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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 November 5, 2026.

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

Hong Kong, November 5, 2026

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. Felix J. Baker and Dr. Xiaodong Wang as Non-executive Directors, and Dr. Olivier Brandicourt, Dr. Margaret Han Dugan, Mr. Anthony C. Hooper, Ms. Elizabeth F. Mooney, Dr. Alessandro Riva, Dr. Charles L. Sawyers and Ms. Shalini Sharp as Independent Non-executive Directors.

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

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 October 30, 2026, 1,484,939,031 ordinary shares, par value $0.0001 per share, were outstanding, of which 766,039,443 ordinary shares were held in the form of 58,926,111 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

TABLE OF CONTENTS

		Page
PART I.	FINANCIAL INFORMATION	3
Item 1.	Financial Statements	3
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	28
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	45
Item 4.	Controls and Procedures	47
PART II.	OTHER INFORMATION	48
Item 1.	Legal Proceedings	48
Item 1A.	Risk Factors	48
Item 2.	Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities	108
Item 3.	Defaults Upon Senior Securities	108
Item 4.	Mine Safety Disclosures	108
Item 5.	Other Information	109
Item 6.	Exhibits	109
SIGNATURES		111

From time to time, we may use our website, our X 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 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 September 30,		Nine Months Ended September 30,	
		2026	2025	2026	2025
		$	$	$	$
Revenues					
Product revenue, net	11	1,855,057	1,395,013	5,022,180	3,805,619
Other revenue	3	34,758	17,271	86,144	39,244
Total revenues		1,889,815	1,412,284	5,108,324	3,844,863
Cost of sales - product		216,896	196,510	558,641	526,118
Gross profit		1,672,919	1,215,774	4,549,683	3,318,745
Operating expenses					
Research and development		660,784	523,662	1,814,288	1,530,445
Selling, general and administrative		593,460	528,998	1,741,771	1,526,199
Total operating expenses		1,254,244	1,052,660	3,556,059	3,056,644
Income from operations		418,675	163,114	993,624	262,101
Interest income		33,663	19,393	89,227	43,735
Interest expense		(42,407)	(16,364)	(115,033)	(31,361)
Other income (expense), net		429	(18,979)	14,216	(6,862)
Income before income taxes		410,360	147,164	982,034	267,613
Income tax expense	8	25,654	22,323	132,964	47,182
Net income		384,706	124,841	849,070	220,431
Earnings per share					
Basic	12	0.26	0.09	0.58	0.16
Diluted	12	0.25	0.08	0.56	0.15
Weighted-average shares outstanding—basic		1,478,074,394	1,432,801,699	1,457,134,424	1,410,497,062
Weighted-average shares outstanding—diluted		1,524,954,790	1,488,750,354	1,511,972,953	1,465,535,004
Earnings per American Depositary Share ("ADS")					
Basic	12	3.38	1.13	7.58	2.03
Diluted	12	3.28	1.09	7.30	1.96
Weighted-average ADSs outstanding—basic		113,698,030	110,215,515	112,087,263	108,499,774
Weighted-average ADSs outstanding—diluted		117,304,215	114,519,258	116,305,612	112,733,462

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Net income	384,706	124,841	849,070	220,431
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	18,529	12,058	70,880	47,046
Other adjustments	230	383	693	685
Comprehensive income	403,465	137,282	920,643	268,162

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 September 30, 2026	As of December 31, 2025
		$ (unaudited)	$ (audited)
Assets			
Current assets:			
Cash and cash equivalents		5,781,128	4,547,530
Accounts receivable, net		1,092,535	865,080
Inventories, net	9	807,922	608,227
Prepaid expenses and other current assets	9	249,654	212,752
Total current assets		7,931,239	6,233,589
Property, plant and equipment, net	6	1,647,231	1,641,678
Operating lease right-of-use assets		150,008	148,184
Other non-current assets	9	147,447	165,122
Total non-current assets		1,944,686	1,954,984
Total assets		9,875,925	8,188,573
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		496,879	479,035
Accrued expenses and other payables	9	1,342,646	1,109,120
Income tax payable	8	14,801	41,625
Operating lease liabilities, current portion		24,462	20,698
Research and development cost share liability, current portion	3	—	64,345
Sale of future royalty liability, current portion	4	106,274	56,714
Short-term debt	10	248,861	57,293
Total current liabilities		2,233,923	1,828,830
Non-current liabilities:			
Long-term debt	10	825,220	961,913
Sale of future royalty liability, non-current portion	4	806,307	850,242
Operating lease liabilities, non-current portion		50,223	52,940
Deferred tax liabilities	8	60,085	53,209
Other long-term liabilities	9	79,773	80,245
Total non-current liabilities		1,821,608	1,998,549
Total liabilities		4,055,531	3,827,379
Commitments and contingencies	16		
Shareholders' equity:			
Ordinary shares, $0.0001 par value per share; 1,541,841,971 and 1,540,975,898 shares issued and 1,483,318,035 and 1,441,075,618 shares outstanding as of September 30, 2026 and December 31, 2025, respectively		148	144
Additional paid-in capital		13,297,690	12,759,137
Accumulated other comprehensive loss	14	(6,611)	(78,184)
Accumulated deficit		(7,470,833)	(8,319,903)
Total shareholders' equity		5,820,394	4,361,194
Total liabilities and shareholders' equity		9,875,925	8,188,573

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	Nine Months Ended September 30, 2026	2025
		$	$
Operating activities:			
Net income		849,070	220,431
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization expense		142,593	105,702
Share-based compensation expenses	13	393,247	387,096
Acquired in-process research and development		20,518	691
Amortization of research and development cost share liability	3	(64,345)	(74,844)
Impairment of equity investments		—	34,216
Non-cash interest expense		7,937	—
Other items, net		12,465	9,595
Changes in operating assets and liabilities:			
Accounts receivable		(227,823)	(167,294)
Inventories		(185,379)	(22,662)
Other assets		(6,746)	55,247
Accounts payable		20,759	(7,381)
Accrued expenses and other payables		201,527	165,886
Other liabilities		9,040	3,550
Net cash provided by operating activities		1,172,863	710,233
Investing activities:			
Purchases of property, plant and equipment		(103,440)	(148,317)
Purchase of intangible assets		—	(20,000)
Proceeds from sale or maturity of investments		5,872	1,800
Purchase of in-process research and development		(20,518)	(60,691)
Other investing activities		(12,537)	(10,612)
Net cash used in investing activities		(130,623)	(237,820)
Financing activities:			
Proceeds from the sale of future royalties	4	—	885,000
Repayment of long-term loan	10	(32,535)	(21,062)
Proceeds from short-term loans	10	58,204	221,521
Repayment of short-term loans	10	—	(275,782)
Repayment of sale of future royalties liability	4	(2,556)	—
Payments of withholding taxes from share-based awards		—	(24,195)
Proceeds from option exercises and employee share purchase plan		145,005	177,038
Other financing activities		(3,346)	—
Net cash provided by financing activities		164,772	962,520
Effect of foreign exchange rate changes, net		49,655	36,862
Net increase in cash, cash equivalents, and restricted cash		1,256,667	1,471,795
Cash, cash equivalents, and restricted cash at beginning of period		4,609,647	2,638,747
Cash, cash equivalents, and restricted cash at end of period		5,866,314	4,110,542
Supplemental cash flow information:			
Cash and cash equivalents		5,781,128	4,036,868
Short-term restricted cash		63,400	52,987
Long-term restricted cash		21,786	20,687
Income taxes paid		156,957	79,962
Interest expense paid		91,965	36,148
Supplemental non-cash information:			
Capital expenditures included in accounts payable and accrued expenses		49,079	52,057
ROU assets obtained in exchange for new operating lease liabilities		23,947	19,127

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	Treasury Shares[1]	Total Outstanding Shares	Ordinary Shares Issued	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
		Shares		$	$	$	$	$
Balance at December 31, 2025	1,540,975,898	(99,900,280)	1,441,075,618	144	12,759,137	(78,184)	(8,319,903)	4,361,194
Exercise of options, ESPP and release of RSUs	—	3,403,760	3,403,760	—	23,834	—	—	23,834
Share-based compensation	—	—	—	—	123,355	—	—	123,355
Other comprehensive income	—	—	—	—	—	24,702	—	24,702
Net income	—	—	—	—	—	—	227,357	227,357
Balance at March 31, 2026	1,540,975,898	(96,496,520)	1,444,479,378	144	12,906,326	(53,482)	(8,092,546)	4,760,442
Exercise of options, ESPP and release of RSUs	—	24,799,437	24,799,437	3	11,029	—	—	11,032
Share-based compensation	—	—	—	—	137,405	—	—	137,405
Other comprehensive income	—	—	—	—	—	28,112	—	28,112
Net income	—	—	—	—	—	—	237,007	237,007
Balance at June 30, 2026	1,540,975,898	(71,697,083)	1,469,278,815	147	13,054,760	(25,370)	(7,855,539)	5,173,998
Issuance of shares reserved for share option exercises	866,073	—	866,073	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	—	13,173,147	13,173,147	1	110,443	—	—	110,444
Share-based compensation	—	—	—	—	132,487	—	—	132,487
Other comprehensive income	—	—	—	—	—	18,759	—	18,759
Net income	—	—	—	—	—	—	384,706	384,706
Balance at September 30, 2026	1,541,841,971	(58,523,936)	1,483,318,035	148	13,297,690	(6,611)	(7,470,833)	5,820,394
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
Exercise of options, ESPP and release of RSUs	—	9,880,286	9,880,286	1	80,759	—	—	80,760
Share-based compensation	—	—	—	—	140,809	—	—	140,809
Other comprehensive income	—	—	—	—	—	12,441	—	12,441
Net income	—	—	—	—	—	—	124,841	124,841
Balance at September 30, 2025	1,540,975,898	(102,892,308)	1,438,083,590	144	12,616,844	(101,257)	(8,386,405)	4,129,326

1. Upon effectiveness of the Continuation, 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 Continuation became part of the Company's issued but not outstanding share capital and are considered 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 ("$"), 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

Formerly known as BeiGene, Ltd., BeOne Medicines Ltd. (the "Company" or "BeOne") is a global oncology company discovering and developing innovative treatments that are more accessible to cancer patients worldwide.

Effective May 27, 2025, the Company changed its 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 (such transaction, the "Continuation"). The Continuation 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 Continuation, ordinary shares held by the Company or one of its controlled subsidiaries immediately prior to the effective date of the Continuation became part of the Company's issued share capital and are considered ordinary shares of the Company, or "treasury shares" under Swiss law. See the Company'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 following the Continuation.

Since its inception in 2010, the Company has become a fully integrated global organization with over 12,000 employees worldwide.

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of September 30, 2026, the condensed consolidated statements of operations and comprehensive income for the three and nine months ended September 30, 2026 and 2025, the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025, and the condensed consolidated statements of shareholders' equity for the three and nine months ended September 30, 2026 and 2025, 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, 2025 (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 nine months ended September 30, 2026 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, assessing the subsequent measurement of certain long-lived assets, initial measurement and recognition of share-based compensation expenses, realizability of deferred tax assets, estimating uncertain tax positions, subsequent measurement of inventory, estimating the allowance for credit losses, measurement of right-of-use assets and lease liabilities, estimates related to the cost of accrued research and development activities, estimates related to the interest cost component of the sale of future royalty liability and the measuring at 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 been adopted

In September 2025, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2025-07, *Derivatives and Hedging* (Topic 815) *and Revenue from Contracts with Customers* (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract. This update adds a new exception for contracts that are not traded on exchange that contain an underlying based on operations or activities specific to one of the parties to the contract, regardless of whether the operations or activities are within the company's control. The ASU also clarifies that an entity should apply the guidance in Topic 606 to a contract with share-based noncash consideration (for example, shares, share options, or other equity instruments) from a customer for the transfer of goods or services. ASU 2025-07 is effective for fiscal years beginning after December 15, 2026, and interim reporting periods within those fiscal years, with early adoption permitted. The Company adopted the amendments to Topic 815 on a prospective basis, effective January 1, 2026. There was no material impact to the Company's financial position or results of operations for prior transactions. The impact in subsequent periods will be dependent upon the nature of future business development activities.

New accounting standards which have not yet been adopted

In December 2025, the FASB issued ASU 2025-10, *Government Grants* (Topic 832): Accounting for Government Grants Received by Business Entities (ASU 2025-10), which establishes authoritative guidance on the recognition, measurement, presentation, and disclosure of government grants. Under ASU 2025-10, government grants are recognized when it is probable that the entity will both comply with the conditions of the grant and the grant will be received. The ASU provides specific accounting models for grants related to assets and grants related to income, including options to recognize government grants as deferred income or as a reduction of the asset's cost basis. The ASU also requires enhanced disclosures regarding the nature of government grants, significant terms and conditions, accounting policies applied, and amounts recognized in the financial statements. ASU 2025-10 is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-10 on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update removes all references to prescriptive and sequential software development stages throughout Subtopic 350-40. The update requires an entity to start capitalizing software costs when management has authorized and committed to funding the software project, and it is probable that the project will be completed and the software will be used to perform the function intended. The update further specifies that the disclosures in Subtopic 360-10 are required for all capitalized internal-use software costs. This update is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The guidance can be applied using a prospective transition approach, a modified transition approach that is based on the status of the project and whether software costs were capitalized before the date of adoption, or a retrospective transition approach. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

In November 2024, the FASB issued 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.

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 Annual Report.

There have been no material changes to the Company's significant accounting policies as of and for the nine months ended September 30, 2026, as compared to the significant accounting policies described in the Annual Report.

2. Fair Value Measurements

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

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

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

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

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

The following tables present the Company's financial assets and liabilities measured and recorded at fair value on a recurring basis using the above input categories as of September 30, 2026 and December 31, 2025:

As of September 30, 2026	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	2,862,842	—	—
Other non-current assets (Note 5):			
Equity securities with readily determinable fair values	—	20	—
Convertible debt instrument	—	—	5,956
Other	3,716	—	—
Total	2,866,558	20	5,956

As of December 31, 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	2,384,656	—	—
Other non-current assets (Note 5):			
Equity securities with readily determinable fair values	—	2	—
Convertible debt instrument	—	—	6,135
Other	1,271	—	—
Total	2,385,927	2	6,135

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 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, net. The Company recorded net gains on fair value adjustment of $49 and $209 for the three and nine months ended September 30, 2026, respectively, and net losses on fair value adjustment of $3,093 and $1,882 for the three and nine months ended September 30, 2025, respectively. Refer to Note 5, *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.

As of September 30, 2026 and December 31, 2025, the Company held time deposits of $174,777 and nil, respectively, that were classified as cash equivalents. As of September 30, 2026 and December 31, 2025, 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's carrying values approximate their fair values 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, Licensing and Other 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 three and nine months ended September 30, 2026 and 2025, the Company's other 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.

The following table summarizes total other revenue recognized for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Other Revenue	$	$	$	$
Amgen royalty revenue	25,744	12,169	62,864	26,721
Novartis broad markets revenue	6,869	4,115	17,088	10,957
Other	2,145	987	6,192	1,566
Other Revenue	34,758	17,271	86,144	39,244

In-Licensing Arrangements - Commercial

Amgen

During the three and nine months ended September 30, 2026 and 2025, 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. 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 nine months ended September 30, 2026 and 2025 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
BeOne's portion of the development funding	12,204	59,325	130,070	152,040
Less: Amortization of research and development cost share liability	6,182	29,275	64,345	74,844
Research and development expense	6,022	30,050	65,725	77,196

The Company fulfilled its research and development cost share liability during the three months ended September 30, 2026. As of September 30, 2026 and December 31, 2025, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Research and development cost share liability, current portion	—	64,345
Total research and development cost share liability	—	64,345

The total reimbursement paid under the commercial profit-sharing agreement for product sales is classified in the income statement for the three and nine months ended September 30, 2026 and 2025 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Cost of sales - product	5,859	9,962	29,772	26,989
Research and development	(1,332)	(371)	(2,657)	(2,480)
Selling, general and administrative	(32,870)	(24,546)	(86,395)	(73,531)
Total	(28,343)	(14,955)	(59,280)	(49,022)

The Company purchases commercial inventory from Amgen to distribute in China. Inventory purchases amounted to $177,997 and $433,707 for the three and nine months ended September 30, 2026, respectively, and $84,243 and $220,275 for the three and nine months ended September 30, 2025, respectively. Net amounts payable to Amgen was $146,707 and $79,097 as of September 30, 2026 and December 31, 2025, 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 nine months ended September 30, 2026 and 2025 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 September 30,		Nine Months Ended September 30,	
		2026	2025	2026	2025
Payments due to collaboration partners	**Classification**	**$**	**$**	**$**	**$**
Upfront payments	Research and development expense	—	191	20,518	691
Development milestones incurred	Research and development expense	757	—	4,070	—
Regulatory and commercial milestone payments	Intangible asset	—	—	—	20,000
Total		757	191	24,588	20,691

4. Sale of Future IMDELLTRA® Royalties

On August 25, 2025, the Company entered into an agreement (the "Royalty Agreement") to sell its royalty rights on the worldwide sales, excluding China, of Amgen's IMDELLTRA® (tarlatamab-dlle) for up to $950,000 to Royalty Pharma Investments 2023 ICAV ("Royalty Pharma"). Under the terms of the Royalty Agreement, the Company received a non-refundable upfront payment of $885,000 upon closing of the Royalty Agreement. Subsequently, the Company exercised its option to sell additional royalties to Royalty Pharma and received $26,000 in the fourth quarter of 2025. The Company will share in a portion of the royalty on annual sales above $1.5 billion, and will maintain royalty and all other rights to other assets under the terms of its collaboration agreement with Amgen.

The Company evaluated the arrangement and determined that the proceeds from the sale of future IMDELLTRA® royalties, as well as the option to sell remaining royalties when and if exercised, should be treated as a financing liability according to ASC 470, *Debt* due to the Company's continuing involvement with the Amgen collaboration. At the transaction date, the Company recognized the upfront proceeds received from Royalty Pharma of $885,000 and, subsequently, the option proceeds of $26,000, as liabilities and is amortizing them using the effective interest method over the life of the arrangement. The Company imputes interest expense associated with the liability using the effective interest rate method. The effective interest rate is the rate that equates the present value of the estimate of remaining royalty revenues payable to Royalty Pharma with the carrying amount of the liability. The interest rate on the sale of future royalty liability may vary during the term of the agreement depending on a number of factors, including the royalty revenues forecast. The Company evaluates the interest rate quarterly based on its expectations of future royalty revenues, historical experience and current market conditions using the prospective method. A significant increase or decrease in future royalty revenues will materially impact the timing of royalty sale liability amortization, interest expense and the time period for repayment. The Company will assess the expected payments to Royalty Pharma quarterly, and, to the extent the amount or timing of such payments is materially different than its initial estimates, the Company will prospectively adjust the amortization of the liability and the related interest expense.

The repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period. The repayment does not follow a fixed repayment schedule and will be recognized over the life of the royalty stream, which is expected to occur through at least 2041. The Royalty Agreement also contains customary representations, warranties, covenants, and indemnification provisions.

As of September 30, 2026 and December 31, 2025, the royalty financing obligation recorded in the Company's balance sheet was as follows:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Sale of future royalty liability, current portion	106,274	56,714
Sale of future royalty liability, non-current portion	806,307	850,242
Total sale of future royalty liability	912,581	906,956

The following table summarizes the royalty sale liability activity during the nine months ended September 30, 2026:

	Royalty Sale Liability
	$
Balance at December 31, 2025	906,956
Debt portion of royalties recognized and settled to Royalty Pharma	(2,556)
Accretion of liability	8,181
Balance at September 30, 2026	912,581

The carrying value of the sale of future royalty liability approximates fair value as of September 30, 2026 and is based on the Company's current estimates of future royalties expected to be paid to Royalty Pharma over the life of the royalty stream, which are considered Level 3 inputs.

Interest expense related to this arrangement was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Interest expense	27,016	—	70,395	—

As of September 30, 2026, $27,016 of interest expense was accrued. The effective annual imputed interest rate was 11.8% as of September 30, 2026.

5. 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 and cash used to settle employee benefit obligations and related taxes. The Company classifies restricted cash as current or non-current based on the term of the restriction. Restricted cash as of September 30, 2026 and December 31, 2025 was as follows:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Short-term restricted cash	63,400	41,284
Long-term restricted cash	21,786	20,833
Total	85,186	62,117

Investments in Equity Securities

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

	As of	
	September 30, 2026	December 31, 2025
	$	$
Equity securities with readily determinable fair values	20	2
Equity securities without readily determinable fair values [1]	36,774	33,154
Equity-method investments [2]	22,657	22,387
Total	59,451	55,543

[1] In the three and nine months ended September 30, 2025, the Company recognized an impairment loss of $15,552 within other income (expense), net, resulting from a decline in the enterprise value related to a business acquisition of one of its investees.

[2] 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 nine months ended September 30, 2025, within unrealized losses from equity-method investments.

The following table summarizes net gains and losses related to investments in equity securities recorded in other income (expense), net for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Equity securities with readily determinable fair values	20	116	18	(1,947)
Equity securities without readily determinable fair values	—	(13,754)	3,188	(16,872)
Equity-method investments	(679)	(576)	(1,886)	(15,850)

The following table summarizes the portion of unrealized losses that relates to equity securities still held by the Company as of September 30, 2026:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net gains (losses) recognized on equity securities	—	(13,754)	3,188	(16,872)
Less: net gains (losses) recognized on equity securities sold	—	(15,552)	3,134	(15,552)
Net unrealized gains (losses) on equity securities held at end of period	—	1,798	54	(1,320)

6. Property, Plant and Equipment, Net

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

	As of	
	September 30, 2026	December 31, 2025
	$	$
Land	71,434	71,434
Building	1,237,680	1,187,836
Manufacturing equipment	289,306	273,769
Laboratory equipment	346,146	309,471
Leasehold improvement	66,534	76,568
Software, electronics and office equipment	144,803	124,136
Property, plant and equipment, at cost	2,155,903	2,043,214
Less: accumulated depreciation	(645,903)	(528,695)
Construction in progress	137,231	127,159
Property, plant and equipment, net	1,647,231	1,641,678

The Company has made a significant investment in its recently opened manufacturing and clinical R&D facility in Hopewell, New Jersey. As of September 30, 2026, the Company had construction in progress of $100,493 related to the Hopewell facility, the majority of which will be put into service in 2026.

Depreciation expense for the three and nine months ended September 30, 2026 and 2025 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Depreciation expense	37,320	35,730	115,611	97,198

7. Intangible Assets

Intangible assets as of September 30, 2026 and December 31, 2025 are summarized as follows:

	As of					
	September 30, 2026			December 31, 2025		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
	$	$	$	$	$	$
Finite-lived intangible assets:						
Developed products	80,329	(42,864)	37,465	77,486	(15,291)	62,195
Other	8,987	(8,528)	459	8,987	(8,478)	509
Total finite-lived intangible assets	89,316	(51,392)	37,924	86,473	(23,769)	62,704

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 9 years. Amortization expense was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Amortization expense - Cost of sales - product	23,598	1,537	26,932	8,459
Amortization expense - Selling, general and administrative	16	17	50	45
Total	23,614	1,554	26,982	8,504

Included within the amortization expense for the three and nine months ended September 30, 2026 was a developed product intangible asset impairment charge of $22,027 associated with the Company’s decision to discontinue promotion of

POBEVCY. As of September 30, 2026, 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
	$	$	$
2026 (remainder of year)	622	18	640
2027	2,490	67	2,557
2028	2,490	67	2,557
2029	2,490	67	2,557
2030	2,490	67	2,557
2031 and thereafter	26,883	173	27,056
Total	37,465	459	37,924

8. Income Taxes

Income tax expense was $25,654 and $132,964 for the three and nine months ended September 30, 2026, respectively, and $22,323 and $47,182 for the three and nine months ended September 30, 2025, respectively. The income tax expense for the three and nine months ended September 30, 2026 and 2025 was primarily attributable to the application of the Company's expected current worldwide effective tax rate for the full year to the year-to-date actual pre-tax income, reflecting the mix of taxable income across jurisdictions as well as the impact of certain discrete items. Specifically, the provision for income taxes for the three months ended September 30, 2026 included a discrete net tax benefit of approximately $11,501, attributable mainly to U.S. share-based compensation. The income tax expense for the three and nine months ended September 30, 2025 included a discrete net tax benefit of $917 and $9,605, respectively, primarily related to updated provision estimates for U.S. R&D credits for prior periods.

On a quarterly basis, the Company evaluates the realizability of deferred tax assets by jurisdiction and assesses the need for a valuation allowance. In assessing the realizability of deferred tax assets, the Company considers historical profitability, evaluation of scheduled reversals of deferred tax liabilities, projected future taxable income and tax-planning strategies. Valuation allowances have been provided on deferred tax assets where, based on all available evidence, it was considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. After consideration of all positive and negative evidence, as of September 30, 2026, the Company maintained a full valuation allowance against its net deferred tax assets. The Company may release all or a portion of the valuation allowance in the near-term; however, the release of the valuation allowance, as well as the exact timing and the amount of such release, continue to be subject to, among other things, the Company's level of profitability, revenue growth, clinical program progression and expectations regarding future profitability. The Company's total deferred tax asset balance subject to the valuation allowance was approximately $3.6 billion as of September 30, 2026.

As of September 30, 2026, the Company had gross unrecognized tax benefits of $28,068. Due to the uncertain and complex application of income tax regulations by certain tax authorities outside of the U.S., it is possible that the ultimate resolution of ongoing audits may result in liabilities that could be materially different from current estimates. The ongoing tax audits in various jurisdictions could impact future tax expenses if tax authorities in their administration of tax laws during open audits may lead us to change our assessment of whether or not it is more likely than not that certain tax benefit positions will be sustained. The Company's reserve for uncertain tax positions increased by $2,021 and $232 in the three and nine months ended September 30, 2026, respectively, primarily due to an increase in U.S. federal and state tax attributes, partially offset by the settlement of the China audit in a prior quarter.

9. Supplemental Balance Sheet Information

Inventories, net consisted of the following:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Raw materials	249,186	236,190
Work in process	90,653	122,681
Finished goods	468,083	249,356
Total	807,922	608,227

Prepaid expenses and other current assets consisted of the following:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Short-term restricted cash	63,400	41,284
Prepaid research and development costs	25,439	52,594
Prepaid taxes	40,400	42,232
Prepaid general and administrative expenses	18,539	22,209
Other current assets	45,298	32,652
Other receivables	56,578	21,781
Total	249,654	212,752

Other non-current assets consisted of the following:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Long-term investments	65,407	61,678
Intangible assets, net	37,924	62,704
Long-term restricted cash	21,786	20,833
Rental deposits and other	13,334	10,470
Prepayment of property and equipment	4,118	4,964
Prepaid VAT	4,138	3,504
Prepaid supply cost	740	969
Total	147,447	165,122

Accrued expenses and other payables consisted of the following:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Revenue rebates and returns related	561,651	398,533
External research and development activities related	134,780	156,525
Compensation related	297,819	305,055
Commercial activities	152,089	118,449
Individual income tax and other taxes	107,896	60,359
Accrued general and administrative expenses	45,600	36,635
Other	42,811	33,564
Total	1,342,646	1,109,120

Other long-term liabilities consisted of the following:

	As of	
	September 30, 2026	December 31, 2025
	$	$
Deferred government grant income	28,124	28,979
Pension liability	17,446	18,170
Asset retirement obligation	4,143	3,565
Other	30,060	29,531
Total	79,773	80,245

10. Debt

Facilities Agreement

In November 2025, BeOne Medicines Ltd. entered into the Facilities Agreement (the "Facilities Agreement"), by and among certain subsidiaries of the Company, as guarantors, the Hongkong and Shanghai Banking Corporation Limited ("HSBC"), as global coordinator, original mandated lead arranger and bookrunner, agent and security agent, and certain financial institutions listed in the Facilities Agreement, as lenders. The Facilities Agreement provides for a $140,000 U.S. dollar-denominated, 2-year B1 revolving credit facility (the "B1 Revolving Loan Facility"), a $560,000 U.S. dollar-denominated, 2-year, B2 term loan facility (the "B2 Term Loan Facility" and, together with the B1 Revolving Loan Facility, the "B Loan Facilities"), and a RMB 2,150,000 Renminbi-denominated, 3-year, A term loan facility (the "A Loan Facility") (collectively, the "Loan Facilities").

The following table presents outstanding borrowings under the Facilities Agreement:

	As of	
	September 30, 2026	December 31, 2025
	$	$
A Loan Facility	25,654	12,298
B2 Term Loan Facility	112,000	—
Less: unamortized debt issuance costs	(9,945)	(3,235)
Total short-term debt	127,709	9,063
A Loan Facility	295,019	295,152
B2 Term Loan Facility	448,000	560,000
Less: unamortized debt issuance costs	(4,505)	(18,783)
Total long-term debt	738,514	836,369

The A Loan Facility requires repayment of 4% of the aggregate amount outstanding every six months beginning on November 24, 2026, with all remaining principal outstanding due on November 24, 2028. The B2 Term Loan Facility requires repayment of 10% of the aggregate amount outstanding every three months beginning on June 15, 2027, with all remaining principal outstanding due on December 15, 2027, unless the final repayment date is extended. The Company may voluntarily prepay borrowings, in whole or in part, under the Facilities Agreement without premium or penalty. The Facilities Agreement also contains certain customary mandatory prepayment provisions in the event that the Company undergoes a change of control and in relation to disposal and insurance proceeds.

The A Loan Facility is subject to an interest rate equal to the Reference Rate (RMB) (as defined in the Facilities Agreement) plus a margin of 0.65% per annum. The B Loan Facilities are subject to an interest rate equal to the Reference Rate (USD) (as defined in the Facilities Agreement) plus a margin of 2.40% per annum. In addition to paying interest on the outstanding principal, the Company is also required to pay a commitment fee of 0.85% on the undrawn and uncancelled amounts under the Loan Facilities. Excluding commitment fees, the interest rate for the A Loan Facility and B2 Term Loan Facility was 3.7% and 6.3%, respectively, as of September 30, 2026.

As of September 30, 2026, the B1 Revolving Loan Facility has been terminated in accordance with its terms. Subject to certain limitations, the Loan Facilities are secured on a first priority basis granted in favor of HSBC (as security agent on behalf of the secured parties) by: (a) a security interest in the equity interests of a member of the Company and its subsidiaries and (b) security interests in, and mortgage on, the Company's manufacturing and clinical R&D facility in New Jersey.

The Company is required to satisfy certain financial and non-financial covenants under the Facilities Agreement. The Company was compliant with the required covenants as of September 30, 2026.

Other Bank Loans

The following table summarizes the Company's working capital and project loans as of September 30, 2026 and December 31, 2025:

Lender	Borrower	Term	Maturity Date	Note	As of	
					September 30, 2026	December 31, 2025
					$	$
China Construction Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	June 11, 2027	1	33,559	21,450
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	January 20, 2029	2	9,375	8,989
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	November 8, 2029	3	8,863	8,497
China CITIC Bank	BeOne Pharmaceutical (Suzhou) Co., Ltd.	10-year	July 28, 2032	4	9,695	9,294
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	1-year	March 18, 2027	5	59,660	—
Total short-term debt					121,152	48,230
China Construction Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	June 11, 2027	1	—	21,450
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	January 20, 2029	2	14,063	20,224
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	November 8, 2029	3	20,440	25,970
China CITIC Bank	BeOne Pharmaceutical (Suzhou) Co., Ltd.	10-year	July 28, 2032	4	52,203	57,900
Total long-term debt					86,706	125,544

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 September 30, 2026. The outstanding principal balance is payable in semi-annual installments. The Company repaid $11,080 (RMB75,000) during the nine months ended September 30, 2026. 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 3.3% as of September 30, 2026. The outstanding principal balance is payable in quarterly installments. The Company repaid $6,883 (RMB47,143) during the nine months ended September 30, 2026. The loan is secured by Guangzhou Factory's south district 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 3.2% as of September 30, 2026. The outstanding principal balance is payable in quarterly installments. The Company repaid $6,551 (RMB44,565) during the nine months ended September 30, 2026. The loan is secured by certain 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 rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.3% as of September 30, 2026. The outstanding principal balance is payable in semi-annual installments. The Company repaid $8,021 (RMB54,900) during the nine months ended September 30, 2026. The loan is secured by BeOne Pharmaceutical (Suzhou) Co., Ltd.'s property ownership certificate of the small molecule manufacturing campus in Suzhou, China.

5 In March 2026, the Company entered into a credit facility agreement with China Merchants Bank for an aggregate facility of RMB 950,000, denominated in RMB, available for a period of 36 months for drawdown as revolving and/or one-time borrowings. The Company drew down $58,204 (RMB 400,000) during the nine months ended September 30, 2026. The borrowing bears floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 2.6% as of September 30, 2026.

The Company has numerous financial and non-financial covenants on its debt obligations with the lenders above. Some of these covenants include default and/or cross-default provisions that could require acceleration of repayment of loans in the event of default. As of September 30, 2026, the Company was in compliance with all covenants of its material debt agreements.

Interest Expense

Interest expense related to bank loans was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Interest expense, excluding amortization of debt issuance costs	13,757	12,650	40,261	37,659
Amortization of debt issuance costs	2,694	—	7,937	—
Capitalized interest expense	1,094	1,886	3,247	11,899

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; BAITUOWEI® in China under a license from Luye Pharma; and POBEVCY® in China under a license from Bio-Thera.

The table below presents the Company's net product revenue for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Product revenue – gross	2,436,062	1,770,689	6,535,151	4,828,593
Less: rebates and sales returns	(581,005)	(375,676)	(1,512,971)	(1,022,974)
Product revenue – net	1,855,057	1,395,013	5,022,180	3,805,619

The following table disaggregates net product revenue by product for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
BRUKINSA®	1,390,936	1,040,691	3,733,419	2,782,195
TEVIMBRA®	243,282	190,623	678,038	555,311
XGEVA®	105,482	84,243	299,901	235,984
BLINCYTO®	38,869	30,476	109,441	79,969
KYPROLIS®	13,900	18,369	46,018	57,513
BAITUOWEI®	22,111	11,243	54,110	25,920
POBEVCY®	10,717	10,499	32,477	35,486
Other	29,760	8,869	68,776	33,241
Total product revenue – net	1,855,057	1,395,013	5,022,180	3,805,619

The following table presents the roll-forward of accrued revenue rebates and returns for the nine months ended September 30, 2026 and 2025:

	Rebates, Returns and Other Deductions	Contra AR Accruals	Total
	$	$	
Balance at December 31, 2025	398,533	79,126	477,659
Accrual	724,460	788,511	1,512,971
Payments	(561,342)	(776,155)	(1,337,497)
Balance at September 30, 2026	561,651	91,482	653,133
Balance at December 31, 2024	235,600	50,699	286,299
Accrual	457,909	565,065	1,022,974
Payments	(310,732)	(564,676)	(875,408)
Balance at September 30, 2025	382,777	51,088	433,865

12. Earnings Per Share/ADS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Numerator:				
Net income	384,706	124,841	849,070	220,431
Denominator:				
Weighted-average shares outstanding—basic	1,478,074,394	1,432,801,699	1,457,134,424	1,410,497,062
Dilutive common share equivalents	46,880,396	55,948,655	54,838,529	55,037,942
Weighted-average shares outstanding—diluted	1,524,954,790	1,488,750,354	1,511,972,953	1,465,535,004
Antidilutive common share equivalents excluded from above	446,534	1,665,727	719,599	1,415,410
Earnings per share:				
Basic	0.26	0.09	0.58	0.16
Diluted	0.25	0.08	0.56	0.15
Earnings per ADS:				
Basic	3.38	1.13	7.58	2.03
Diluted	3.28	1.09	7.30	1.96

For the three and nine months ended September 30, 2026 and 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, performance stock units and ESPP shares. The dilutive effect of outstanding stock options, restricted stock units, performance stock units and ESPP shares is reflected in diluted net earnings per share using the treasury stock method.

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

13. Share-Based Compensation Expense

Share Option, Restricted Share Units and Performance Share Units

During the nine months ended September 30, 2026, the Company granted options for 1,222,884 ordinary shares, restricted share units for 23,174,216 ordinary shares, and performance share units for 2,093,507 ordinary shares under the Company's share option and incentive plan. As of September 30, 2026, options, restricted share units, and performance share units for ordinary shares outstanding totaled 35,589,170, 67,416,141, and 6,530,381, respectively. As of September 30, 2026, share-based awards to acquire 113,721,802 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 September 30, 2026, 4,822,408 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	
August 31, 2026	812,149	$ 314.36	$ 24.18	$ 267.21	$ 20.55	$ 16,693
February 28, 2026	741,299	$ 316.99	$ 24.38	$ 269.44	$ 20.73	$ 15,364
August 31, 2025	818,506	$ 245.53	$ 18.89	$ 208.70	$ 16.05	$ 13,140
February 28, 2025	955,396	$ 188.26	$ 14.48	$ 160.02	$ 12.31	$ 11,760

[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 nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
Research and development	56,474	58,839	168,866	164,998
Selling, general and administrative	76,143	81,947	224,566	221,792
Total	132,617	140,786	393,432	386,790

14. Accumulated Other Comprehensive Loss

The movement of accumulated other comprehensive loss was as follows:

	Foreign Currency Translation Adjustments	Other Adjustments	Total
	$	$	$
Balance as of December 31, 2025	(66,252)	(11,932)	(78,184)
Other comprehensive income before reclassifications	70,880	168	71,048
Amounts reclassified from accumulated other comprehensive loss	—	525	525
Net-current period other comprehensive income	70,880	693	71,573
Balance as of September 30, 2026	4,628	(11,239)	(6,611)

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 a general reserve fund prior to payment of dividends, the Company's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulations in the PRC may further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of dividends, loans and advances. As of September 30, 2026 and December 31, 2025, amounts restricted were the net assets of the Company's PRC subsidiaries, which, after intercompany eliminations, amounted to $1,964,450 and $2,012,019, respectively.

16. Commitments and Contingencies

Purchase Commitments

As of September 30, 2026, the Company had non-cancellable purchase commitments amounting to $237,266, of which $22,579 related to non-utilization fees and minimum purchase requirements for supply purchased from contract manufacturers and $214,687 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 $18,676 for the acquisition of property, plant and equipment as of September 30, 2026, related to various facilities across the globe.

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 funded its portion of the co-development costs by contributing cash and/or development services and reached the funding cap during the quarter ended September 30, 2026.

Funding Commitment

The Company had committed capital related to equity investments in the amount of $16,958. As of September 30, 2026, the remaining capital commitment was $4,058 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. Significant segment expenses reviewed by the CODM on a regular basis included within net income 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 include interest income, interest expense, 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 other revenue is recorded in the jurisdiction in which the related income is expected to be sourced from. Total revenues by geographic area are presented as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	$	$	$	$
U.S. - total revenue	**1,027,915**	**754,856**	**2,724,375**	**2,016,494**
Product revenue	1,013,241	742,687	2,677,470	1,991,430
Other revenue	14,674	12,169	46,905	25,064
China - total revenue	**536,365**	**439,885**	**1,514,360**	**1,272,401**
Product revenue	527,351	434,783	1,492,247	1,259,947
Other revenue	9,014	5,102	22,113	12,454
Europe - total revenue	**239,555**	**166,576**	**642,306**	**437,514**
Product revenue	234,180	166,576	633,904	435,788
Other revenue	5,375	—	8,402	1,726
Rest of world - total revenue	**85,980**	**50,967**	**227,283**	**118,454**
Product revenue	80,285	50,967	218,559	118,454
Other revenue	5,695	—	8,724	—
Total Revenue	**1,889,815**	**1,412,284**	**5,108,324**	**3,844,863**

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; the timing, progress and results of our research and development ("R&D") programs, preclinical studies and clinical trials of our drug candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available; 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; 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; our ability to comply with the covenants and other requirements under our facilities agreements and to borrow available amounts under such agreements; the impact of macroeconomic conditions, including uncertainties associated with geopolitical conflicts, tariff and trade policies, and inflation and capital market disruptions; statements regarding future revenue, key milestones, expenses, capital expenditures, capital requirements and share performance; the future trading price of our American Depositary Shares ("ADSs") listed on Nasdaq, our ordinary shares listed on HKEx, and our ordinary shares issued to permitted investors in China and listed and traded on the STAR in Renminbi ("RMB Shares"), as well as the impact of securities analysts' reports on these prices; and the effects of the redomiciliation to Switzerland, including its tax treatment and our name change in 2025. 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 whether 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 Cost of Sales-Product, Adjusted Operating Expenses, Adjusted Income (Loss) from Operations, Adjusted Income Tax Expense, 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 effect. The Company currently records a valuation allowance on its net deferred tax assets, so there is no net impact recorded for deferred tax effects in our tax expense. 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

BeOne Medicines is a global oncology company that is discovering and developing innovative treatments for cancer patients worldwide. With a portfolio spanning hematology and solid tumors, BeOne is expediting development of its diverse pipeline of novel therapeutics through its internal capabilities and collaborations.

Key highlights for the third quarter of 2026 are as follows:

- Third quarter 2026 total global revenues increased 34% to $1.9 billion versus third quarter 2025
- BRUKINSA® (zanubrutinib) global revenues increased 34% to $1.4 billion versus third quarter 2025
- Diluted GAAP Earnings per American Depositary Share ("ADS") of $3.28, non-GAAP diluted Earnings per ADS of $4.59.

Recent Developments

Recent Business Developments

On August 31, 2026, we announced our entry into a voluntary agreement with the U.S. government to expand access to innovative cancer medicines for American patients while strengthening our U.S. manufacturing footprint and further expanding the capabilities needed to deliver medicines at scale.

On August 31, 2026, we announced positive topline results from the second interim analysis of the Phase 3 HERIZON-GEA-01 trial evaluating ZIIHERA® (zanidatamab), in combination with chemotherapy, with and without TEVIMBRA® (tislelizumab), as first-line treatment for HER2-positive ("HER2+") locally advanced or metastatic gastroesophageal adenocarcinoma ("GEA").

On August 25, 2026, we announced that the U.S. Food and Drug Administration ("FDA") approved the supplemental Biologics License Application ("sBLA") for TEVIMBRA in combination with ZIIHERA and chemotherapy for the first-line treatment of adult patients with unresectable locally advanced or metastatic HER2+ gastric, gastroesophageal junction, or GEA.

On August 18, 2026, we announced the renewal of our partnership with the BeOne Care Foundation and The Max Foundation through 2028 to expand access to BRUKINSA® (zanubrutinib) for the treatment of chronic lymphocytic leukemia in low- and middle-income countries, with the program projected to support approximately 1,000 patients cumulatively.

On August 10, 2026, we announced a multi-part collaboration with Revolution Medicines, Inc., including: a clinical collaboration to evaluate drug combinations incorporating select clinical-stage oncology assets from our pipeline with any of Revolution Medicines' four clinical RAS(ON) inhibitors; and a separate regional rights agreement granting us exclusive development and commercialization rights to these Revolution Medicines assets in select Asian markets.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(dollars in thousands)							
Revenues								
Product revenue, net	$1,855,057	$1,395,013	$ 460,044	33.0 %	$5,022,180	$3,805,619	$1,216,561	32.0 %
Other revenue	34,758	17,271	17,487	101.3 %	86,144	39,244	46,900	119.5 %
Total revenues	1,889,815	1,412,284	477,531	33.8 %	5,108,324	3,844,863	1,263,461	32.9 %
Cost of sales - product	216,896	196,510	20,386	10.4 %	558,641	526,118	32,523	6.2 %
Gross profit	1,672,919	1,215,774	457,145	37.6 %	4,549,683	3,318,745	1,230,938	37.1 %
Operating expenses								
Research and development	660,784	523,662	137,122	26.2 %	1,814,288	1,530,445	283,843	18.5 %
Selling, general and administrative	593,460	528,998	64,462	12.2 %	1,741,771	1,526,199	215,572	14.1 %
Total operating expenses	1,254,244	1,052,660	201,584	19.1 %	3,556,059	3,056,644	499,415	16.3 %
Income from operations	418,675	163,114	255,561	156.7 %	993,624	262,101	731,523	279.1 %
Interest income	33,663	19,393	14,270	73.6 %	89,227	43,735	45,492	104.0 %
Interest expense	(42,407)	(16,364)	(26,043)	159.1 %	(115,033)	(31,361)	(83,672)	266.8 %
Other income (expense), net	429	(18,979)	19,408	(102.3)%	14,216	(6,862)	21,078	(307.2)%
Income before income taxes	410,360	147,164	263,196	178.8 %	982,034	267,613	714,421	267.0 %
Income tax expense	25,654	22,323	3,331	14.9 %	132,964	47,182	85,782	181.8 %
Net income	$ 384,706	$ 124,841	$ 259,865	208.2 %	$ 849,070	$ 220,431	$ 628,639	285.2 %

Comparison of the Three Months Ended September 30, 2026 and 2025

Revenue

Total revenue increased to $1,889.8 million for the three months ended September 30, 2026, from $1,412.3 million for the three months ended September 30, 2025, due to increased sales of BRUKINSA and TEVIMBRA, as well as increased sales of in-licensed products from Amgen.

Net product revenue consisted of the following:

	Three Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
BRUKINSA®	$ 1,390,936	$ 1,040,691	$ 350,245	33.7 %
TEVIMBRA®	243,282	190,623	52,659	27.6 %
XGEVA®	105,482	84,243	21,239	25.2 %
BLINCYTO®	38,869	30,476	8,393	27.5 %
KYPROLIS®	13,900	18,369	(4,469)	(24.3)%
BAITUOWEI®	22,111	11,243	10,868	96.7 %
POBEVCY®	10,717	10,499	218	2.1 %
Other	29,760	8,869	20,891	235.6 %
Total product revenue	$ 1,855,057	$ 1,395,013	$ 460,044	33.0 %

Net product revenue increased 33.0% to $1,855.1 million for the three months ended September 30, 2026, compared to $1,395.0 million in the prior-year period, primarily due to increased sales of BRUKINSA globally, driven by growth in the U.S. and Europe. In addition, product revenues in the third quarter of 2026 were positively impacted by growth from in-licensed products from Amgen and TEVIMBRA.

Global sales of BRUKINSA totaled $1,390.9 million in the third quarter, representing a 33.7% increase compared to the prior-year period; U.S. sales of BRUKINSA totaled $1,005.1 million in the third quarter, compared to $738.7 million in the prior-year period, representing growth of 36.1%, driven primarily by demand growth. BRUKINSA sales in Europe totaled $217.6 million in the third quarter, compared to $163.2 million in the prior-year period, representing growth of 33.3%, driven by continued gains in market share across all major markets, including Germany, Italy, Spain, France and the UK. BRUKINSA sales in China totaled $103.1 million, representing growth of 11.6%. BRUKINSA rest of world revenue totaled $65.2 million in the third quarter, representing growth of 40.4% compared to the prior-year period.

Sales of TEVIMBRA totaled $243.3 million in the third quarter, compared to $190.6 million in the prior-year period, representing an 27.6% increase.

Revenue for Amgen products in China totaled $167.0 million in the third quarter, compared to $133.1 million in the prior-year period, representing a 25.5% increase, driven primarily by increased XGEVA® sales volume.

Other revenue totaled $34.8 million and $17.3 million for the three months ended September 30, 2026 and 2025, respectively, primarily related to royalty revenue under the Amgen collaboration and revenue generated under the Novartis broad markets marketing and promotion agreement.

Gross Margin

Gross margin as a percentage of product sales increased to 88.3% for the three months ended September 30, 2026, from 85.9% 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 production productivity improvements resulting in lower costs for both BRUKINSA and TEVIMBRA, which was offset by a non-cash intangible asset impairment charge of $22.0 million associated with our decision to discontinue promotion of POBEVCY. On an adjusted basis, which does not include depreciation and amortization or the impairment charge, gross margin as a percentage of product sales increased to 89.9%, from 86.3% in the comparable period of the prior year.

Research and Development Expense

Research and development expense increased by $137.1 million, or 26.2%, to $660.8 million for the three months ended September 30, 2026 from $523.7 million for the three months ended September 30, 2025. The following table summarizes the external cost of development programs, upfront license and development milestone fees, and internal research and development expense for the three months ended September 30, 2026 and 2025, respectively:

	Three Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 230,259	$ 173,626	$ 56,633	32.6 %
Upfront license and development milestone fees	757	191	566	296.3 %
Amgen co-development expense[1]	6,022	30,050	(24,028)	(80.0)%
Total external research and development expenses	237,038	203,867	33,171	16.3 %
Internal research and development expenses	423,746	319,795	103,951	32.5 %
Total research and development expenses	$ 660,784	$ 523,662	$ 137,122	26.2 %
Adjusted research and development expenses[2]	$ 586,168	$ 445,904	$ 140,264	31.5 %

1. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended September 30, 2026 totaled $12.2 million, of which $6.0 million was recorded as R&D expense. The remaining $6.2 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.

External research and development expenses increased in the third quarter of 2026 compared to the same period in 2025. This was primarily driven by increased investment in the continued advancement of several programs across the pipeline, including BTK CDAC, CDK4, PRMT5 and GPC3x4-1BB bsAb, offset by decreased Amgen co-development expenses as we met the co-funding cap under the collaboration during the quarter.

Internal research and development expense increased by $104.0 million, or 32.5%, to $423.7 million for the three months ended September 30, 2026, from $319.8 million for the three months ended September 30, 2025, as we continue to invest in capabilities to support a growing portfolio. This increase was primarily attributable to the expansion of resources within the global development organization, alongside higher spending for toxicology studies, reagents, and consumables necessary to advance our clinical and preclinical candidates.

Selling, General and Administrative Expense

	Three Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
Selling, general and administrative expenses	$ 593,460	$ 528,998	$ 64,462	12.2 %
Adjusted selling, general and administrative expenses[1]	$ 503,719	$ 434,484	$ 69,235	15.9 %

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 $64.5 million, or 12.2%, to $593.5 million for the three months ended September 30, 2026, from $529.0 million for the three months ended September 30, 2025. 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 32.0% in the third quarter of 2026 compared to 37.9% in the prior-year period.

Interest Income

Interest income increased by $14.3 million, or 73.6%, to $33.7 million for the three months ended September 30, 2026, from $19.4 million for the three months ended September 30, 2025. The increase in interest income was primarily attributable to a higher cash and cash equivalents balance.

Interest Expense

Interest expense increased by $26.0 million, or 159.1%, to $42.4 million for the three months ended September 30, 2026, from $16.4 million for the three months ended September 30, 2025. The increase in interest expense was primarily attributable to interest expense recorded under the effective interest method related to the sale of future royalty liability, higher interest rates on debt balances, and lower interest capitalized related to the completion of certain phases of our Hopewell facility.

Other Income (Expense), Net

Other income, net was $0.4 million for the three months ended September 30, 2026, primarily due to government subsidy income, offset by foreign exchange losses. For the three months ended September 30, 2025, other expense, net was $19.0 million, primarily due to impairment losses recognized on our equity investments and foreign exchange losses.

Income Tax Expense

	Three Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
GAAP income tax expense	$ 25,654	$ 22,323	$ 3,331	14.9 %
Plus: Discrete tax items*	11,527	926	10,601	1,144.8 %
Plus: Income tax effect of non-GAAP adjustments	27,995	17,044	10,951	64.3 %
Adjusted income tax expense	$ 65,176	$ 40,293	$ 24,883	61.8 %
GAAP effective income tax rate	6.3 %	15.2 %		
Adjusted effective income tax rate	10.8 %	11.7 %		

*Certain US GAAP discrete tax items are not adjusted for purposes of non-GAAP adjusted results above.

Income tax expense was $25.7 million for the three months ended September 30, 2026 as compared to $22.3 million for the three months ended September 30, 2025. The income tax expense for the three months ended September 30, 2026 and 2025 was primarily attributable to the application of our expected current worldwide effective tax rate for the full year to year-to-date actual pre-tax income, reflecting the mix of taxable income across jurisdictions as well as the impact of certain discrete items. Specifically, the provision for income taxes for the three months ended September 30, 2026 included a discrete net tax benefit of approximately $11.5 million, attributable mainly to U.S. share-based compensation. The income tax expense for the three months ended September 30, 2025 included a discrete net tax benefit of $0.9 million, primarily related to updated provision estimates for U.S. R&D credits for prior periods.

Given the Company's recent history of earnings, management believes that there is a reasonable possibility that, within the next twelve months, sufficient positive evidence may become available to allow management to reach a conclusion that a significant portion of the valuation allowance recorded against the deferred tax assets held will be reversed. The reversal would result in an income tax benefit for the quarterly and annual fiscal period in which the Company releases the valuation allowance. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that the Company actually achieves. Prior to reversal, excluding any significant discrete items, income tax expense should trend with earnings per historical relationship.

As of September 30, 2026, the Company had gross unrecognized tax benefits of $28.1 million. Due to the uncertain and complex application of income tax regulations by certain tax authorities outside of the U.S., it is possible that the ultimate resolution of ongoing audits may result in liabilities that could be different from current estimates. The ongoing tax audits in various jurisdictions could impact future tax expense if tax authorities in their administration of tax laws during open audits may lead us to change our assessment of whether or not it is more likely than not that certain tax benefit positions will be sustained. The Company's reserve for uncertain tax positions increased by $2.0 million in the three months ended September 30, 2026, primarily due to an increase in U.S. federal and state tax attributes.

Net Income and Earnings Per Share

Net income for the third quarter of 2026 improved over the prior-year period on both a GAAP and adjusted basis, primarily attributable to revenue growth and improved operating leverage.

For the third quarter of 2026, basic and diluted earnings per share were $0.26 and $0.25 per share and $3.38 and $3.28 per American Depositary Share ("ADS"), respectively, compared to $0.09 and $0.08 per share and $1.13 and $1.09 per ADS in the prior-year period. On an adjusted basis, basic and diluted earnings per share was $0.36 and $0.35 per share and $4.74 and $4.59 per ADS, respectively, compared to $0.21 and $0.20 per share and $2.76 and $2.65 per ADS in the prior-year period.

Comparison of the Nine Months Ended September 30, 2026 and 2025

Revenue

Total revenue increased to $5,108.3 million, or 32.9%, for the nine months ended September 30, 2026, from $3,844.9 million for the nine months ended September 30, 2025, primarily due to increased sales of our internally developed products, BRUKINSA and TEVIMBRA, as well as increased sales of in-licensed Amgen products.

Net product revenues consisted of the following:

	Nine Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
BRUKINSA®	$ 3,733,419	$ 2,782,195	$ 951,224	34.2 %
TEVIMBRA®	678,038	555,311	122,727	22.1 %
XGEVA®	299,901	235,984	63,917	27.1 %
BLINCYTO®	109,441	79,969	29,472	36.9 %
KYPROLIS®	46,018	57,513	(11,495)	(20.0)%
BAITUOWEI®	54,110	25,920	28,190	108.8 %
POBEVCY®	32,477	35,486	(3,009)	(8.5)%
Other	68,776	33,241	35,535	106.9 %
Total product revenue	$ 5,022,180	$ 3,805,619	$ 1,216,561	32.0 %

Net product revenue increased 32.0% to $5,022.2 million for the nine months ended September 30, 2026, compared to $3,805.6 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 nine months ended September 30, 2026 were positively impacted by sales of TEVIMBRA and in-licensed products from Amgen, primarily XGEVA®.

Global sales of BRUKINSA totaled $3,733.4 million in the nine months ended September 30, 2026, representing a 34.2% increase compared to the prior-year period. U.S. sales of BRUKINSA totaled $2,658.7 million in the nine months ended September 30, 2026, compared to $1,985.6 million in the prior-year period, representing growth of 33.9%, driven primarily by demand growth across all indications as well as favorable net pricing, of which approximately $20.0 million relates to non-recurring gross to net adjustments realized in the first quarter of 2026. BRUKINSA sales in Europe totaled $595.6 million in the nine months ended September 30, 2026, representing growth of 38.6% driven by increased market share across all major European markets. BRUKINSA revenue in China totaled $294.3 million, representing growth of 14.6%. BRUKINSA rest of world revenue totaled $184.8 million in the nine months ended September 30, 2026, representing growth of 67.6% compared to the prior-year period.

Revenue for TEVIMBRA totaled $678.0 million in the nine months ended September 30, 2026, compared to $555.3 million in the prior-year period, representing a 22.1% increase.

Revenue for Amgen products in China totaled $466.5 million in the nine months ended September 30, 2026, compared to $373.5 million in the prior-year period, driven primarily by increased XGEVA® sales volume.

Other revenue totaled $86.1 million and $39.2 million for the nine months ended September 30, 2026 and 2025, respectively, primarily related to royalty revenue under the Amgen collaboration and revenue generated under the Novartis broad markets marketing and promotion agreement.

Gross Margin

Gross margin on product sales increased to $4,463.5 million for the nine months ended September 30, 2026, compared to $3,279.5 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 88.9% for the nine months ended September 30, 2026, from 86.2% 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 production productivity improvements for both BRUKINSA and TEVIMBRA, which was offset by a non-cash intangible asset impairment charge of $22.0 million associated with our decision to discontinue promotion of POBEVCY. On an adjusted basis, which does not include depreciation and amortization or the impairment charge, gross margin as a percentage of product sales increased to 89.7%, from 86.7% in the comparable period of the prior year.

Research and Development Expense

Research and development expense increased by $283.8 million, or 18.5%, to $1,814.3 million for the nine months ended September 30, 2026 from $1,530.4 million for the nine months ended September 30, 2025. The following table summarizes external clinical, external non-clinical and internal research and development expense for the nine months ended September 30, 2026 and 2025, respectively:

	Nine Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 581,851	$ 526,239	$ 55,612	10.6 %
Upfront license and development milestone fees	24,588	691	23,897	3,458.3 %
Amgen co-development expense[1]	65,725	77,196	(11,471)	(14.9)%
Total external research and development expenses	672,164	604,126	68,038	11.3 %
Internal research and development expenses	1,142,124	926,319	215,805	23.3 %
Total research and development expenses	$ 1,814,288	$ 1,530,445	$ 283,843	18.5 %
Adjusted research and development expenses[2]	$ 1,586,022	$ 1,311,156	$ 274,866	21.0 %

1. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the nine months ended September 30, 2026 totaled $130.1 million, of which $65.7 million was recorded as R&D expense. The remaining $64.3 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 nine months ended September 30, 2026 was primarily attributable to increased investment in the continued advancement of several programs across the pipeline, including BTK CDAC, CDK4, PRMT5 and GPC3x4-1BB bsAb and an increase in development upfront and milestone fees, offset by a decrease in Amgen co-development expenses as we met the co-funding cap under the collaboration during the quarter ended September 30, 2026.

Internal research and development expense increased by $215.8 million, or 23.3%, to $1,142.1 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

	Nine Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
Selling, general and administrative expenses	$ 1,741,771	$ 1,526,199	$ 215,572	14.1 %
Adjusted selling, general and administrative expenses[1]	$ 1,476,386	$ 1,271,650	$ 204,736	16.1 %

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 $215.6 million, or 14.1%, to $1,741.8 million, for the nine months ended September 30, 2026, from $1,526.2 million for the nine months ended September 30, 2025. 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 34.7% for the nine months ended September 30, 2026 compared to 40.1% in the prior-year period.

Interest Income

Interest income increased by $45.5 million, or 104.0%, to $89.2 million for the nine months ended September 30, 2026, from $43.7 million for the nine months ended September 30, 2025. The increase in interest income was primarily attributable to higher cash and cash equivalents balance.

Interest Expense

Interest expense increased by $83.7 million, or 266.8%, to $115.0 million for the nine months ended September 30, 2026, from $31.4 million for the nine months ended September 30, 2025. The increase in interest expense was primarily attributable to interest expense recorded under the effective interest method related to the sale of future royalty liability, higher interest rates on debt balances and lower interest capitalized related to completion of certain phases of our Hopewell facility.

Other Income (Expense), Net

Other income, net was $14.2 million for the nine months ended September 30, 2026, primarily due to government subsidy income, offset by foreign exchange losses. For the nine months ended September 30, 2025, other expense, net was $6.9 million, primarily due to impairment losses recognized on our equity investments, partially offset by government subsidy income and foreign exchange gains.

Income Tax Expense

	Nine Months Ended September 30,		Changes	
	2026	2025	$	%
	(dollars in thousands)			
GAAP income tax expense	$ 132,964	$ 47,182	$ 85,782	181.8 %
Plus: Discrete tax items*	(41,847)	9,663	(51,510)	(533.1)%
Plus: Income tax effect of non-GAAP adjustments	68,668	45,747	22,921	50.1 %
Adjusted income tax expense	$ 159,785	$ 102,592	$ 57,193	55.7 %
GAAP effective income tax rate	13.5 %	17.6 %		
Adjusted effective income tax rate	10.5 %	12.9 %		

*Certain US GAAP discrete tax items are not adjusted for purposes of non-GAAP adjusted results above.

Income tax expense increased to $133.0 million for the nine months ended September 30, 2026, from $47.2 million for the nine months ended September 30, 2025. The income tax expense for the nine months ended September 30, 2026 and 2025 was primarily attributable to the application of our expected current worldwide effective tax rate for the full year to year-to-date actual pre-tax income, reflecting the mix of taxable income across jurisdictions as well as the impact of certain discrete items. Specifically, the provision for income taxes for the nine months ended September 30, 2026 included a discrete net tax expense of approximately $41.3 million. This figure primarily relates to the settlement of the audit of one of our China subsidiaries amounting to $59.6 million, partially offset by certain discrete items mainly related to U.S. share-based compensation. The income tax expense for the nine months ended September 30, 2025 included a discrete net tax benefit of $9.6 million, primarily related to updated provision estimates for U.S. R&D tax credits.

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. While we have estimated the impact of certain elective provisions of the OBBBA, we do not expect the legislation to have a material impact on our consolidated financial statements.

Net Income and Earnings Per Share

Net income for the nine months ended September 30, 2026 improved over the prior-year period on both a GAAP and adjusted basis, primarily attributable to revenue growth and improved operating leverage.

For the nine months ended September 30, 2026, basic and diluted earnings per share was $0.58 and $0.56 per share and $7.58 and $7.30 per ADS, respectively, compared to basic and diluted earnings per share of $0.16 and $0.15 per share and $2.03 and $1.96 per ADS in the prior-year period. On an adjusted basis, basic and diluted earnings per share was $0.93 and $0.90 per share and $12.12 and $11.68 per ADS, respectively, compared to $0.49 and $0.47 per share and $6.38 and $6.14 per ADS in the prior-year period.

Non-GAAP Reconciliation

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(Amounts in thousands of U.S. dollars, except for per share and per ADS data)			
Reconciliation of GAAP to adjusted cost of sales - products:				
GAAP cost of sales - products	$ 216,896	$ 196,510	$ 558,641	$ 526,118
Less: Depreciation	5,596	4,261	15,442	10,195
Less: Amortization of intangibles	23,598	1,537	26,932	8,459
Less: Other	—	—	—	893
Adjusted cost of sales - products	$ 187,702	$ 190,712	$ 516,267	$ 506,571
Reconciliation of GAAP to adjusted research and development:				
GAAP research and development	$ 660,784	$ 523,662	$ 1,814,288	$ 1,530,445
Less: Share-based compensation expenses	56,474	58,839	168,866	164,998
Less: Depreciation	18,142	18,919	59,400	54,291
Adjusted research and development	$ 586,168	$ 445,904	$ 1,586,022	$ 1,311,156
Reconciliation of GAAP to adjusted selling, general and administrative:				
GAAP selling, general and administrative	$ 593,460	$ 528,998	$ 1,741,771	$ 1,526,199
Less: Share-based compensation expenses	76,143	81,947	224,566	221,792
Less: Depreciation	13,582	12,550	40,769	32,712
Less: Amortization of intangibles	16	17	50	45
Adjusted selling, general and administrative	$ 503,719	$ 434,484	$ 1,476,386	$ 1,271,650
Reconciliation of GAAP to adjusted operating expenses				
GAAP operating expenses	$ 1,254,244	$ 1,052,660	$ 3,556,059	$ 3,056,644
Less: Share-based compensation expenses	132,617	140,786	393,432	386,790
Less: Depreciation	31,724	31,469	100,169	87,003
Less: Amortization of intangibles	16	17	50	45
Adjusted operating expenses	$ 1,089,887	$ 880,388	$ 3,062,408	$ 2,582,806
Reconciliation of GAAP to adjusted income from operations:				
GAAP income from operations	$ 418,675	$ 163,114	$ 993,624	$ 262,101
Plus: Share-based compensation expenses	132,617	140,786	393,432	386,790
Plus: Depreciation	37,320	35,730	115,611	97,198
Plus: Amortization of intangibles	23,614	1,554	26,982	8,504
Plus: Other	—	—	—	893
Adjusted income from operations	$ 612,226	$ 341,184	$ 1,529,649	$ 755,486
Reconciliation of GAAP to adjusted income tax expense:				
GAAP income tax expense	$ 25,654	$ 22,323	$ 132,964	$ 47,182
Plus: Discrete tax items	11,527	926	(41,847)	9,663
Plus: Income tax effect of non-GAAP adjustments	27,995	17,044	68,668	45,747
Adjusted income tax expense	$ 65,176	$ 40,293	$ 159,785	$ 102,592

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(Amounts in thousands of U.S. dollars, except for per share and per ADS data)			
Reconciliation of GAAP to adjusted net income:				
GAAP net income	$ 384,706	$ 124,841	$ 849,070	$ 220,431
Plus: Share-based compensation expenses	132,617	140,786	393,432	386,790
Plus: Depreciation	37,320	35,730	115,611	97,198
Plus: Amortization of intangibles	23,614	1,554	26,982	8,504
Plus: Other	—	—	—	893
Plus: Impairment of equity investments	—	18,722	—	34,216
Plus: Discrete tax items	(11,527)	(926)	41,847	(9,663)
Plus: Income tax effect of non-GAAP adjustments	(27,995)	(17,044)	(68,668)	(45,747)
Adjusted net income	$ 538,735	$ 303,663	$ 1,358,274	$ 692,622
Reconciliation of GAAP to adjusted EPS - basic				
GAAP earnings per share - basic	$ 0.26	$ 0.09	$ 0.58	$ 0.16
Plus: Share-based compensation expenses	0.09	0.10	0.27	0.27
Plus: Depreciation	0.03	0.02	0.08	0.07
Plus: Amortization of intangibles	0.02	0.00	0.02	0.01
Plus: Other	0.00	0.00	0.00	0.00
Plus: Impairment of equity investments	0.00	0.01	0.00	0.02
Plus: Discrete tax items	(0.01)	0.00	0.03	(0.01)
Plus: Income tax effect of non-GAAP adjustments[1]	(0.02)	(0.01)	(0.05)	(0.03)
Adjusted earnings per share - basic	$ 0.36	$ 0.21	$ 0.93	$ 0.49
Reconciliation of GAAP to adjusted EPS - diluted				
GAAP earnings per share - diluted	$ 0.25	$ 0.08	$ 0.56	$ 0.15
Plus: Share-based compensation expenses	0.09	0.09	0.26	0.26
Plus: Depreciation	0.02	0.02	0.08	0.07
Plus: Amortization of intangibles	0.02	0.00	0.02	0.01
Plus: Other	0.00	0.00	0.00	0.00
Plus: Impairment of equity investments	0.00	0.01	0.00	0.02
Plus: Discrete tax items	(0.01)	0.00	0.03	(0.01)
Plus: Income tax effect of non-GAAP adjustments[1]	(0.02)	(0.01)	(0.05)	(0.03)
Adjusted earnings per share - diluted	$ 0.35	$ 0.20	$ 0.90	$ 0.47
Reconciliation of GAAP to adjusted earnings per ADS - basic				
GAAP earnings per ADS - basic	$ 3.38	$ 1.13	$ 7.58	$ 2.03
Plus: Share-based compensation expenses	1.17	1.28	3.51	3.56
Plus: Depreciation	0.33	0.32	1.03	0.90
Plus: Amortization of intangibles	0.21	0.01	0.24	0.08
Plus: Other	0.00	0.00	0.00	0.01
Plus: Impairment of equity investments	0.00	0.17	0.00	0.32
Plus: Discrete tax items	(0.10)	(0.01)	0.37	(0.09)
Plus: Income tax effect of non-GAAP adjustments[1]	(0.25)	(0.15)	(0.61)	(0.42)
Adjusted earnings per ADS - basic	$ 4.74	$ 2.76	$ 12.12	$ 6.38

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(Amounts in thousands of U.S. dollars, except for per share and per ADS data)			
Reconciliation of GAAP to adjusted earnings per ADS - diluted				
GAAP earnings per ADS - diluted	$ 3.28	$ 1.09	$ 7.30	$ 1.96
Plus: Share-based compensation expenses	1.13	1.23	3.38	3.43
Plus: Depreciation	0.32	0.31	0.99	0.86
Plus: Amortization of intangibles	0.20	0.01	0.23	0.08
Plus: Other	0.00	0.00	0.00	0.01
Plus: Impairment of equity investments	0.00	0.16	0.00	0.30
Plus: Discrete tax items	(0.10)	(0.01)	0.36	(0.09)
Plus: Income tax effect of non-GAAP adjustments[1]	(0.24)	(0.15)	(0.59)	(0.41)
Adjusted earnings per ADS - diluted	$ 4.59	$ 2.65	$ 11.68	$ 6.14

[1] Tax effect of non-GAAP adjustments is based on the statutory tax rate in the relevant tax jurisdiction. Please note that the Company currently records a valuation allowance on its net deferred tax assets, so there is no net impact recorded for deferred tax effects.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Free Cash Flow (Non-GAAP):				
Net cash provided by operating activities (GAAP)	$ 508,707	$ 402,553	$ 1,172,863	$ 710,233
Less: Purchases of property, plant and equipment	(35,175)	(48,084)	(103,440)	(148,317)
Free Cash Flow (Non-GAAP)	$ 473,532	$ 354,469	$ 1,069,423	$ 561,916

Liquidity and Capital Resources

The following table represents our cash and debt balances as of September 30, 2026 and December 31, 2025:

	As of	
	September 30, 2026	December 31, 2025
	(in thousands)	
Cash, cash equivalents and restricted cash	$ 5,866,314	$ 4,609,647
Total debt	$ 1,074,081	$ 1,019,206

We have generated positive cash flow from operations since the third quarter of 2024.

Based on our current operating plan, we expect that our operating cash flows and existing cash and cash equivalents as of September 30, 2026 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. In 2025, we generated proceeds from long-term debt of $855.0 million which was used to pay off all existing short-term working capital loans, and is associated with certain restrictive covenants as described below with respect to certain coverage ratios and maximum investment amounts. 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 as they become due principally in 2027 and 2028.

Facilities Agreement

In November 2025, we entered into a Facilities Agreement (the "Facilities Agreement") with a syndicate of banks. The Facilities Agreement provides for a $140 million U.S. dollar-denominated, 2-year B1 revolving credit facility (the "B1 Revolving Loan Facility"), a $560 million U.S. dollar-denominated, 2-year, B2 term loan facility (the "B2 Term Loan Facility" and, together with the B1 Revolving Loan Facility, the "B Loan Facilities"), and a RMB $2.15 billion Renminbi-denominated, or approximately $300 million, 3-year, A term loan facility (the "A Loan Facility") (collectively, the "Loan Facilities"). Subsequently, we consummated the refinancing of our short-term (1 year tenor) working capital loans of approximately $768 million in aggregate through the proceeds from the B2 Term Loan Facility and A Loan Facility. We paid $23 million in debt issuance costs for the Facilities Agreement from available cash and cash equivalents.

The refinancing extended the maturity of our working capital loans. The A Loan Facility requires repayment of 4% of the aggregate amount outstanding every six months beginning on November 24, 2026, with all remaining principal outstanding due on November 24, 2028. The B2 Term Loan Facility requires repayment of 10% of the aggregate amount outstanding every three months beginning on June 15, 2027, with all remaining principal outstanding due on December 15, 2027, unless the final repayment date is extended.

As of September 30, 2026, we had $321 million A Loan Facility and $560 million B2 Term Loan Facility outstanding under our Facilities Agreement. The A Loan Facility is subject to an interest rate equal to the Reference Rate (RMB) (as defined in the Facilities Agreement) plus a margin of 0.65% per annum. The B Loan Facilities are subject to an interest rate equal to the Reference Rate (USD) (as defined in the Facilities Agreement) plus a margin of 2.40% per annum. In addition to paying interest on the outstanding principal, we are also required to pay a commitment fee of 0.85% on the undrawn and uncancelled amounts under the Loan Facilities.

The Facilities Agreement contains certain affirmative and negative covenants customary for financings of this type. In addition, the Facilities Agreement contains financial covenants applicable to the Loan Facilities, including covenants requiring the maintenance of: (i) a minimum cash interest coverage ratio of not less than 5.00 to 1.00; (ii) a net leverage ratio of not greater than 2.50 to 1.00; (iii) a minimum total consolidated shareholders' equity of the Group of not less than $2.7 billion; (iv) a minimum cash balance held outside the PRC by the Company and the Guarantors of $500.0 million; (v) a maximum financial indebtedness of the Company and its subsidiaries not to exceed $2.0 billion; and (vi) a maximum financial indebtedness of the Company's subsidiaries that are incorporated or registered in the PRC not to exceed $500.0 million. We were compliant with the required covenants as of September 30, 2026.

Sale of Future Royalties

The proceeds from sale of future royalties of $911 million in 2025 increased our cash and cash equivalents through financing cash inflows. However, the repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period; therefore, it has not been included in the total debt balance above, as there is no claim on unrestricted cash. Our classification of the liability between current and non-current is based on our expectations of royalty revenue from Amgen over the next 12 months, which will be paid to Royalty Pharma in accordance with the terms of the Royalty Agreement. Cash inflows from Amgen are classified as operating cash inflows, while the corresponding payments to Royalty Pharma are allocated between interest cash outflows within operating cash flows and a portion to reduce the liability, classified as a financing cash outflow. Pursuant to the Royalty Agreement, in the nine months ended September 30, 2026, we paid to Royalty Pharma an aggregate of $52 million, of which $49 million was allocated as interest expense and recognized within operating cash flows, and $3 million was recorded as reduction to the liability and recognized within financing activities. An additional $27 million of interest expense was accrued as of September 30, 2026. Any cash received from Amgen but not yet remitted to Royalty Pharma as of the balance sheet date will be reflected as restricted cash in the Consolidated Balance Sheet. There was no such restricted cash as of September 30, 2026.

The following table provides information regarding our cash and cash equivalents, cash flows and unused borrowing capacity available for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,	
	2026	2025
	(dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 4,609,647	$ 2,638,747
Net cash provided by operating activities	1,172,863	710,233
Net cash used in investing activities	(130,623)	(237,820)
Net cash provided by financing activities	164,772	962,520
Net effect of foreign exchange rate changes	49,655	36,862
Net increase in cash, cash equivalents, and restricted cash	1,256,667	1,471,795
Cash, cash equivalents and restricted cash at end of period	$ 5,866,314	$ 4,110,542
Unused borrowing capacity available, at end of period	$ 82,033	$ 140,000

Operating Activities

Cash provided by operating activities increased by $462.6 million in the nine months ended September 30, 2026, versus the prior year period due primarily to our significantly improved gross margins in the current year period, partially offset by continued funding of our development pipeline and commercial operations, increasing working capital to support our global expansion and the timing of compensation-related payments.

Investing Activities

Investing activities used $130.6 million of cash in the nine months ended September 30, 2026, compared to $237.8 million in the prior year period due primarily to a decrease in capital expenditures, principally related to our manufacturing and clinical R&D facility in Hopewell, New Jersey, and acquired in-process research and development and regulatory milestone payments and purchase of equity investments.

Financing Activities

Financing activities provided $164.8 million of cash in the nine months ended September 30, 2026, compared to $962.5 million in the prior year period. This decline was primarily due to $885 million of proceeds from the sale of future royalties in the prior year period, as well as lower proceeds from option exercises and the employee share purchase plan, partially offset by a net increase in debt borrowings in the current year period.

We expect to repay approximately $258.8 million of outstanding bank loans in the next 12 months.

Effects of Exchange Rates on Cash

In the nine months ended September 30, 2026, we incurred realized losses on cash of $6.2 million, which 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 monetary assets and liabilities denominated in currencies other than the USD to USD.

We also have substantial operations in China and Europe, where the functional currency is the RMB and Euro, respectively, and as such the net cash flows are translated to the U.S. dollar for financial reporting. This process generates translation gains and losses on non-USD cash held in those currency markets 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 September 30, 2026:

	Payments Due by Period		
	Total	Short Term	Long Term
	(dollars in thousands)		
Contractual obligations			
Operating lease commitments	$ 80,504	$ 7,193	$ 73,311
Purchase commitments	237,266	237,266	—
Debt obligations	1,088,531	258,806	829,725
Interest on debt	75,856	50,571	25,285
Funding commitment	4,058	4,000	58
Capital commitments	18,676	18,676	—
Total	$ 1,504,891	$ 576,512	$ 928,379

Operating Lease Commitments

We lease office facilities in California and Massachusetts in the U.S.; Basel, Switzerland; and office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou 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 September 30, 2026, non-cancellable purchase commitments amounted to $237.3 million, of which $22.6 million related to non-utilization fees and minimum purchase requirements for supply purchased from contract manufacturers and $214.7 million related to binding purchase order 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 $258.8 million. Total long-term debt obligations are $829.7 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. As of September 30, 2026, 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 on 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 remaining contractual life of the outstanding borrowings.

Royalty Sale Liability

As described above, we have a contractual commitment to pay Royalty Pharma amounts received from Amgen related to Amgen's sales of IMDELLTRA® in certain markets outside of China. While we have classified the upfront payment and the option exercise payment received from Royalty Pharma as a liability, the repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period, which is anticipated to extend at least through 2041. We have not included this liability in the table above because it does not constitute a fixed contractual obligation or a cancellable commitment from which the upfront payment and the option exercise payment could be demanded for refund.

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 $1.25 billion. The Company funded its portion of the co-development costs by contributing cash and/or development services and reached the funding cap during the quarter ended September 30, 2026.

Funding Commitments

Funding commitments represent our committed capital related to equity investments. As of September 30, 2026, our remaining capital commitment was $4.1 million and is expected to be paid from time to time over the investment period.

Capital Commitments

We had capital commitments amounting to $18.7 million for the acquisition of property, plant and equipment as of September 30, 2026, related to various facilities across the globe.

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, estimates related to the sale of future royalty liability and the fair value of financial instruments. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies as of and for the three and nine months ended September 30, 2026, 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, 2025.

For new accounting policies adopted during the three and nine months ended September 30, 2026, 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 $1.1 billion of outstanding floating rate debt as of September 30, 2026. A 100-basis point increase in interest rates as of September 30, 2026 would increase our annual pre-tax interest expense by approximately $10.9 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 4.3% in the nine months ended September 30, 2026 and depreciated approximately 4.4% in the year ended December 31, 2025, 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 nine months ended September 30, 2026 and 2025, we recognized $6.2 million of foreign exchange losses and $4.0 million of foreign exchange gains, 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 entity, BeOne Medicines Ltd.

Translational Risk

We also face foreign currency exposure that arises from translating the financial position and 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 nine months ended September 30, 2026.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation, required by paragraph (b) of Rules 13a-15 or 15d-15, promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act are effective, at a reasonable assurance level, as of September 30, 2026, to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in U.S. Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2026 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.

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 BTK degrader program, including the lead compound, BGB-16673 (tacabrutideg). The complaint seeks an unspecified amount of monetary damages, declaratory judgment, restitution and other equitable remedies. The Company filed a motion to dismiss the complaint in its entirety on December 19, 2024. On May 12, 2026, the Court denied the Company's motion to dismiss. The litigation remains ongoing, no trial date has been scheduled, and the Company is vigorously defending against the claims.

ANDA Litigation

On February 25, 2026, our subsidiaries, BeOne Medicines USA Inc. and BeOne Medicines I GmbH, filed a patent infringement suit under the Hatch-Waxman Act against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus") in the United States District Court for the District of New Jersey. The patent infringement suit is in response to Zydus' notice to BeOne concerning the filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking FDA approval to market a generic version of BRUKINSA® (zanubrutinib) tablets along with "Paragraph IV certifications" challenging certain BRUKINSA® Orange Book patents for invalidity and/or non-infringement. According to the notice, Zydus has not challenged BRUKINSA's composition of matter patent, which remains intact and protects BRUKINSA® from generic competition until its expiration in 2034.

BeOne's complaint alleges that by filing the ANDA, Zydus infringes certain of BRUKINSA's Orange Book patents and seeks a permanent injunction to prevent Zydus from commercializing a generic version of BRUKINSA® tablets until the expiration of the asserted patents.

ANDA litigation is common in the U.S. pharmaceutical industry. We may receive additional notices from other generic drug companies and may file additional ANDA lawsuits in the future.

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, 2025 (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.
- Restrictive covenants in our facilities agreements may limit our ability to respond to changes in market conditions or pursue business opportunities.
- 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.
- As a Swiss corporation, our flexibility is limited with respect to certain aspects of capital management.
- 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®, TEVIMBRA®, 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 more efficiently that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our medicines. In addition, the increasing use of artificial intelligence ("AI") by third parties (including actual or potential competitors) may allow them to develop more effective methods to accelerate discovery and development timelines, identify targets or optimize development decisions more rapidly, or reduce such costs relative to us. 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.

In April 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 ("HHS") to take steps to reduce drug prices. In May 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 facilitate direct-to-consumer and direct-to-business purchasing programs and directs the Secretary of the U.S. Department 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." Subsequently, the Trump administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer "most-favored nation"("MFN") pricing equal to or lower than those paid in other developed nations for certain prescription drugs under Medicaid and for certain newly launched products across all market channels in the U.S., and some pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices or reached agreement with the federal government regarding prices for prescription drugs sold to U.S. patients and through Medicaid programs. In February 2026, the Trump administration announced the launch of TrumpRx, a website operated by the federal government that is intended to redirect consumers to pharmaceutical companies' direct-to-consumer channels. Additionally, in December 2025, the Centers for Medicare and Medicaid Services ("CMS") proposed a rule to implement the Global Benchmark for Efficient Drug Pricing ("GLOBE") Model and the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Model – both are new Medicare payment models under section 1115A of the Social Security Act. The scope, timing, and implementation details of these policies remain uncertain and may be subject to legal challenges, regulatory rulemaking, and changes in administrative priorities. If implemented, these policies could have a material impact on the pricing and reimbursement of our products in the United States, particularly those covered under Medicare Part B or Part D. Potential effects include reduced pricing flexibility, downward pressure on reimbursement rates and changes to market access dynamics and to pricing negotiations with commercial payors and international markets. Because the outcome, timing, and specifics of these policies are uncertain, we cannot predict the effect on our business, financial condition, results of operations, or prospects, but the impact could be material and adverse.

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, TEVIMBRA, 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, accounting 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. In addition, on August 28, 2026, the Standing Committee of the National People's Congress adopted the Medical Security Law of the PRC (the "Medical Security Law"), which will take effect on January 1, 2027. The Medical Security Law codifies, at the level of national law, the fundamental framework for the medical security system in China, including the administration of the basic medical insurance system, the medical security fund, and the drug catalogue for basic medical insurance. We are evaluating the potential impact of the Medical Security Law on our business, and any implementation measures promulgated thereunder may materially affect the pricing of, and reimbursement for, our medicines 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 trade policy, including tariffs that have been or may in the future be imposed by the U.S. or other countries, trade disputes, 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 our employees;
- 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, such as the ongoing conflicts between Russia and Ukraine or in Iran, and related sanctions.

For example, in 2025, the U.S. imposed tariffs on imports on its trading partners, including Canada, Mexico, the EU and China, and has subsequently proposed additional or alternative tariffs. While certain tariffs have been subsequently invalidated, suspended, modified or temporarily reduced, and the U.S. Supreme Court ruling in February 2026 invalidated a significant portion of the tariffs previously adopted by the U.S. government under emergency statutory authority, the Trump administration has imposed new tariffs under different statutory authority and is conducting investigations that could lead to additional tariffs. These actions could lead to corresponding punitive actions by the countries with which the U.S. trades.

Furthermore, in April 2025, the Bureau of Industry and Security of the U.S. Department of Commerce ("BIS") initiated an investigation under Section 232 of the Trade Expansion Act of 1962 ("Section 232") into whether imports of pharmaceutical products present a risk to the national security of the U.S. Subsequently, in late 2025, the Trump administration announced that it had "begun preparing" tariffs on manufacturers that do not build in the United States or enter into an MFN drug pricing agreement with the Trump administration. In April 2026, based on the Section 232 investigation, President Trump issued a proclamation (the "Proclamation") invoking Section 232 to impose tariffs on imports of certain patented pharmaceuticals, biologics, and associated ingredients into the U.S. The Proclamation affects pharmaceutical manufacturers, importers, and supply chain participants, and, beginning in September 2026, imposed tariffs ranging from 10% to 100% on pharmaceutical articles that are subject to a valid, unexpired U.S. patent and are listed either in the Orange Book or in the FDA's Lists of Licensed Biological Products, or the Purple Book. These tariffs apply to active pharmaceutical ingredients and key starting materials for such articles. Certain categories of products are exempt from these tariffs, including generic pharmaceuticals and biosimilars; U.S.-origin pharmaceutical products, active pharmaceutical ingredients and key starting materials; products classified in certain 10-digit tariff codes, listed in Annex IV of the Proclamation; drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act; drugs for certain specific uses, including nuclear medicines; plasma-derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological, and nuclear threats; animal health; other specialty pharmaceutical products to be later identified by the Secretary of Commerce; and goods that qualify "for use in clinical trials, research and development, or other non-commercial applications," may be excluded from the additional tariffs. In August 2026, we entered into an onshoring agreement with the U.S. government, securing an exemption from Section 232 pharmaceutical tariffs. Given the uncertainty regarding the scope and duration of tariffs and other aspects of U.S. and foreign government trade policies, any impact on our business remains uncertain.

Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. The applicability of, and lack of clarity around, trade tariffs imposed by the U.S. government and retaliatory tariffs imposed by other governments may have a significant impact on the financial condition of companies. 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, and increased tariffs may make certain products no longer commercially viable. The scope or scale of any resulting tariffs as well as their secondary effects could adversely impact our business. Additionally, in October 2026, the U.S. Department of the Treasury proposed draft regulations under the Comprehensive Outbound Investment National Security Act of 2025, which, among other things, would prohibit certain U.S. investments and other transactions involving a broad range of biotechnology activities in certain countries of concern, including China. To the extent these regulations ultimately take effect, our ability to collaborate with parties affiliated with certain countries, including China, in certain types of transactions may be diminished or eliminated. These and other risks, including the risks described in "Risks Related to Our Doing Business in the PRC", may materially adversely affect our ability to attain or sustain revenue in international markets.

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

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

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and we cannot predict with any certainty the success of any clinical trial or whether or when we might complete a given clinical trial. We may also experience delays in initiating and conducting clinical trials of our drug candidates, and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all.

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 grant 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 grants 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 were originally 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.

Federal legislative and regulatory efforts to implement reference pricing or most-favored-nation pricing models could impact our product revenues and materially harm our business.

On May 12, 2025, President Trump issued an executive order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. and directing the Secretary of HHS to communicate MFN price targets to pharmaceutical manufacturers to align prices with those in comparably developed nations and, in the event significant progress towards MFN pricing is not delivered, to propose rulemaking to impose MFN pricing.

Since the May 12, 2025 order, the Trump administration has continued to exert pressure on drug manufacturers to implement MFN pricing, including by suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement MFN pricing, and the Trump administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer MFN pricing equal to or lower than those paid in other developed nations for certain prescription drugs under Medicaid and for certain newly launched products across all market channels in the U.S. Further, in November 2025, CMS introduced the GENEROUS (GENErating cost Reductions for U.S. Medicaid) Model, a voluntary Medicaid payment initiative under which participating drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with an MFN price for the manufacturers' products. Additionally, in December 2025, CMS announced proposals for new mandatory demonstration payment models through two proposed rules under its Center for Medicare and Medicaid Innovation ("CMMI") authority, the GLOBE for Medicare Part B and GUARD for Medicare Part D. If finalized, these models would impose additional mandatory rebates on manufacturers of certain Medicare Part B and Medicare Part D drugs, for select Medicare populations intended to represent 25% of Medicare patients, if the Medicare prices for such products exceed those paid in economically comparable countries. Both the GLOBE and GUARD models have proposed seven-year testing periods, with both the GLOBE model and the GUARD model proposed to begin on January 1, 2027. In August 2026, we entered into a voluntary agreement with the U.S. government intended to expand patient access to certain innovative cancer medicines and strengthen our U.S. manufacturing footprint. In connection with this agreement, we intend to participate in the GENEROUS Model and secured an exemption from the Section 232 pharmaceutical tariffs announced by the Trump administration. While these arrangements with the U.S. government are intended to support certain policy objectives underlying recent U.S. pharmaceutical pricing initiatives, we cannot predict the scope, duration, implementation, or future application of such initiatives or whether the agreement will achieve its intended objectives. In addition, there can be no assurance that future pricing, reimbursement, trade, tariff, or related measures will not adversely affect our business.

If the GLOBE and GUARD models are finalized as proposed under CMMI authority, we could be required to pay additional rebates on products reimbursed by Medicare for the covered populations during the applicable model periods. In addition, if MFN pricing or similar reference pricing policies are enacted or implemented in the U.S. outside of the CMMI framework and applied more broadly, we could be required to pay rebates on products on utilization by a broader portion of U.S. patients to align with prices in certain reference countries. We currently derive a substantial portion of our revenue from U.S. sales, and any requirement to pay additional rebates in the U.S. to match international reference prices would impact our overall net revenue.

MFN pricing models in the U.S. could also affect our international pricing strategy and future decisions on reimbursement and commercialization in certain jurisdictions. If our U.S. pricing becomes tied to international reference prices, we may face decisions regarding pricing in foreign markets that could result in reduced patient access internationally, affect our relationships with foreign regulatory authorities and payers, or impact our ability to obtain or maintain reimbursement approvals in ex-U.S. markets.

These reforms remain subject to change, potential legal challenges, or expansion through additional rulemaking or sub regulatory guidance, creating uncertainty for our overall pricing strategy. It remains to be seen whether and how these drug pricing initiatives will apply to our products, how they will affect the broader pharmaceutical industry, and whether similar reform measures may be adopted in the future.

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, European Medicines Agency ("EMA") and Medicines and Healthcare products Regulatory Agency ("MHRA"), 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, NMPA, EMA, MHRA 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 March 2024, we subsequently received FDA approval for TEVIMBRA for this second-line indication. In 2024, the FDA deferred approval for TEVIMBRA in first-line unresectable, recurrent, locally advanced, or metastatic ESCC on account of a delay in scheduling clinical site inspections. In March 2025, we subsequently received FDA approval for TEVIMBRA for this first-line indication.

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 experiencing development delays or not receiving approval for commercialization in the applicable jurisdictions. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

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 the NMPA, EMA, MHRA and other 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, MHRA 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, MHRA 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, MHRA 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, MHRA 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-marketing 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, MHRA 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, MHRA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. For example, in September 2025, the FDA and HHS announced reforms to limit the use of misleading direct-to-consumer pharmaceutical advertisements and increased enforcement activity, including through the issuance of dozens of publicly-posted untitled and warning letters, regarding direct-to-consumer advertising. Subsequently, in December 2025 and January 2026, we received untitled letters from the FDA relating to certain promotional communications relating to BRUKINSA® and TEVIMBRA®. We submitted responses to the FDA regarding the untitled letters. 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, MHRA 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, MHRA 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 TEVIMBRA, 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 TEVIMBRA, 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*."

In addition, in July 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law. This legislation reduces funding to federal healthcare programs and imposes additional requirements to be eligible for healthcare, and, to the extent the OBBBA reduces the number of enrollees in federal healthcare programs and covered services, our business could be adversely impacted.

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, with exceptions in 2025 and periods when we were profitable due to revenue recognized from up-front license fees from collaboration agreements or the settlement of legal proceedings. As of September 30, 2026 and December 31, 2025, we had an accumulated deficit of $7.5 billion and $8.3 billion, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs, including $1.25 billion that was contributed to the global development of a portfolio of Amgen pipeline assets under our collaboration agreement, and from selling, general and administrative expenses associated with our operations.

Although we have achieved positive GAAP operating income and net income for full year 2025 as product sales growth exceeded 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, 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 not be profitable in future periods. To the extent we achieve profitability in any future periods, we may not be able to sustain profitability in subsequent periods. Our failure to sustain profitability 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 provided $1.1 billion, and used $0.1 billion and $1.2 billion of net cash during the years ended December 31, 2025, 2024 and 2023, respectively. Our operating activities provided approximately $1,173 million and $710 million of net cash during the nine months ended September 30, 2026 and 2025, respectively. We recorded positive net cash flows from operating activities in 2025 and negative net cash flows from operating activities in 2024 and 2023 primarily due to our net income of $0.3 billion, and net losses of $0.6 billion and $0.9 billion, respectively. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future.

Since September 2017, we have generated revenues from the sale of medicines in China licensed from BMS, and since the fourth quarter of 2019, we have generated revenues from our internally developed medicines. These revenues may not be 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, and our ability to obtain additional financing may be subject to shareholder approval requirements or other regulatory approvals and requirements.

We have indebtedness outstanding and may incur additional short-term and long-term debt in the future. In November 2025, we and certain of our subsidiaries, as guarantors, entered into the Facilities Agreement with Hongkong and Shanghai Banking Corporation Limited and certain financial institutions, as lenders (the “Facilities Agreement”). 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 September 30, 2026, we had approximately $2,862.8 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 $5.8 billion and restricted cash of $85.2 million as of September 30, 2026, 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 September 30, 2026, 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. For example, on February 25, 2026, our subsidiaries, BeOne Medicines USA, Inc. and BeOne Medicines I GmbH, filed a patent infringement suit against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus") in the U.S. District Court for the District of New Jersey, in response to Zydus's notice informing its filing of an ANDA with the FDA in connection with BRUKINSA® (zanubrutinib) tablets. For additional information on this litigation, please see "Legal Proceedings." The success of ANDA litigation depends on the strength of the OB Patents and our ability to prove infringement. The outcome of ANDA litigation is inherently uncertain and may result in potential loss of market exclusivity for our product 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. Our medicines and drug candidates have given rise, and may in the future give rise, to claims of infringement of the patent rights of others, and 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 Inc. 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 TEVIMBRA, 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 commercial supply agreements with third-party manufacturers for TEVIMBRA, BRUKINSA and sonrotoclax. 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;
- a dispute may arise with one or more of our third-party manufacturers;
- 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.

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. Even if we achieve the expected benefits, they may not be achieved within the anticipated time frame. Additionally, strategic collaborations can be terminated for various reasons, including future acquisitions.

We face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic collaboration for our medicines and drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort. If and when we collaborate with a third party for development and commercialization of a medicine or drug candidate, we can expect to relinquish some or all of the control over the future success of that medicine or drug candidate to the third-party. For any medicines or drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

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

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

As a result, we may not be able to realize the benefit of current or future collaborations, licensing arrangements or strategic alliances if we are unable to successfully integrate products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will be able to fulfill all of our contractual obligations in a timely manner or achieve the revenue, specific net income or other goals that justify such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

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

We rely on third-party distributors to distribute our approved medicines. For example, we rely on sole third-party distributors to distribute some of our in-licensed approved medicines in China and multiple third-party distributors for the distribution of our internally developed medicines. We also expect to rely on third-party distributors to distribute our other internally developed and in-licensed medicines, if approved. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our medicines. However, we have relatively limited control over our distributors, who may fail to distribute our medicines in the manner we contemplate. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our medicines to hospitals, medical institutions and sub-distributors, they may terminate their relationship with us. While we believe alternative distributors are readily available, there is a risk that, if the distribution of our medicines is interrupted, our sales volumes and business prospects could be adversely affected.

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

We have a collaboration agreement with Amgen pursuant to which we and Amgen have agreed to collaborate on the commercialization of Amgen's oncology products XGEVA®, BLINCYTO® and KYPROLIS® in China, and the global development and commercialization in China of a portfolio of Amgen's clinical- and late-preclinical-stage pipeline products. Amgen has paused or stopped development of some of the pipeline assets due to portfolio prioritization, and the parties expect that the development plan for the pipeline assets will continue to evolve over time. 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 or filing with the HGRAC may be required for the initiation of clinical trials involving the collection of human genetic materials in China, depending on the nature of the trial and whether Human Genetic Resources ("HGR") materials are exported. 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 2025, we had approximately 11,000 employees, and we ended the year with over 12,000 employees, an increase of approximately 9%. As of the date of this Quarterly Report, we had over 12,000 employees worldwide. 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 our 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 (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 requires approval for the sampling of certain 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 have 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 scope of "important data" has to be further clarified by the Chinese government. If HGR data is classified as "important data," it can be expected that the cross-border data transfer rules 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 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. The Biosecurity Law 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. Since the transfer of HGR administration to the National Health Commission in 2024, the National Health Commission has issued service guides, filing and prior reporting procedures and FAQs relating to HGR administration, and regulatory practice in this area continues to evolve. In addition, the interpretation and application of data protection laws in China are often uncertain and constantly evolving.

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 ("IT") 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 IT systems, and those of our contractors, vendors, and collaborators, are vulnerable to damage, compromise, or disruption. These risks originate from a variety of sources, including state-sponsored actors, organized criminals, or negligent/malicious internal actors, and 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. Cyber incidents, such as ransomware, business email compromise, social engineering (including phishing), and distributed denial-of-service attacks, continue to evolve in frequency and sophistication, and threat actors may use synthetic media and related techniques (including deepfakes) that may be increasingly difficult to identify. The increasing use of emerging technologies, such as generative artificial intelligence and highly autonomous reasoning agents, may further amplify these threats by expanding attack surfaces, automating the discovery of zero-day vulnerabilities, and enhancing the effectiveness of threat actor tactics, including through more targeted exploits and social engineering campaigns and through autonomous, multi-step execution of complex cyberattacks. These attacks could be used to misappropriate or redirect funds or payments, gain unauthorized access to systems or data, or circumvent internal controls and approval workflows. Moreover, our internal use of advanced AI models for research and operational efficiency subjects us to risks, including "prompt injection" attacks, model hallucinations that could compromise data integrity in clinical or manufacturing processes, and the potential for unintended disclosure of trade secrets through the training or fine-tuning of third-party models. Any such compromise, whether involving our systems or those of third parties on whom we depend, could result in loss, misappropriation or unauthorized disclosure of proprietary information or personal data, disrupt our operations (including research, clinical, manufacturing or commercialization activities), and trigger investigation, notification or other obligations under global privacy and cybersecurity laws and regulations.

We rely heavily on a complex ecosystem of cloud-based, on-premises, and software-as-a-service platforms. In the ordinary course of business, we process and store sensitive data, including legally protected patient health information, personally identifiable information of employees, and proprietary intellectual property. Because IT systems are critical to our research, manufacturing, and commercialization activities, any shutdown or breach, whether at our company or within our third-party supply chain, could materially impair our ability to operate. Our risk profile is further heightened by remote work arrangements and our increasing reliance on third-party service providers to manage critical applications. Furthermore, the rapid deployment of autonomous AI agents across our supply chain introduces risks, where vulnerabilities in the underlying logic or training data of third-party AI systems could lead to unauthorized data exfiltration or systemic failures that are difficult to detect via traditional monitoring.

We have implemented a multi-layered, AI-enabled security program comprised of technical, administrative, and physical controls, including, but not limited to, multi-factor authentication, endpoint detection and response, data loss prevention, encryption, role-based access control, security awareness training, incident response plans, and physical security measures. While these controls are designed to identify and mitigate cybersecurity risks, the evolving nature of cyber threats, particularly the advent of AI agents capable of bypassing traditional multi-factor authentication and mimicking human-like interactions, means no system can provide absolute security. We, and our third-party collaborators, have experienced and expect to continue to experience cyber-based attacks. Although no past cyber incidents have been determined to be individually, or in the aggregate, material to our business operations or financial condition, future incidents could result in the loss of data, exposure of sensitive information, or the inability to access critical applications. A material breach could necessitate significant remediation costs, damage our reputation, and trigger notification obligations under global privacy laws and regulations.

Furthermore, we are subject to rigorous regulatory oversight. As regulatory bodies begin to implement specific frameworks for AI governance and safety, any perceived failure to align with evolving standards, such as those governing the use of autonomous agents, could result in additional liability. Alleged noncompliance with data protection laws or a significant data breach could lead to government investigations, private litigation, and substantial contractual liability. While we maintain cybersecurity insurance, such coverage may be inadequate to offset the full financial or reputational impact of a significant incident. Any failure to protect our data or systems, or those of the third parties upon whom we rely, could have a material adverse effect on our business, financial condition, and results of operations.

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

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. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. 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, disclosure, or compromise of confidential information or other proprietary intellectual property through the use of generative artificial intelligence tools, or other cybersecurity incidents which may impact our ability to realize the benefit of our intellectual property.

Our employees and personnel, and third parties or vendors with whom we work, may use generative AI and other AI-enabled tools to perform their work. Employee or vendor use of unapproved or inadequately governed AI tools (including third-party tools) could create ungoverned data flows, unmonitored compliance gaps and data protection risks that are not visible until an adverse event occurs. In addition, in the ordinary course of using AI tools, users may inadvertently input or upload confidential, proprietary or other sensitive information (including trade secrets or competitively sensitive data). The providers of these artificial intelligence tools may not meet regulatory standards, including with respect to privacy and data security, and such information may be retained, processed or used in ways that are inconsistent with our policies, contractual protections, or applicable legal requirements. Further, through the use of AI-enabled tools, third parties may infer non-public information about us from public sources, data brokers or other means that reveal commercially sensitive information about our business, strategic priorities or development plans, which could be used to adversely impact our competitive positioning. 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.

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., dozens of states have passed laws to regulate various uses and applications of artificial intelligence, including addressing deployment of artificial intelligence in healthcare settings. At the federal level, the FDA has advanced guidance and proposed frameworks for regulating AI in drug discovery, marketing submissions, and medical device development. At the same time, the Trump administration has endorsed a federal moratorium on enforcement of certain state-level AI regulation, including through a December 11, 2025 Executive Order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork that may be litigated in state and federal courts. 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 or if use of such technologies results in harms or other causes of actions we did not predict.

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"), which was incorporated into the laws of the United Kingdom, or similar laws), security breach notification laws (such as China's Measures on National Cybersecurity Incident Reporting), health information privacy laws (such as the United States' Health Insurance Portability and Accountability Act ("HIPAA")), 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 PRC (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the PRC (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, in the U.S., in early 2025, the U.S. Department of Justice ("the DOJ") issued a January 8, 2025 rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," to 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. Additionally, numerous U.S. states now have passed or proposed privacy laws that add complexity, variation in requirements, restrictions and potential legal risk requiring additional investment of resources in compliance programs. For example, state laws regulating consumer personal information may impact clinical trial recruitment, marketing, and other activities, and state laws regulating health and genetic information may restrict access to data from outside the U.S. and our ability to collaborate with certain institutions. For example, Texas passed the Texas Genomic Act of 2025, which regulates access by "Foreign adversaries" to genomic data or biosamples collected in Texas and forbids use of genetic sequencers or associated software made or developed by Foreign Adversaries. 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.

The GDPR in the EU and the UK, which have been incorporated into their respective laws, impose stringent requirements on the processing of personal data (especially, health and other sensitive data). These requirements encompass: (i) providing information to individuals regarding data processing activities; (ii) ensuring a legal basis or condition applies to the processing of personal data and, where applicable, obtaining consent from individuals to whom the data processing relates; (iii) responding to data subject requests; (iv) imposing requirements to notify the competent national data protection authorities and data subjects of personal data breaches; (v) implementing safeguards in connection with the security and confidentiality of the personal data; (vi) accountability requirements; and (vii) taking certain measures when engaging third-party processors.

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. Despite our best efforts and those of our outside counsel, regulators and courts may disagree with our interpretation of the regulations, which may impact how we operate and result in penalties being imposed on us. 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 PRC (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the PRC (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 PRC (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, which was amended effective January 1, 2026, requires companies to take certain organizational, technical and administrative measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt a multi-level protection scheme ("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 which became effective in January 2025, impose detailed and prescriptive requirements for protecting network security. In addition, the Administrative Measures on National Cybersecurity Incident Reporting which became effective in November 2025, define the levels of cybersecurity incidents and the corresponding reporting requirements. 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 Regulating Cross-Border Data Flows (effective March 2024), as well as further question-and-answer guidance issued in April and May 2025 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 PRC (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. The CAC has also issued new and updated regulatory measures focused on data security and cross-border data flows, and increased its enforcement activity. We expect the CAC and additional Chinese regulators to maintain a high level of scrutiny in the data security, cross-border data transfer and artificial intelligence space. 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. Certain industry-specific laws and regulations may also affect our collection and transfer of data. For example, the HGR Regulation and the Biosecurity Law of the PRC stipulate that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources.

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 our business 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. While 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. In February 2025, the CAC finalized the Administrative Measures on Personal Information Protection Compliance Audit, which specifies the requirements on companies to implement and conduct the compliance audit under the PIPL. 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 the 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 the 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 the 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 the 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, such as occurred in October 2025, 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, government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Without appropriation of necessary 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. In addition, U.S. state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

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 compliance 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. 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. For example, along with other recent U.S. federal tax reforms, the IRA and recently-enacted OBBBA have resulted in significant changes to the taxation of business entities including, among other changes, the imposition of a minimum tax on the book income of certain large corporations, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years. 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.

In addition, we evaluate our deferred income tax assets and record a valuation allowance if it is "more likely than not" that all or a portion of the deferred tax asset will not be realized. The assessment of the appropriate amount of valuation allowance against the deferred tax assets is dependent upon several factors, including estimates of the realization of deferred income tax assets, which realization will be primarily based on future taxable income, including the reversal of existing taxable temporary differences. Given our recent history of earnings, our management believes that there is a reasonable possibility that, within the next twelve months, sufficient positive evidence may become available to allow management to reach a conclusion that a significant portion of the valuation allowance recorded against the deferred tax assets held will be reversed. We will continue to monitor the likelihood of a reversal, and the exact timing and amount of a valuation allowance release are subject to change based on the level of profitability that we actually achieve. Moreover, if actual results differ significantly from these estimates of future taxable income, we may need to maintain the valuation allowance for all or a significant portion of our deferred tax assets. Changes in the amount of any valuation allowance could materially increase or decrease our provision for income taxes in a given period.

We are regularly under examination by tax authorities, including U.S. and non-U.S. tax authorities. The final resolution of any tax examinations could result in unanticipated increases in our tax expense and changes to the timing of required tax payments, which could affect our cash flows for any particular reporting period and have a material impact on our financial condition and results of operations in such period. For example, in June 2026, we concluded a statutory tax audit in China, and as a result of a settlement with the local tax authority, we agreed to certain adjustments to previously filed tax returns, which resulted in an income tax payment (including both tax and late payment interest) to the local tax authority of approximately RMB 446 million in July 2026. This settlement did not involve any administrative penalty.

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.

Restrictive covenants in our facilities agreements may limit our ability to respond to changes in market conditions or pursue business opportunities.

The Facilities Agreement and our other facilities agreements contain restrictive covenants that, among other things, limit certain activities or actions, including incurring additional indebtedness or liens, dispositions of assets, making certain fundamental changes, entering into restrictive agreements, making certain investments, entering into certain joint ventures, making certain loans, advances, guarantees or acquisitions, prepaying certain indebtedness, paying dividends or making certain other distributions or redemptions/repurchases on certain equity interests, and engaging in transactions with affiliates or amending certain material documents. As a result of these covenants, we are limited in the manner in which we conduct our business and we may be unable to react to changes in market conditions, take advantage of business opportunities we believe to be desirable, obtain future financing, fund needed capital expenditures or withstand a continuing or future downturn in our business.

In addition, the Facilities Agreement and our other facilities agreements require us to maintain certain financial ratios and to make certain required payments of principal, premium, if any, and interest. If we fail to comply with these provisions or other financial and operating covenants in such agreements, we could be in default under the terms of such agreements. In the event of such default and we were unable to cure such default, the holders of such indebtedness could elect to declare all the funds borrowed thereunder to be due and payable, together with accrued and unpaid interest, and the lenders thereunder could elect to terminate their commitments thereunder, cease making further loans and institute foreclosure proceedings against our assets. If any of these events occurred, then our business, operating results and financial condition could be materially and adversely affected.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under applicable debt instruments, which may not be successful.

Our ability to make scheduled payments on or to refinance our indebtedness obligations depends on our financial condition and operating performance, which are subject to financial, macroeconomic, competitive and other factors, some of which may be beyond our control. We may not be able to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund debt service obligations, we may be forced to reduce or delay investments and R&D expenditures, sell assets, seek additional capital or restructure or refinance indebtedness. These alternative measures may not be successful and may not permit us to meet scheduled debt service obligations. Our ability to restructure or refinance indebtedness will depend on the condition of the capital markets and our financial condition at such time. Also, we may not be able to consummate dispositions at such time on terms acceptable to us or at all, and the proceeds of any such dispositions may not be adequate to meet such debt service obligations. Furthermore, any refinancing of indebtedness could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict business operations. In addition, the terms of existing or future debt instruments may restrict us from adopting some of these alternatives. For example, the Facilities Agreement may restrict our ability to dispose of assets under certain circumstances and our use of the proceeds from such disposition. Our inability to generate sufficient cash flows to satisfy our debt obligations, and resulting actions we may be forced to take or restricted from taking pursuant to our debt instruments, would have a material adverse effect on our business, results of operations, financial condition and prospects.

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.

In January 2023, the National Development and Reform Commission (the "NDRC") promulgated the Administrative Measures for Examination and Registration of Medium and Long-term Foreign Debts of Enterprises (the "Foreign Debts Measures"), which became effective as of February 10, 2023. According to the Foreign Debts Measures, overseas enterprises that have material business operations in Chinese mainland may be required to complete applications for registration of foreign debts with the NDRC prior to the borrowing of foreign debts with a term of over one year. If any of our debt financing is subject to the Foreign Debt Measures and we fail to successfully complete such registrations or obtain approval from the NDRC in a timely manner or at all, we may need to seek alternative, shorter-term financing, and our ability to finance strategic transactions may be limited, which could adversely affect our business.

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, and our ability to incur debt. 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. The five-year transition period available to foreign-invested enterprises established under the previous foreign-investment laws expired on December 31, 2024. Any failure to comply with the applicable organizational form and governance requirements could affect our current corporate governance practices and business operations. 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 both September 30, 2026 and December 31, 2025, these restricted assets totaled $2.0 billion.

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.

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, 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 pharmaceutical products. For example, the Provisions on the Administration of Pharmaceutical Representatives became effective on August 1, 2026, which impose requirements on the filing, conduct and management of pharmaceutical representatives, including restrictions on certain interactions between pharmaceutical representatives and healthcare professionals and medical institutions. Our commercialization activities in China must comply with these requirements, and any violation thereof may result in administrative penalties and adversely affect our reputation and business in China. 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 or investor expectations; 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 October 30, 2026, 1,484,939,031 ordinary shares, par value $0.0001 per share, were outstanding, of which 766,039,443 ordinary shares were held in the form of 58,926,111 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 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 Swiss articles of association (as may be amended from time to time) (the "Swiss Articles"). 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, 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. Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. 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. Actions for which our shareholders must vote will require that we file a proxy statement with the SEC and convene a shareholders' meeting that could delay the timing to execute such actions.

Furthermore, under Swiss law, a staggered or classified board is not permitted and all directors are elected or re-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 Hong Kong, mainland China, or U.S. federal court.

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 domiciled in 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.

The enforceability in Switzerland of a foreign judgment rendered against the Company or our directors and officers is subject to applicable international treaties by which Switzerland is bound and the Swiss Federal Private International Law Act. A foreign judgment may only be enforced in Switzerland if the foreign court had jurisdiction, such judgment became final and non-appealable, the court procedures leading to such judgment following the due process of law (including proper service of process), and such judgment does not violate Swiss legal principles of public policy. We have been advised that the U.S. and Switzerland currently do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters. Some remedies available under the laws of U.S. jurisdictions, including under U.S. federal securities laws, may not be recognized in Swiss courts as they are contrary to Swiss public policy.

In view of the above, our shareholders may have more difficulty protecting their interests regarding actions taken by management or members of the board of directors, compared to 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 the Swiss Articles, 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 discourage third parties from seeking to obtain control in a tender offer or similar transaction, which may deprive our shareholders of an opportunity to sell their shares, at a premium over prevailing market prices.

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 certain disputes 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 have moved, and may in the future move, a portion of our issued ordinary shares from our principal 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 29% of our outstanding ordinary shares as of October 30, 2026. 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, 2025. 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 Swiss Incorporation

As a Swiss corporation, our flexibility is limited with respect to certain aspects of capital management.

Swiss law regulates a corporation's ability to hold, purchase or repurchase its own shares. We and our subsidiaries may only purchase or repurchase our own shares (the "treasury shares") to the extent that sufficient freely available equity is available. The aggregate par value of the treasury shares may not exceed 10% of our stated share capital, unless our shareholders authorize (including through the capital band) our board of directors to purchase or repurchase our registered shares in an amount in excess of 10% and the treasury shares are dedicated for cancellation to effect a capital reduction.

Swiss law allows our shareholders to authorize the board of directors to issue shares without additional shareholder approval, but this authorization is limited to (i) 50% of our stated share capital (among other things, for the issuance of shares in connection with an acquisition or to raise new equity capital, subject to compliance with shareholders' preemptive rights, unless withdrawn for the reasons specified in the Swiss Articles) (the "capital band"), and (ii) an additional 20% of our stated share capital for the issuance of shares in connection with convertible or similar financial instruments and our equity incentive plans (the "conditional share capital"). The authority of the board of directors to issue shares based on the capital band must be renewed by our shareholders every five years. The Swiss Articles provide for a capital band authorizing the board of directors to issue or increase the nominal value of up to 769,621,876 shares or to cancel or reduce the nominal value of up to 154,963,663 shares up until April 28, 2029. After April 28, 2029, the capital band will only be available to the board of directors for issuance or cancellation of registered shares if a renewed authorization is approved by shareholders.

Additionally, Swiss law grants existing shareholders preemptive rights to subscribe for newly issued shares and advance subscription rights to subscribe for convertible and similar financial instruments. Preemptive rights and advance subscription rights may be limited or withdrawn only for valid reasons. In connection with share issuances based on the capital band and the conditional share capital, the preemptive rights and the advance subscription rights may only be limited or withdrawn for the reasons specified in the Swiss Articles.

In comparison to Cayman Islands law, Swiss law does not provide as much flexibility in the various terms that can attach to different classes of shares. Further, Swiss law also reserves for approval by shareholders many corporate actions, including the declaration and approval of dividends under certain circumstances. 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, Swiss law requirements may limit our flexibility to swiftly implement certain initiatives or strategies and situations may arise where greater 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, 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 Continuation, even though you will not have realized any income or liquidity as a result of the Continuation. For a more detailed description of the tax consequences associated with the Continuation, see "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 $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 change 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 amount must be withheld from the gross dividend 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 amount withheld in excess of the U.S.-Swiss Treaty 15% rate (or for a full refund in the case of qualified pension funds, or a refund in excess of the 5% U.S.-Swiss Treaty rate if you are a corporate shareholder that directly holds at least 10% of our share capital). A shareholder domiciled in China that qualifies for benefits under the Agreement between the Government of the PRC and the Swiss Federal Council for the Avoidance of Double Taxation with Respect to Taxes on Income and on Capital (the "PRC-Swiss Treaty") may apply for a refund of the tax amount withheld in excess of the 10% or 5% PRC-Swiss 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 PRC and the Swiss Federal Council for the Avoidance of Double Taxation with respect to Taxes on Income (the "Hong Kong-Swiss Treaty") may apply for a refund of the tax amount withheld in excess of the 10% Hong Kong-Swiss Treaty rate (or a full refund in the case of specific qualified persons, including a pension fund or a corporate shareholder that directly holds at least 10% of our share capital). Subject to applicable laws and regulations, this may also apply to other shareholders entitled to a dividend withholding tax rate lower than the Swiss withholding tax rate under 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, share repurchases for 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 shareholder's tax residency. Share repurchases for purposes other than capital reduction, such as for retention 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 share 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 the section in our Annual Report titled "Part II—Item 5—Taxation—Swiss Taxation—Repurchases of Shares."

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

Effective August 3, 2026, we issued 866,073 ordinary shares (the "New Shares") to BG NC 2, Ltd., a company incorporated in the Cayman Islands with limited liability and our wholly owned subsidiary ("BGNC2") for an aggregate subscription price of $86.61, representing the aggregate par value of the New Shares, pursuant to a share transfer agreement between us and BGNC2. The New Shares were issued to BGNC2 to facilitate the delivery of ordinary shares to participants under our Sixth Amended and Restated 2018 Employee Share Purchase Plan.

The New Shares were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act.

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 the Company's securities adopted, modified or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement," or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K):

Name (Title)	**Action Taken (Date of Action)**	**Type of Trading Arrangement**	**Nature of Trading Arrangement**	**Duration of Trading Arrangement**	**Aggregate Number of Securities**
Xiaobin Wu *(President and Chief Operating Officer)*	Termination *(September 15, 2026)*	Rule 10b5-1 trading arrangement	Sale	February 26, 2027	Up to 30,000 ADSs.
Xiaobin Wu *(President and Chief Operating Officer)*	Adoption *(September 15, 2026)*	Rule 10b5-1 trading arrangement	Sale	December 15, 2027	Up to 86,082 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
10.1#	Waiver under Collaboration Agreement, dated July 10, 2026, by and between the Registrant, BeOne Medicines I 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			
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.

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

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: November 5, 2026

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

Date: November 5, 2026

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

CERTAIN INFORMATION (INDICATED BY "[…*…]") HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE SUCH INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL.**

Exhibit 10.1

July 10, 2026

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
United States
Attention: Corporate Secretary

Re: Waiver of Certain Rights Related to […***…]-Targeting Molecules Under the Collaboration Agreement

Dear Sir or Madam:

Reference is made to the Collaboration Agreement, dated as of October 31, 2019, as amended (the "Collaboration Agreement"), by and among Amgen Inc. ("Amgen"), BeOne Medicines I GmbH (f/k/a BeiGene Switzerland GmbH) ("BeOne") and, solely with respect to Section 13.6, BeOne Medicines Ltd. (f/k/a BeiGene, Ltd.). Capitalized terms used but not defined herein have the meanings ascribed to them in the Collaboration Agreement.

Amgen has notified BeOne that Amgen is undergoing discussions with a potential counterparty ("Counterparty") regarding a […***…] combination study (the "[…***…] Study") with Amgen's IMDELLTRA® and the Counterparty's […***…] (the "Counterparty […***…] Product").

In accordance with Section 15.16 (Waivers and Modifications) of the Collaboration Agreement, this letter serves to document BeOne's and Amgen's agreement that, with respect to the Counterparty […***…] Product, the Distracting Program Restrictions under Article IX of the Collaboration Agreement are hereby irrevocably waived with respect to the […***…] Study and all research, development (including any bridging study or other clinical trial), regulatory, manufacturing, and commercialization activities relating to the combination of IMDELLTRA® and the Counterparty […***…] Product, in and outside of the Collaboration Territory, excluding any Excluded Activity. "Excluded Activity" means any arrangement, agreement or transaction pursuant to which Amgen or any of its Affiliates (a) sells, distributes, invoices or books revenue for the Counterparty […***…] Product or (b) receives revenue, profit, royalty, milestone or other sales-based economics or payments in respect of the Counterparty […***…] Product. For avoidance of doubt, Excluded Activity does not include (i) any co-promotion of IMDELLTRA® and the Counterparty […***…] Product in combination, (ii) any activities related solely to IMDELLTRA® or (iii) any economics derived solely from sales of IMDELLTRA®.

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

[*Signature Page Follows*]

Yours sincerely,
BEONE MEDICINES I GMBH

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

BEONE MEDICINES LTD.

/s/ Chan Lee
By: Chan Lee
Title: SVP, General Counsel and Corporate Secretary

Acknowledged and agreed:
AMGEN INC.

/s/ Rachna Khosla
By: Rachna Khosla
Title: SVP, Business Development

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: November 5, 2026

/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: November 5, 2026

/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 September 30, 2026 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2026

/s/ JOHN V. OYLER

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

Date: November 5, 2026

/s/ AARON ROSENBERG

Aaron Rosenberg
Chief Financial Officer
(Principal Financial Officer)