator, an Offering will begin on the first business day occurring on or after each March 1 and September 1 and will end on the last business day occurring on or before the following February 28 (or February 29, if applicable) and August 31, respectively. The Administrator may, in its discretion, designate a different period for any Offering, provided that no Offering shall exceed 27 months in duration.

5. *Eligibility.* All individuals classified as employees on the payroll records of the Company and each Designated Subsidiary (the "Participants") are eligible to participate in any one or more of the Offerings under the Plan, provided that, unless otherwise determined by the Administrator, as of the first day of the applicable Offering (the "Offering Date") they are employed by the Company or a Designated Subsidiary and have been employed as of the commencement of the enrollment period for such Offering. Participation shall not otherwise be subject to any minimum performance targets. Notwithstanding any other provision herein, individuals who are not classified as employees of the Company or a Designated Subsidiary for purposes of the Company's or applicable Designated Subsidiary's payroll system as of the Offering Date are not considered to be eligible employees of the Company or any Designated Subsidiary and shall not be eligible to participate in the Plan. In the event any such individuals are reclassified as employees of the Company or a Designated Subsidiary for any purpose, including, without limitation, common law or statutory employees, by any action of any third party, including, without limitation, any government agency, or as a result of any private lawsuit, action or administrative proceeding, such individuals shall, notwithstanding such reclassification, remain ineligible for participation. Notwithstanding the foregoing, the exclusive means for individuals who are not classified as employees of the Company or a Designated Subsidiary on the Company's or Designated Subsidiary's payroll system as of the Offering Date to become eligible to participate in this Plan is through an amendment to this Plan, duly executed by the Company, which specifically renders such individuals eligible to participate herein.

6. Participation

(a) An eligible employee who is not a Participant in any prior Offering may participate in a subsequent Offering by submitting an enrollment form to the Company at least 15 business days before the Offering Date (or by such other deadline as shall be established by the Administrator for the Offering).

(b) *Enrollment.* The enrollment form (which may be in an electronic format or such other method as determined by the Company in accordance with the Company's practices) will (i) state a whole percentage or the amount to be deducted from an eligible employee's Compensation (as defined in Section 1) per pay period, (ii) authorize the purchase of Shares in each Offering in accordance with the terms of the Plan, (iii) specify the exact name or names in which Shares purchased for such individual are to be issued pursuant to Section 13, and (iv) provide such other terms as required by the Company. An employee who does not enroll in accordance with these procedures will be deemed to have waived the right to participate. Unless a Participant files a new enrollment form or withdraws from the Plan, such Participant's deductions and purchases will continue at the same percentage or amount of Compensation for future Offerings, provided he or she remains eligible.

(c) Notwithstanding the foregoing, participation in the Plan will neither be permitted nor be denied contrary to the requirements of the Code.

7. Employee Contributions. Each eligible employee may authorize payroll deductions from his or her after-tax Compensation at a minimum of 1 percent up to a maximum of 10 percent of such employee's Compensation for each pay period. The Company will maintain book accounts showing the amount of payroll deductions made by each Participant for each Offering. No interest will accrue or be paid on payroll deductions, except as may be required by applicable law. If payroll deductions for purposes of the Plan are prohibited or otherwise problematic under applicable law (as determined by the Administrator in its sole discretion), the Administrator may require Participants to contribute to the Plan by such other means as determined by the Administrator, to the extent permitted under Section 423 of the Code with respect to the 423 Component. Any reference to "payroll deductions" in this Section 7 (or in any other sections of this Plan) will similarly cover contributions by other means made pursuant to this Section 7.

8. Deduction Changes. Except as may be determined by the Administrator in advance of an Offering, a Participant may not increase or decrease his or her payroll deduction during any Offering, but may increase or decrease his or her payroll deduction with respect to the next Offering (subject to the limitations of Section 7) by filing a new enrollment form at least 15 business days before the next Offering Date (or by such other deadline as shall be established by the Administrator for the Offering). The Administrator may, in advance of any Offering, establish rules permitting a Participant to increase, decrease or terminate his or her payroll deduction during an Offering.

9. Withdrawal. A Participant may withdraw from participation in the Plan by delivering a written notice of withdrawal to the Company. The Participant's withdrawal will be effective as of the next business day, or as soon as practicable thereafter. Following a Participant's withdrawal, the Company will promptly refund such individual's entire account balance under the Plan to him or her (after payment for any Shares purchased before the effective date of withdrawal). Partial withdrawals are not permitted. Such an employee may not begin participation again during the remainder of the Offering, but may enroll in a subsequent Offering in accordance with Section 6.

10. *Grant of Options.* On each Offering Date, the Company will grant to each eligible employee who is then a Participant in the Plan an option ("Option") to purchase on the last day of such Offering (the "Exercise Date"), at the Option Price hereinafter provided for, the lowest of (a) a number of Shares determined by dividing such Participant's accumulated payroll deductions on such Exercise Date by the lower of (i) 85 percent of the Fair Market Value of the Shares on the Offering Date, or (ii) 85 percent of the Fair Market Value of the Shares on the Exercise Date, (b) a number of Shares determined by multiplying $2,083 by the number of full months in the Offering and dividing the result by the Fair Market Value on the Offering Date; or (c) such other lesser maximum number of Shares as shall have been established by the Administrator in advance of the Offering; provided, however, that such Option shall be subject to the limitations set forth below. Each Participant's Option shall be exercisable only to the extent of such Participant's accumulated payroll deductions on the Exercise Date. The purchase price for each Share purchased under each Option (the "Option Price") will be 85 percent of the Fair Market Value of the Shares on the Offering Date or the Exercise Date, whichever is less.

Notwithstanding the foregoing, no Participant may be granted an Option hereunder if such Participant, immediately after the Option was granted, would be treated as owning Shares possessing 5% or more of the total combined voting power or value of all classes of share capital of the Company or any Parent or Subsidiary (as defined in Section 1). For purposes of the preceding sentence, the attribution rules of Section 424(d) of the Code shall apply in determining the share ownership of a Participant, and all Shares which the Participant has a contractual right to purchase shall be treated as Shares owned by the Participant. In addition, no Participant may be granted an Option which permits his or her rights to purchase Shares under the Plan, and any other employee share purchase plan of the Company and its Parents and Subsidiaries, to accrue at a rate which exceeds $25,000 of the fair market value of such Shares (determined on the option grant date or dates) for each calendar year in which the Option is outstanding at any time. The purpose of the limitation in the preceding sentence is to comply with Section 423(b)(8) of the Code and shall be applied taking Options into account in the order in which they were granted. Furthermore, unless approved by the Company's shareholders in a general meeting, the total number of Ordinary Shares issued and to be issued upon the exercise of Options and awards granted and to be granted under the Plan and any other plan of the Company to a Participant within any 12-month period shall not exceed 1% of the Ordinary Shares of the Company in issue (excluding Treasury Shares) at the date of any grant.

11. *Exercise of Option and Purchase of Shares.* Each employee who continues to be a Participant in the Plan on the Exercise Date shall be deemed to have exercised his or her Option on such date and shall acquire from the Company such number of whole Shares reserved for the purpose of the Plan as his or her accumulated payroll deductions on such date will purchase at the Option Price, subject to any other limitations contained in the Plan. Any amount remaining in a Participant's account at the end of an Offering solely by reason of the inability to purchase a fractional Share will be carried forward to the next Offering; any other balance remaining in a Participant's account at the end of an Offering will be refunded to the Participant promptly. The Administrator may take all actions necessary to alter the method of Option exercise and the exchange and transmittal of proceeds with respect to Participants resident in the PRC not having permanent residence in a country other than the PRC in order to comply with applicable PRC foreign exchange and tax regulations, and any other applicable PRC laws and regulations.

12. *Lapse of Options.* Any Option granted but not exercised by the end of an Offering will automatically lapse. In the event that the Plan is terminated while any Option remains outstanding and unexercised, then any such Options shall lapse.

13. *Issuance of Certificates.* Certificates representing Shares purchased under the Plan may be issued only in the name of the employee, in the name of the employee and another person of legal age as joint tenants with rights of survivorship, or in the name of a broker authorized by the employee to be his, her or their, nominee for such purpose.

14. Rights on Termination or Transfer of Employment. If a Participant's employment terminates for any reason before the Exercise Date for any Offering, no payroll deduction will be taken from any pay due and owing to the Participant and the balance in the Participant's account will be paid to such Participant or, in the case of such Participant's death, to his or her designated beneficiary as if such Participant had withdrawn from the Plan under Section 9. An employee will be deemed to have terminated employment, for this purpose, if the corporation that employs him or her, having been a Designated Subsidiary, ceases to be a Subsidiary, or if the employee is transferred to any corporation other than the Company or a Designated Subsidiary. If a Participant transfers from an Offering under the 423 Component to an Offering under the Non-423 Component, the exercise of the Participant's Option will be qualified under the 423 Component only to the extent that such exercise complies with Section 423 of the Code. If a Participant transfers from an Offering under the Non-423 Component to an Offering under the 423 Component, the exercise of the Participant's Option will remain non-qualified under the Non-423 Component. Further, an employee will not be deemed to have terminated employment for purposes of the Plan, if the employee is on an approved leave of absence for military service or sickness or for any other purpose approved by the Company, if the employee's right to reemployment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise provides in writing.

15. Special Rules and Sub-Plans; Non-U.S. Employees. Notwithstanding anything herein to the contrary, the Administrator may adopt special rules or sub-plans applicable to the employees of a particular Designated Subsidiary, whenever the Administrator determines that such rules are necessary or appropriate for the implementation of the Plan in a jurisdiction where such Designated Subsidiary has employees, regarding, without limitation, eligibility to participate in the Plan, handling and making of payroll deductions, establishment of bank or trust accounts to hold payroll deductions, payment of interest, conversion of local currency, obligations to pay payroll tax, withholding procedures and handling of share issuances, any of which may vary according to applicable requirements; provided that if such special rules or sub-plans are inconsistent with the requirements of Section 423(b) of the Code, the employees subject to such special rules or sub-plans will participate in the Non-423 Component. Notwithstanding the preceding provisions of this Plan, employees of the Company or a Designated Subsidiary who are citizens or residents of a non-United States jurisdiction (without regard to whether they are also citizens or resident aliens (within the meaning of Section 7701(b)(1)(A) of the Code)) may be excluded from eligibility under the Plan if (a) the grant of an Option under the Plan to a citizen or resident of the non-United States jurisdiction is prohibited under the laws of such jurisdiction or (b) compliance with the laws of the foreign jurisdiction would cause the Plan to violate the requirements of Section 423 of the Code.

16. Optionees Not Shareholders. Neither the granting of an Option to a Participant nor the deductions from his or her pay shall constitute such Participant a holder of the Shares covered by an Option under the Plan until such Shares have been purchased by and issued to him or her. Accordingly, Participants shall not have any voting rights, or rights to participate in any dividends or distributions (including those arising on a liquidation of the Company) declared or recommended or resolved to be paid to the shareholders on the register on a date prior to such Shares having been purchased by and issued to him or her.

17. Rights Not Transferable. Rights under the Plan are not transferable by a Participant other than by will or the laws of descent and distribution, and are exercisable during the Participant's lifetime only by the Participant.

18. Application of Funds. All funds received or held by the Company under the Plan may be combined with other corporate funds and may be used for any corporate purpose.

19. Adjustment in Case of Changes Affecting Shares; Change in Control.

(a) In the event of a capitalization issue, rights issue, subdivision of shares, share split, consolidation of shares, reverse share split, or reduction of the share capital of the Company affecting the Shares, the number of Shares approved for the Plan and the share limitation set forth in Section 10 shall be equitably or proportionately adjusted to give proper effect to such event. Any such adjustment under the Plan will be made in accordance with Rule 17.03(13) of the Hong Kong Listing Rules.

(b) In the event of a Change in Control, each outstanding Option will be assumed or an equivalent option substituted by the successor corporation or a Parent or Subsidiary of the successor corporation. In the event that the successor corporation refuses to assume or substitute for the Option, the Offering with respect to which such Option relates will be shortened by setting a new Exercise Date (the "New Exercise Date") on which such Offering Period shall end. The New Exercise Date will occur before the date of the proposed Change in Control. The Administrator will notify each Participant in writing or electronically prior to the New Exercise Date, that the Exercise Date for the Participant's Option has been changed to the New Exercise Date and that the Participant's Option will be exercised automatically on the New Exercise Date, unless prior to such date the Participant has withdrawn from the Offering as provided in Section 9 hereof.

20. *Amendment of the Plan.* The Board may at any time and from time to time amend the Plan in any respect, provided that the terms of the Plan or Options so altered must comply with the applicable rules of any stock exchange on which the Shares are listed except that without the approval of the shareholders, no amendment shall be made increasing the number of Ordinary Shares approved for the Plan or making any other change that would require shareholder approval in order for the 423 Component of the Plan, as amended, to qualify as an "employee stock purchase plan" under Section 423(b) of the Code or any other material changes that would require shareholder approval in order to comply with the applicable rules of any stock exchange on which the Shares are listed.

21. *Insufficient Shares.* If the total number of Shares that would otherwise be purchased on any Exercise Date plus the number of Shares purchased under previous Offerings under the Plan exceeds the maximum number of Shares issuable under the Plan, the Shares then available shall be apportioned among Participants in proportion to

the amount of payroll deductions accumulated on behalf of each Participant that would otherwise be used to purchase Shares on such Exercise Date.

22. *Termination of the Plan.* The Plan may be terminated at any time by the Board. Upon termination of the Plan, all amounts in the accounts of Participants shall be promptly refunded.

23. *Application of Hong Kong Listing Rules.* The Plan is a discretionary employee share purchase scheme and does not constitute a share option scheme for the purposes of Chapter 17 of the Hong Kong Listing Rules.

24. *Governmental Regulations.* The Company's obligation to sell and deliver Shares under the Plan is subject to obtaining all governmental approvals required in connection with the authorization, issuance, or sale of such Shares.

25. *Clawback Policy.* Options under the Plan shall be subject to the Company's clawback policy, as in effect from time to time, which may allow the Company to recover remuneration (which may include any Options granted) to a Participant in the event of a material misstatement in the Company's financial statements, related intentional misconduct or other circumstances as described in the clawback policy.

26. *Participants' Compliance with Laws.* Participants shall comply with all applicable laws and regulations with respect to their participation in the Plan.

27. *Governing Law.* This Plan and all Options and actions taken thereunder shall be governed by, and construed in accordance with, the laws in which the Company is incorporated. In relation to any proceeding arising out of or in connection with this Plan, the Company and the Participants irrevocably submit to the exclusive jurisdiction of the courts at the place at which the Company has its corporate seat.

28. *Issuance of Shares.* Shares may be issued upon exercise of an Option from authorized but unissued Shares, from Shares held in the treasury of the Company, or from any other proper source. Any such Shares shall be identical to all existing issued Shares and shall be issued subject to all the provisions of the Company's articles of association for the time being in force and will rank *pari passu* with the other fully paid Shares in issue on the date the name of the Participant is registered on the register of members of the Company, subject to applicable laws.

29. Tax Withholding. Participation in the Plan is subject to any applicable U.S. and non-U.S. federal, state, or local tax withholding requirements on income the Participant realizes in connection with the Plan. Each Participant agrees, by entering the Plan, that the Company and its Subsidiaries shall have the right to withhold any applicable withholding taxes by any such method as may be determined by the Company, including by withholding from a Participant's wages, salary or other compensation. Applicable withholding taxes may include any withholding required to make available to the Company or any Subsidiary and tax deductions or benefits attributable to the sale or disposition of Common Stock by such Participant. The Company will not be required to issue any Common Stock under the Plan until all withholding obligations are satisfied.

30. Notification Upon Sale of Shares Under 423 Component. Each Participant who is or may become subject to U.S. income tax agrees, by entering the 423 Component of the Plan, to give the Company prompt notice of any disposition of Shares purchased under the Plan where such disposition occurs within two years after the date of grant of the Option pursuant to which such Shares were purchased or within one year after the date such Shares were purchased.

31. Code Section 409A; Tax Qualification.

(a) Code Section 409A. Options granted under the 423 Component are exempt from the application of Section 409A of the Code and Options granted under the Non-423 Component are intended to be exempt from Section 409A of the Code pursuant to the "short-term deferral" exemption contained therein. In furtherance of the foregoing and notwithstanding any provision in the Plan to the contrary, if the Administrator determines that an Option granted under the Plan may be subject to Section 409A of the Code or that any provision in the Plan would cause an Option to be subject to Section 409A of the Code, the Administrator may amend the terms of the Plan and/or of an outstanding Option, or take such other action the Administrator determines is necessary or appropriate, in each case, without the Participant's consent, to exempt any outstanding Option or future Option that may be granted under the Plan from or to allow any such Options to comply with Section 409A of the Code, but only to the extent any such amendments or action by the Administrator would not violate Section 409A of the Code. Notwithstanding the foregoing, the Company will have no liability to a Participant or any other party if an Option that is intended to be exempt from or compliant with Section 409A of the Code is not so exempt or compliant or for any action taken by the Administrator with respect thereto. The Company makes no representation that the Options under the Plan are compliant with Section 409A of the Code.

(b) Tax Qualification. Although the Company may endeavor to (i) qualify an Option for favorable tax treatment under the laws of the United States or jurisdictions outside of the United States or (ii) avoid adverse tax treatment (e.g., under Section 409A of the Code), the Company makes no representation to that effect and expressly disavows any covenant to maintain favorable or avoid unfavorable tax treatment, notwithstanding anything to the contrary in this Plan, including Section 31(a) hereof. The Company will be unconstrained in its corporate activities without regard to the potential negative tax impact on Participants under the Plan.

32. Effective Date. The Plan shall take effect on the date approved by the Board and set forth below and shall remain in effect until December 7, 2028 unless terminated earlier by the Board in accordance with Section 22.

DATE OF APPROVAL OF FIFTH AMENDED AND RESTATED PLAN BY BOARD OF DIRECTORS: May 27, 2025

Exhibit 10.19

Amgen Inc.
1 Amgen Center Drive
Thousand Oaks, CA 91320 USA
(805) 447-1000

amgen.com



May 9, 2025

BeiGene Switzerland GmbH
Aeschengraben 27
4051 Basel
Switzerland
Attention: Managing Director

BeOne Medicines USA, Inc.
55 Cambridge Parkway, Suite 700W
Cambridge, Massachusetts 02142
USA
Attention: General Counsel

Re: Sales Force FTE Invoicing Methodology

Reference is made to that certain Collaboration Agreement, dated as of October 31, 2019 (as amended from time to time, the "**Collaboration Agreement**"), between BeiGene Switzerland GmbH ("**BeiGene Switzerland**"), Amgen Inc. ("**Amgen**"), and, solely with respect to Section 13.6 thereof, BeiGene, Ltd. (together with BeiGene Switzerland, "**BeiGene**"). BeiGene and Amgen are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**." Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Collaboration Agreement.

This letter clarifies the invoice methodology and determination of Sale Force FTEs under the Collaboration Agreement agreed by the Parties, applicable to calendar year 2024. The methodology described in this letter will apply in subsequent years unless a different methodology is mutually agreed by the Parties.

The Parties adopted the following invoicing methodology for calculating Sales Force Costs applicable to calendar year 2024 (the "**2024 SF Invoicing Methodology**"):

(a) The Parties shall approve and incorporate a baseline target number of Sales Force FTEs for each Product into the Commercialization Budget for calendar year 2024 (the "**2024 Target SF FTEs**"). The JSC shall update the 2024 Target SF FTEs in each subsequent annual Commercialization Budget for calendar years 2025 and beyond.

(b) As part of the quarterly budget review, the Parties will adjust the 2024 Target SF FTEs for each Product based on the vacancy rate of the Sales Force FTEs for such Product in such calendar quarter (the "**2024 Vacancy Corrected Rate**") pursuant to (c) below. The monthly vacancy rate for a Product in a calendar quarter will be determined according to the following calculation: Vacancy rate *equals* one (1) *minus* the sum of actual onboarded Sales Force FTEs for such Product *divided by* 2024 Target SF FTEs, calculated using the month-end onboarded Sales Force FTEs and the vacancy rate calculation for each month shall be averaged across the three months of each applicable calendar quarter to determine the quarterly vacancy rate. The following Sales Force positions are included in the vacancy rate calculation: medical representative (MR), district sales manager (DSM) and regional sales manager (RSM).

(c) The Parties will adjust (increase or decrease) the 2024 Target SF FTEs for each Product based on the 2024 Vacancy Corrected Rate (the "**2024 Vacancy Corrected FTEs**") on a calendar quarterly basis. For example, if the 2024 Target SF FTEs for a Product is 100 Sales Force FTEs and the actual onboarded Sales Force FTEs is 90 in each month of a calendar quarter, reflecting a 2024 Vacancy Corrected Rate of -10% for such calendar quarter, the 2024 Target SF FTEs for such Product shall be adjusted to 90 (i.e. the 2024 Vacancy Corrected FTEs, reflecting a 10% reduction to the 2024 Sales Force FTEs). The Parties will compare the 2024 Vacancy Corrected FTEs for each Product to the Sales Force FTEs determined by BeiGene using BeiGene's CRM system (the "**2024 CRM SF FTEs**"). In any given calendar quarter, the Sales Force FTEs used for calculation of Sales Force Costs for each Product will reflect up to a maximum of one hundred five percent (105%) (the "**2024 Sales Force FTE Upper Cap**") and a minimum of ninety-five percent (95%) (the "**2024 Sales Force FTE Lower Cap**") of the 2024 Vacancy Corrected FTEs.

(i) If the 2024 CRM SF FTEs is between the 2024 Sales Force FTE Lower Cap and the 2024 Sales Force FTE Upper Cap in a given calendar quarter, then the 2024 CRM SF FTEs applies for that calendar quarter.

(ii) If the 2024 CRM SF FTEs is equal to or exceeds the 2024 Sales Force FTE Upper Cap in a given calendar quarter, then the 2024 Sales Force FTE Upper Cap applies for that calendar quarter.

(iii) If the 2024 CRM SF FTEs is equal to or below the 2024 Sales Force FTE Lower Cap in a given calendar quarter, then the 2024 Sales Force FTE Lower Cap applies for that calendar quarter.

Prior to December 31 of each calendar year, the Parties shall determine whether to renew the 2024 SF Invoicing Methodology for the following calendar year or whether to adopt a different mutually agreed invoicing methodology. If the Parties do not mutually agree on a different methodology, then the Parties shall apply the 2024 SF Invoicing Methodology.

Please acknowledge your agreement and consent to the foregoing by counter-signing this letter in the space provided below and returning a copy to us.

[Signature page follows.]

Yours sincerely,

Amgen Inc.

/s/ LINDA H. LOUIE
By: Linda H. Louie
Title: VP Finance

Acknowledged and agreed:

BeiGene Switzerland GmbH

/s/ JEFF HYNES
By: Jeff Hynes
Title: Managing Director

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 BeOne Medicines 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: August 6, 2025

/s/ JOHN V. OYLER

John V. Oyler

Chief Executive Officer and Chairman

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Aaron Rosenberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BeOne Medicines 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: August 6, 2025

/s/ AARON ROSENBERG

Aaron Rosenberg
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 BeOne Medicines Ltd., a corporation organized under the laws of Switzerland (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the three months ended June 30, 2025 (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: August 6, 2025

/s/ JOHN V. OYLER

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

Date: August 6, 2025

/s/ AARON ROSENBERG

Aaron Rosenberg
Chief Financial Officer
(Principal Financial Officer)