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

FORM 10-Q

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

For the quarterly period ended March 31, 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: 001-35703

PUMA BIOTECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

10880 Wilshire Boulevard, Suite 1700, Los Angeles, CA 90024
(Address of principal executive offices) (Zip code)

(424) 248-6500
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	PBYI	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

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 ☒.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. 50,899,456 shares of Common Stock, par value $0.0001 per share, were outstanding as of May 4, 2026.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, (this "Quarterly Report"), contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements about our expectations, beliefs, plans, objectives, assumptions, future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

- the commercialization of NERLYNX® (neratinib) tablets ("NERLYNX");
- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our drug candidates;
- the anticipated timing of regulatory filings;
- the regulatory approval of our drug candidates;
- our use of clinical research organizations ("CRO") and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- efforts of our sub-licensees to obtain regulatory approval and commercialize NERLYNX in areas outside the United States;
- our ability to market any of our products;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our intention and ability to vigorously defend against any litigation to which we are or may become party;
- our ability to in-license additional drugs;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing on favorable terms or at all.

These statements are often, but not always, made through the use of words or phrases such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend" and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report, including, in Part I, the section entitled "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, and this Quarterly Report on Form 10-Q, that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	March 31, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,193	$ 29,635
Marketable securities	65,352	67,893
Accounts receivable	26,329	53,654
Inventory	8,693	5,515
Prepaid expenses, current	3,405	3,642
Restricted cash, current	2,091	2,091
Other assets, current	196	256
Total current assets	142,259	162,686
Lease right-of-use assets, net	4,574	5,373
Property and equipment, net	124	187
Intangible assets, net	38,957	41,392
Deferred tax assets	3,830	3,830
Prepaid expenses and other, long-term	2,955	2,834
Total assets	$ 192,699	$ 216,302
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,166	$ 5,056
Accrued expenses	38,378	50,031
Lease liabilities, current	125	1,314
Post-marketing commitment liability	1,684	2,187
Current portion of long-term debt	11,283	22,523
Other liabilities, current	101	142
Total current liabilities	59,737	81,253
Lease liabilities, long-term	4,546	4,709
Total liabilities	64,283	85,962
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 50,879,204 shares issued and outstanding at March 31, 2026 and 50,408,023 issued and outstanding at December 31, 2025	5	5
Additional paid-in capital	1,415,970	1,414,074
Accumulated other comprehensive (loss) income	(31)	36
Accumulated deficit	(1,287,528)	(1,283,775)
Total stockholders' equity	128,416	130,340
Total liabilities and stockholders' equity	$ 192,699	$ 216,302

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	For the Three Months Ended March 31,	
	2026	**2025**
Revenues:		
Product revenue, net	$ 41,959	$ 43,104
Royalty revenue	2,855	2,903
Total revenue	44,814	46,007
Operating costs and expenses:		
Cost of sales	10,424	10,556
Selling, general and administrative	18,423	17,604
Research and development	19,795	13,863
Total operating costs and expenses	48,642	42,023
(Loss) income from operations	(3,828)	3,984
Other income (expenses):		
Interest income	1,002	1,101
Interest expense	(731)	(2,177)
Other income	130	359
Total other income (expenses), net	401	(717)
Net (loss) income before income taxes	$ (3,427)	$ 3,267
Income tax expense	(326)	(293)
Net (loss) income	$ (3,753)	$ 2,974
Net (loss) income per share of common stock—basic	$ (0.07)	$ 0.06
Net (loss) income per share of common stock—diluted	$ (0.07)	$ 0.06
Weighted-average shares of common stock outstanding—basic	50,845,130	49,595,697
Weighted-average shares of common stock outstanding—diluted	50,845,130	49,906,341

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2026	**2025**
Net (loss) income	$ (3,753)	$ 2,974
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net of tax of $0	(67)	(17)
Comprehensive (loss) income	$ (3,820)	$ 2,957

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)
(unaudited)

For the Three Months Ended March 31, 2026

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2025	50,408,023	$ 5	1,414,074	36	(1,283,775)	130,340
Stock-based compensation	—	—	1,896	—	—	1,896
Shares issued or restricted stock units vested under employee stock plans	471,181	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(67)	—	(67)
Net loss	—	—	—	—	(3,753)	(3,753)
Balance at March 31, 2026	50,879,204	$ 5	$ 1,415,970	$ (31)	$ (1,287,528)	$ 128,416

For the Three Months Ended March 31, 2025

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2024	49,105,834	$ 5	$ 1,407,000	$ 6	$ (1,314,886)	92,125
Stock-based compensation	—	—	2,026	—	—	2,026
Shares issued or restricted stock units vested under employee stock plans	509,340	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(17)	—	(17)
Net income	—	—	—	—	2,974	2,974
Balance at March 31, 2025	49,615,174	$ 5	$ 1,409,026	$ (11)	$ (1,311,912)	$ 97,108

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2026	**2025**
Operating activities:		
Net (loss) income	$ (3,753)	$ 2,974
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	2,584	2,796
Stock-based compensation	1,896	2,026
Provision for credit loss recovery	—	213
Loss on disposal of property and equipment	6	—
Changes in operating assets and liabilities:		
Accounts receivable, net	27,325	6,626
Inventory, net	(3,178)	(27)
Prepaid expenses and other	116	(789)
Other current assets	60	(7)
Accounts payable	3,110	517
Operating lease assets and liabilities, net	(553)	(433)
Accrued expenses and other	(11,694)	(9,882)
Post-marketing commitment liability	(503)	(402)
Net cash provided by operating activities	15,416	3,612
Investing activities:		
Purchase of property and equipment	—	(61)
Purchase of available-for-sale securities	(24,863)	(12,507)
Maturity of available-for-sale securities	27,337	14,099
Net cash provided by investing activities	2,474	1,531
Financing activities:		
Payment of debt	(11,110)	(11,110)
Payment of exit costs	(222)	(222)
Net cash used in financing activities	(11,332)	(11,332)
Net increase (decrease) in cash, cash equivalents and restricted cash	6,558	(6,189)
Cash, cash equivalents and restricted cash, beginning of period	31,726	71,310
Cash, cash equivalents and restricted cash, end of period	38,284	65,121
Supplemental disclosure of cash flow information:		
Interest paid	$ 639	$ 1,917
Income taxes paid	$ 9	$ 101

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business and Liquidity:

Puma Biotechnology, Inc., (the "Company") is a biopharmaceutical company based in Los Angeles, California that develops and commercializes innovative products to enhance cancer care and improve treatment outcomes for patients. The Company is currently commercializing NERLYNX®, an oral version of neratinib ("NERLYNX"), for the treatment of HER2-positive breast cancer. Additionally, the Company in-licensed, and is responsible for the global development and commercialization of, alisertib. Alisertib is a selective, small molecule inhibitor of Aurora Kinase A that is designed to disrupt mitosis leading to apoptosis of rapidly proliferating tumor cells dependent on Aurora Kinase. The Company believes alisertib has potential application in the treatment of a range of different cancer types, including hormone receptor-positive breast cancer, triple-negative breast cancer and small cell lung cancer.

The Company has one subsidiary, Puma Biotechnology, B.V., a Netherlands company. This subsidiary was established for the purpose of legal representation in the European Union ("EU"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated.

The accompanying consolidated financial statements of the Company and its subsidiary have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP").

The Company has incurred significant operating losses since its inception. While the Company has previously reported net income, the Company cannot ensure that it will continue to do so and will need to continue to generate significant revenue to sustain operations and successfully commercialize neratinib. In 2017, the Company received U.S. Food and Drug Administration ("FDA") approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib, oral), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Following FDA approval in July 2017, NERLYNX became available by prescription in the United States, and the Company commenced commercialization.

In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

In 2018, the European Commission ("EC") granted marketing authorization for NERLYNX in the EU for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy.

The Company is required to make substantial payments to Pfizer upon the achievement of certain milestones and has contractual obligations for clinical trial contracts.

The Company has entered into other exclusive sub-license agreements with various parties to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved, in many regions outside the United States, including Europe (excluding Ukraine), Australia, Canada, China, Southeast Asia, Israel, South Korea, Russia and various countries and territories in Central America, South America, Africa and the Middle East. The Company plans to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved.

In September 2022, the Company entered into an exclusive license agreement with a subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of Aurora Kinase A. Alisertib is an adenosine triphosphate–competitive and reversible inhibitor of Aurora Kinase A and results in disruption of mitosis, leading to apoptosis of rapidly proliferating tumor cells that are dependent on Aurora Kinase A. Alisertib has been tested in clinical trials in patients with metastatic cancers, including breast cancer, small cell lung cancer, head and neck cancer, ovarian cancer, peripheral T-cell lymphoma and acute myeloid leukemia. Under the terms of the exclusive license agreement, the Company assumed sole responsibility for the global development and commercialization of alisertib. The Company paid Takeda an upfront license fee of $7.0 million in October 2022, and Takeda is eligible to receive potential future milestone payments of up to $287.3 million upon the Company's achievement of certain regulatory and commercial milestones over the course of the exclusive license agreement, as well as tiered royalty payments for any net sales of alisertib. As of March 31, 2026, no milestones had been accrued as the underlying contingencies were not probable.

The Company has reported net loss of approximately $3.8 million and cash provided by operations of approximately $15.4 million for the three months ended March 31, 2026. The Company's commercialization, research and development or marketing efforts may require funding in addition to the cash and cash equivalents and marketable securities totaling approximately $101.5 million at March 31, 2026.

The Company believes that its existing cash and cash equivalents and marketable securities as of March 31, 2026 and proceeds that are expected to become available to the Company through product sales and sub-license payments are sufficient to satisfy its operating cash needs, including amounts due under the Company's Note Purchase Agreement with Athyrium Opportunities IV Co-Invest 1 LP ("Athyrium") (see Note 9—Debt), for at least one year after the filing of the Quarterly Report on Form 10-Q in which these financial statements are included. The Company continues to remain dependent, in part, on its ability to obtain sufficient funding to sustain operations and continue to successfully commercialize neratinib in the United States. While the Company has been successful in raising capital in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market and economic conditions, including the Company's success in commercializing neratinib and unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. Additionally, the terms of the Company's Note Purchase Agreement place restrictions on the Company's ability to operate the business and on the Company's financial flexibility, and the Company may be unable to achieve the revenue necessary to satisfy the minimum revenue and cash balance covenants as specified in the agreement.

Since its inception through March 31, 2026, the Company's financing has primarily consisted of proceeds from product, royalty and license revenue, public offerings of its common stock, private equity placements, and various debt instruments.

In the opinion of management, the included disclosures are adequate, and the accompanying unaudited condensed consolidated financial statements contain all adjustments necessary for a fair statement of its consolidated financial position as of March 31, 2026. Such adjustments are of a normal and recurring nature. The condensed consolidated balance sheet as of December 31, 2025 was derived from audited annual financial statements but does not contain all of the footnote disclosures from the audited annual financial statements. The condensed consolidated results of operations for the quarter ended March 31, 2026 are not necessarily indicative of the consolidated results of operations that may be expected for the fiscal year ending December 31, 2026.

The Company does not believe that tariffs imposed or proposed to be imposed by the United States, particularly with the EU and China, will have a material impact on its product costs or results of operations. However, shifts in trade policies in the United States and other countries have been rapidly evolving and are difficult to predict. The ultimate impact of any announced or future tariffs will depend on various factors, including what tariffs are ultimately implemented, the timing of implementation and the amount, scope and nature of such tariffs and potential exclusions from the application of those tariffs.

On April 2, 2026, the U.S. government issued a proclamation under Section 232 of the Trade Expansion Act of 1962, imposing new tariffs on imported patented pharmaceutical products and associated active pharmaceutical ingredients (APIs). Any potential impact of the proclamation on the Company is uncertain and under review.

Note 2—Significant Accounting Policies:

The significant accounting policies followed in the preparation of these unaudited consolidated financial statements are as follows:

Principles of Consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Segment Reporting:

Management has determined that the Company operates in one reporting segment, which is the development and commercialization of innovative products to enhance cancer care. The Company derives its global product, license and royalty revenue through the sales of NERLYNX®. The majority of the Company's royalty revenue is derived from its sub-licensee sales into China. The accounting policies of this operating segment are the same as those described below in Note 2—Significant Accounting Policies.

The Company's Chief Operating Decision Maker (“CODM”) is its President, Chief Executive Officer and Chairman of the Board, Alan H. Auerbach. The CODM primarily uses the Company's Consolidated Statement of Operations and related revenues, expenses and net (loss) income in evaluating the performance of the single operating segment and determining how to allocate resources of the Company as a whole, including its sales force and related marketing, research and development programs, including alisertib, and licensing strategy. Consolidated revenue, expenses and net (loss) income are also used to monitor budget versus actual results.

In addition to the significant expense categories included within consolidated net (loss) income presented on the Company's Condensed Consolidated Statements of Operations, see below for disaggregated amounts that comprise operating expenses:

	For the Three Months Ended March 31,	
	2026	2025
Cost of sales	$ 10,424	$ 10,556
General and administrative	6,401	6,180
Commercialization	10,883	10,190
Research and development:		
Clinical research and development	11,444	6,414
Medical affairs	1,339	1,153
Other research and development (1)	6,255	5,504
Operating costs and expenses	46,746	39,997
Stock based compensation	1,896	2,026
Total operating costs and expenses	$ 48,642	$ 42,023

(1) Other research and development expense includes regulatory affairs, pharmacovigilance, quality assurance, chemical manufacturing and other costs.

Use of Estimates:

The preparation of consolidated financial statements in conformity with Generally Accepted Accounting Principles (“GAAP”) in the United States, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of revenues and expenses for the period presented. Accordingly, actual results could differ from those estimates.

Significant estimates include estimates for variable consideration for which reserves were established. These estimates are included in the calculation of net revenues and include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company’s sale of its products. Other significant estimates include those related to the valuation of deferred income taxes, legal and other expense accruals.

Net (Loss) Income per Share of Common Stock:

Basic net (loss) income per share of common stock is computed by dividing net (loss) income available to common stockholders by the weighted-average number of shares of common stock outstanding during the periods presented, as required by Accounting Standards Codification ("ASC"), ASC 260, *Earnings per Share*. For purposes of calculating diluted net (loss) income per share of common stock, the denominator includes both the weighted-average number of shares of common stock outstanding and the number of dilutive common stock equivalents, such as stock options, restricted stock units ("RSUs") and warrants. A common stock equivalent is not included in the denominator when calculating diluted earnings per common share if the effect of such common stock equivalent would be anti-dilutive.

The Company's potentially dilutive securities include potential common shares related to its stock options and RSUs granted in connection with the Puma Biotechnology, Inc. 2011 Incentive Award Plan ("2011 Plan") and the Puma Biotechnology, Inc. 2017 Employment Inducement Incentive Award Plan ("2017 Plan"). Diluted earnings per share ("Diluted EPS") considers the impact of potentially dilutive securities except in periods in which there is a loss because the inclusion of the potential common shares would have an anti-dilutive effect. Diluted EPS excludes the impact of potential common shares related to the Company's stock options in periods in which the option exercise price is greater than the average market price of its common stock for the period. The following potentially dilutive outstanding common stock equivalents for the respective periods were excluded from diluted net (loss) income per share because of their anti-dilutive effect:

	For the Three Months Ended March 31,	
	2026	**2025**
Options outstanding	1,747,461	4,022,555
Warrant outstanding	2,116,250	2,116,250
Unvested restricted stock units	9,342	712,508
Totals	3,873,053	6,851,313

The 2,116,250 shares underlying the warrant will not have an impact on the Company's diluted net (loss) income per share until the average market price of its common stock exceeds the exercise price of $16 per share (see Note 10—Stockholders' Equity).

A reconciliation of the numerators and denominators of the basic and diluted net (loss) income per share of common stock computations is as follows (in thousands, except share and per share amounts):

	For the Three Months Ended March 31,	
	2026	**2025**
Numerator:		
Net (loss) income	$ (3,753)	$ 2,974
Denominator:		
Weighted average common stock outstanding for basic net (loss) income per share	50,845,130	49,595,697
Net effect of dilutive common stock equivalents	—	310,644
Weighted average common stock outstanding for diluted net (loss) income per share	50,845,130	49,906,341
Net (loss) income per share of common stock		
Basic	$ (0.07)	$ 0.06
Diluted	$ (0.07)	$ 0.06

Revenue Recognition:

Under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when its customer obtains control of the promised goods or services in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods or services. The Company had no contracts with customers until the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with specialty pharmacies and specialty distributors in the United States to distribute NERLYNX. These arrangements are the Company's initial contracts with customers. The Company has determined that these sales channels with customers are similar.

Product Revenue, Net:

The Company sells NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. These customers subsequently resell the Company's products to patients and certain medical centers or hospitals. In addition to distribution agreements with these customers, the Company enters into arrangements with healthcare providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the specialty pharmacy or specialty distributor, as applicable, obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 10 and 68 days.

Product revenue also consists of product sales under sub-license agreements to the Company's sub-licensees, who then sell into their respective international territories.

Shipping and handling costs for product shipments occur prior to the customer obtaining control of the goods and are recorded in cost of sales.

If taxes relating to product sales should be collected from customers and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three months ended March 31, 2026 and 2025.

Reserves for Variable Consideration:

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the related sales, and are classified as reductions of accounts receivable, net when the right of offset exists in accordance with Accounting Standards Update ("ASU") ASU 2013-1, *Balance Sheet (Topic 210): Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities,* or as a current liability. These estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a significant reversal of revenue would not likely occur in a future period for the estimates detailed below as of March 31, 2026, and, therefore, the transaction price was not reduced further during the quarter ended March 31, 2026. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

The Company generally provides customers with discounts, which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. The reserve for discounts is established in the same period that the related revenue is recognized, together with reductions to accounts receivable, net on the consolidated balance sheets. In addition, the Company compensates its customers for sales order management, data, and distribution services. The Company has determined such services received to date are not distinct from the Company's sale of products to its customers and, therefore, these payments have been recorded as a reduction of revenue within the condensed consolidated statements of operations.

Product Returns:

Consistent with industry practice, the Company offers the specialty pharmacies and specialty distributors that are its customers limited product return rights for damaged and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as a reduction to accounts receivables, net on the consolidated balance sheets. The Company currently estimates product returns using its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has an insignificant number of returns to date and believes that returns of its products will continue to be minimal.

Provider Chargebacks and Discounts:

Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to its customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. The reserve for chargebacks is established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and a reduction to accounts receivable, net on the consolidated balance sheets. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel at each reporting period end that the Company expects will be sold to qualified healthcare providers and chargebacks that customers have claimed, but for which the Company has not yet issued a payment.

Government Rebates:

The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses on the condensed consolidated balance sheets. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimates of future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Payor Rebates:

The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses on the consolidated balance sheets.

Other Incentives:

Other incentives the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included as a component of accrued expenses on the consolidated balance sheets.

License Revenue:

The Company also recognizes license revenue under certain of the Company's sub-license agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. The Company evaluates these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, upfront fees that are not contingent on any future performance and require no consequential continuing involvement by the Company, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. The Company defers recognition of non-refundable upfront license fees if the performance obligations are not satisfied. The Company's payment terms range between the execution date of the sub-license agreement and 45 days.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost-plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure.

Since 2018, the Company has entered into sub-license agreements with certain sub-licensees in territories outside of the United States. These sub-licensing agreements grant certain intellectual property rights and set forth various obligations with respect to actions such as development, pursuit and maintenance of regulatory approvals, commercialization and supply of NERLYNX in the sub-licensees' respective territories.

License fees under the sub-license agreements include one-time upfront payments when each sub-license agreement was executed and potential additional one-time milestone payments due to the Company upon successful completion of certain performance obligations, such as achieving regulatory approvals or sales target thresholds, and potential double-digit royalties on sales of the licensed product, calculated as a percentage of net sales of the licensed product throughout each sub-licensee's respective territory.

As of March 31, 2026, the total potential milestone payments that would be due to the Company upon achievement of all respective performance obligations under the sub-license agreements is approximately $579.8 million. At this time, the Company cannot estimate if or when these milestone-related performance obligations might be achieved.

Royalty Revenue:

For sub-license agreements that are within the scope of ASC 606, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception under ASC 606-10-55-65.

Royalty revenue consists of consideration earned related to international sales of NERLYNX made by the Company's sub-licensees in their respective territories. The Company recognizes royalty revenue when the performance obligations have been satisfied. The Company's payment terms range between 10 and 60 days.

Royalty Expenses:

Royalties incurred in connection with the Company's license agreement with Pfizer, as disclosed in Note 12—Commitments and Contingencies, are expensed to cost of sales as revenue from product sales is recognized.

Legal Contingencies and Expense:

For legal contingencies, the Company accrues a liability for an estimated loss if the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated. Legal fees and expenses are expensed as incurred based on invoices or estimates provided by legal counsel. The Company periodically evaluates available information, both internal and external, relative to such contingencies and adjusts the accrual as necessary. The Company determines whether a contingency should be disclosed by assessing whether a material loss is deemed reasonably possible. In determining whether a loss should be accrued, the Company evaluates, among other factors, the degree of probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of the loss (see Note 12—Commitments and Contingencies).

Research and Development Expenses:

Research and development expenses are charged to operations as incurred. The major components of research and development costs include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and CRO costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Stock-Based Compensation:

Stock Option Awards:

ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718") requires the fair value of all share-based payments to employees and non-employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee and non-employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. The Company's estimate of expected volatility is based on its average volatility using its expected life, or approximately the last six years of publicly traded history. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. Option forfeitures are estimated when the option is granted to reduce the option expense to be recognized over the life of the award. The estimated forfeiture rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The option expense is adjusted upon the actual forfeiture of a stock option grant, and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Due to its limited history of stock option exercises, the Company uses the simplified method to determine the expected life of the option grants. Compensation expense related to modified stock options is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Restricted Stock Units:

RSUs are valued on the grant date and the fair value of the RSUs is equal to the market price of the Company's common stock on the grant date. The RSU expense is recognized over the requisite service period. When the requisite service period begins prior to the grant date (because the service inception date occurs prior to the grant date), the Company is required to begin recognizing compensation cost before there is a measurement date (i.e., the grant date). The service inception date is the beginning of the requisite service period. If the service inception date precedes the grant date, accrual of compensation cost for periods before the grant date shall be based on the fair value of the award at the reporting date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on fair value at the grant date rather than the fair value previously used at the service inception date (or any subsequent reporting date). RSU forfeitures are estimated when the RSU is granted to reduce the RSU expense to be recognized over the life of the award. The estimated forfeiture rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The RSU expense is adjusted upon the actual forfeiture of an RSU grant and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Compensation expense related to modified RSUs is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

***Warrants*:**

Warrants (see Note 10—Stockholders' Equity for further details) granted to employees and non-employees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing Method. The Company's estimate of expected volatility is based on its average volatility using its past nine years of publicly traded history. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value of the warrant until the terms are fixed, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair value of the warrant at the time of issuance as an equity stock-based compensation transaction. The grant date is determined when all pertinent information, such as exercise price and quantity are known.

Income Taxes:

The Company follows ASC Topic 740, *Income Taxes* ("ASC 740") which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of March 31, 2026, the Company's uncertain tax positions include a reserve for its research and development credits.

Financial Instruments:

The carrying value of financial instruments, such as cash equivalents, accounts receivable and accounts payable, approximate their fair value because of their short-term nature. The carrying value of long-term debt approximates its fair value as the principal amounts outstanding are subject to variable interest rates that are based on market rates that are regularly reset.

Cash and Cash Equivalents:

The Company classifies all highly liquid instruments with an original maturity of three months or less as cash equivalents.

Restricted Cash:

Restricted cash represents cash held at financial institutions that is pledged as collateral for stand-by letters of credit for office leases. The lease-related letters of credit will lapse at the end of the respective lease terms through 2026. At each of the periods ended March 31, 2026 and December 31, 2025, the Company had restricted cash of approximately $2.1 million.

Investment Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. In accordance with ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, credit losses on available-for-sale securities are reported using an expected loss model and recorded to an allowance. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

ASC Topic 820, *Fair Value Measurement* ("ASC 820") provides a single definition of fair value and a common framework for measuring fair value as well as disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of March 31, 2026 and December 31, 2025, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

March 31, 2026	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 86	$ 26,194	$ —	$ 26,280
U.S. Government securities	17,274	18,444	—	35,718
Corporate Bonds	—	7,380	—	7,380
Commercial paper	—	22,254	—	22,254
	$ 17,360	$ 74,272	$ —	$ 91,632

December 31, 2025	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 5,060	$ 18,710	$ —	$ 23,770
U.S. Government securities	27,903	14,873	—	42,776
Corporate Bonds	—	6,865	—	6,865
Commercial paper	—	18,252	—	18,252
Totals	$ 32,963	$ 58,700	$ —	$ 91,663

The Company's investments in commercial paper, corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for commercial paper, corporate bonds and U.S. government securities are based upon the quoted prices of similar items in active markets multiplied by the number of securities owned.

The following tables summarize the Company's cash equivalents and short-term investments (in thousands):

March 31, 2026	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents		$ 26,285	$ —	$ (5)	$ 26,280
U.S. Government securities	Less than 1	35,730	5	(17)	35,718
Corporate Bonds	Less than 1	7,387	—	(7)	7,380
Commercial paper	Less than 1	22,261	—	(7)	22,254
Totals		$ 91,663	$ 5	$ (36)	$ 91,632

December 31, 2025	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents		$ 23,772	$ —	$ (2)	$ 23,770
U.S. Government securities	Less than 1	42,739	37	—	42,776
Corporate Bonds	Less than 1	6,866	1	(2)	6,865
Commercial paper	Less than 1	18,250	3	(1)	18,252
Totals		$ 91,627	$ 41	$ (5)	$ 91,663

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents, marketable securities, and accounts receivable, net. The Company's cash and cash equivalents and restricted cash in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at March 31, 2026 were approximately $37.5 million. The Company does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Rating Service and Moody's Investors Service at the time of purchase.

The Company sells its products in the United States primarily through specialty pharmacies and specialty distributors. Therefore, wholesale distributors and large pharmacy chains account for a large portion of its accounts receivables, net and product revenues, net. The creditworthiness of its customers is continuously monitored, and the Company has internal policies regarding customer credit limits. The Company estimates an allowance for credit loss primarily based on the creditworthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions.

The Company's success depends on its ability to successfully commercialize NERLYNX. The Company currently has a single product and limited commercial sales experience, which makes it difficult to evaluate its current business, predict its future prospects and forecast financial performance and growth. The Company has invested a significant portion of its efforts and financial resources in the development and commercialization of the lead product, NERLYNX, and expects NERLYNX to constitute the vast majority of product revenue for the foreseeable future.

The Company relies exclusively on third parties to formulate and manufacture NERLYNX and its drug candidates. The commercialization of NERLYNX and any other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide sufficient quantities of product or fail to do so at acceptable quality levels or prices. The Company has no experience in drug formulation or manufacturing and does not intend to establish its own manufacturing facilities. The Company lacks the resources and expertise to formulate or manufacture NERLYNX and other drug candidates. While the drug candidates were developed by Pfizer, both the drug substance and drug product are manufactured by third-party contractors. The Company is using the same third-party contractors to manufacture, supply, store and distribute drug supplies for clinical trials and the commercialization of NERLYNX. If the Company is unable to continue its relationships with one or more of these third-party contractors, it could experience delays in the development or commercialization efforts as it locates and qualifies new manufacturers. The Company intends to rely on one or more third-party contractors to manufacture the commercial supply of drugs.

Inventory:

The Company values its inventories at the lower of cost and estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis and uses standard costing. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within the cost of sales in the condensed consolidated statements of operations. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of sales in the condensed consolidated statements of operations.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if any, when, based on management's judgment, future commercialization is considered probable, and the future economic benefit is expected to be realized. Inventory that can be used in either the production of clinical or commercial product is recorded as research and development expense when selected for use in a clinical trial. Starter kits, provided to patients prior to insurance approval, are expensed by the Company to selling, general and administrative expense as incurred. Of the total inventory amounts noted below, approximately $8.1 million is located at contract manufacturing organizations in Europe as of March 31, 2026.

The Company's inventory balances are as follows:

	March 31, 2026	December 31, 2025
Raw materials	$ 5,998	$ 3,212
Work-in-process	1,928	1,343
Finished goods	767	960
Total inventories	$ 8,693	$ 5,515

Property and Equipment, Net:

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the useful lives of the assets, which is generally three years for computer hardware and software, three years for phone equipment, and seven years for furniture and fixtures. Leasehold improvements are amortized using the straight-line method over the lesser of the useful life or the lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

The Company reviews its long-lived assets used in operations for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, as required by ASC Topic 360, *Property, Plant, and Equipment* ("ASC 360"). The Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows over the life of the asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would then determine the fair value of the long-lived asset and recognize an impairment loss for the amount in excess of the carrying value. No impairments were recorded during the three months ended March 31, 2026 and 2025.

Leases:

ASC Topic 842, *Leases*, as adopted in the first quarter of 2019, requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset ("ROU asset"). ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance, as required by ASC 360. A significant indication of impairment of an ROU asset would include a change in the extent or manner in which the asset is being used. The Company must make assumptions that underlie the most significant and subjective estimates in determining whether any impairment exists. Those estimates, and the underlying assumptions, include estimates of future cash flow utilizing market lease rates and determination of fair value. If an ROU asset related to an operating lease is impaired, the carrying value of the ROU asset post-impairment should be amortized on a straight-line basis through the earlier of the end of the useful life of the ROU asset or the end of the lease term. Post impairment, a lessee must calculate the amortization of the ROU asset and interest expense on the lease liability separately, although the sum of the two continues to be presented as a single lease cost. If a lease is planned to be abandoned with no intention of subleasing, the ROU asset should be assessed for impairment.

Leases are classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them. For additional information, see Note 5—Leases.

The Company leases office space and copy machines, all of which are operating leases. Most leases include the option to renew, and the exercise of the renewal options is at the Company's sole discretion. Options to extend or terminate a lease are considered in the lease term to the extent that the option is reasonably certain of exercise. The leases do not include options to purchase the leased property. The depreciable life of assets and leasehold improvements is limited by the expected lease term. Covenants imposed by the leases include letters of credit required to be obtained by the lessee.

The Company is required to remeasure the lease liability and make an adjustment in the following instances:

- The term of the lease has been modified or there has been a change in the Company's assessment of a purchase option being exercised, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate;

- A lease contract is modified, and the lease modification is not accounted for as a separate lease, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate; and

- The lease payments are adjusted due to changes in the index or a change in expected payment under a guaranteed residual value, in which cases the lease liability is remeasured by discounting the revised lease payments using the initial discount rate.

The incremental borrowing rate ("IBR") represents the rate of interest the Company would expect to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. As the implicit rate on the Company's leases is not readily determinable, the Company uses its IBR based on the information available at the commencement date in determining the present value of lease payments. The Company's average IBR for existing leases as of March 31, 2026 is 12.4%.

License Fees and Intangible Assets:

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its drug candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale. The Company capitalizes technology licenses upon reaching technological feasibility.

The Company maintains definite-lived intangible assets related to the license agreement with Pfizer. These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated. Amortization costs are recorded as part of cost of sales.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or non-clinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales of the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the

Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

Recently Issued Accounting Standards:

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures*: The ASU requires more detailed information about specified categories of expenses included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and related disclosures.

Note 3—Accounts Receivable, Net:

Accounts receivable, net consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Trade accounts receivable	$ 23,519	$ 38,146
Royalty revenue receivable	2,810	15,508
Total accounts receivable	$ 26,329	$ 53,654

Trade accounts receivable consist entirely of amounts owed from the Company's customers related to product sales. Royalty revenue receivable represents amounts owed related to royalty revenue recognized based on the Company's sub-licensees' sales in their respective territories in the periods ended March 31, 2026 and December 31, 2025.

For all accounts receivable, the Company recognizes credit losses based on lifetime expected losses to selling, general and administrative expense in the condensed consolidated statements of operations. In determining estimated credit losses, the Company evaluates its historical loss rates, current economic conditions and reasonable and supportable forecasts of future economic conditions. The Company did not record a provision for credit loss (recovery) for the three months ended March 31, 2026, compared to a provision for credit loss of $0.2 million for the three months ended March 31, 2025.

Note 4—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Current:		
CRO services	$ 37	$ 37
Other clinical development	288	324
Insurance	837	1,128
Professional fees	525	381
Prepaid Taxes	—	117
Other	1,718	1,655
	3,405	3,642
Long-term:		
CRO services	194	52
Insurance	7	8
Other clinical development	97	101
Other	2,657	2,673
	2,955	2,834
Totals	$ 6,360	$ 6,476

Other current prepaid amounts consist primarily of deposits, signing bonuses, licenses, subscriptions and software. Other long-term prepaid amounts consist primarily of funding for commercial copay support programs.

Note 5—Leases:

In December 2011, the Company entered into a non-cancelable operating lease for office space in Los Angeles, California, which was subsequently amended in November 2012, December 2013, March 2014, July 2015 and December 2017. The initial term of the lease was for seven years and commenced on December 10, 2011. Concurrent with the execution of the lease, the Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $1.0 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets. As amended, the Company rents approximately 65,656 square feet. The term of the lease runs until March 2026. In July 2025, the Company executed an amendment to its office space in Los Angeles, California to surrender certain suites effective March 31, 2026 and extend the lease term for the remaining 26,700 rentable square feet for an additional five years and five months through August 31, 2031. Base rent escalates annually and is abated from April 2026 through August 2026. Lease payments also include variable charges for the Company's proportionate share of building operating expenses and real estate taxes based on a 2026 base year. The Company has the option to renew such lease for an additional five year term. Management determined that the renewal option is not reasonably certain to occur.

In June 2012, the Company entered into a long-term lease agreement for office space in South San Francisco, California, which was subsequently amended in May 2014 and July 2015. As amended, the Company rents approximately 29,470 square feet. The term of this lease expired on March 31, 2026. The Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $1.1 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, current on the accompanying consolidated balance sheets until 60 days after the expiration of the lease.

Total rent expense for the three months ended March 31, 2026 and 2025 was approximately $1.1 million and $1.2 million, respectively. For purposes of determining straight-line rent expense, the lease term is calculated from the date the Company first takes possession of the facility, including any periods of free rent and any renewal option periods that the Company is reasonably certain of exercising. The Company's office leases generally have contractually specified minimum rent and annual rent increases that are included in the measurement of the ROU asset and related lease liability. Additionally, under these lease arrangements, the Company may be required to pay directly, or reimburse the lessors, for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are generally variable and therefore not included in the measurement of the ROU asset and related lease liability but are instead recognized as variable lease expense in selling, general and administrative costs in the condensed consolidated statements of operations when they are incurred.

Supplemental cash flow information related to leases for the three months ended March 31, 2026:		
Operating cash flows used for operating leases (in thousands)	$	1,667
Right-of-use assets obtained in exchange for new operating lease liabilities		—
Weighted-average remaining lease term (in years)		5.4
Weighted average discount rate		12.4%

Future minimum lease payments as of March 31, 2026 were as follows (in thousands):

	Amount
2026	$ 406
2027	1,248
2028	1,292
2029	1,337
2030	1,384
2031	951
Total minimum lease payments	$ 6,618
Less: imputed interest	(1,947)
Total lease liabilities	$ 4,671

During the three month period ended March 31, 2025, the Company signed a sublease agreement for the 12,429 square feet of office space with a sublease commencement date of April 1, 2025. This sublease expired on March 31, 2026.

In August 2023, the Company entered into a long-term sublease agreement for 13,916 square feet of the office space in Los Angeles, California, which commenced in November 2023. This sublease expired on March 31, 2026.

The Company recorded operating sublease income of $0.2 million for each of the three months ended March 31, 2026 and 2025, in other income (expenses) in the condensed consolidated statements of operations.

Note 6—Property and Equipment, Net:

Property and equipment, net consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Leasehold improvements	$ 1,696	$ 2,549
Computer equipment	406	761
Furniture and fixtures	910	1,475
Total property and equipment	3,012	4,785
Less: accumulated depreciation	(2,888)	(4,598)
Property and equipment, net	$ 124	$ 187

For the three months ended March 31, 2026 and 2025, the Company incurred depreciation expense of $0.1 million and $0.1 million, respectively.

Note 7—Intangible Assets, Net:

Intangible assets, net consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Acquired and in-licensed rights	$ 102,500	$ 102,500
Less: accumulated amortization	(63,543)	(61,108)
Total intangible assets, net	$ 38,957	$ 41,392

For each of the three months ended March 31, 2026 and 2025, the Company incurred amortization expense of $2.4 million and $2.4 million, respectively. The estimated remaining useful life of the intangible assets as of March 31, 2026 is 4.0 years.

As of March 31, 2026, estimated future amortization expense related to the Company's intangible assets is approximately $7.3 million for the remainder of 2026 and $9.7 million for each year starting 2027 through 2029, and $2.4 million for 2030.

Note 8—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Current:		
Accrued royalties	$ 7,454	$ 15,858
Accrued CRO services	5,772	3,793
Accrued variable consideration	14,130	14,215
Accrued bonus	1,862	8,377
Accrued compensation	5,359	5,797
Accrued other clinical development	928	567
Accrued professional fees	950	132
Accrued legal fees	1,101	990
Accrued manufacturing costs	469	93
Other	353	209
Totals	$ 38,378	$ 50,031

Accrued variable consideration represents estimates of adjustments to product revenue, net for which reserves are established. Accrued royalties represent royalties incurred in connection with the Company's license agreement with Pfizer. Accrued CRO services, accrued other clinical development expenses, and accrued legal fees represent the Company's estimates of such costs and are recognized as incurred. Accrued compensation includes severance, commissions and vacation.

Note 9—Debt:

Long term debt consisted of the following (in thousands):

	March 31, 2026	Maturity Date
Total debt, inclusive of $2.0 million exit payment	$ 102,000	July 23, 2026
Less: unamortized debt issuance costs and discounts	(59)	
Less: current portion	(11,283)	
Less: debt repayment	(90,658)	
Total long-term debt, net	$ 0	

Athyrium Note Purchase Agreement:

The Company issued senior notes for an aggregate principal amount of $100.0 million pursuant to a note purchase agreement dated July 23, 2021 by the Company, and its subsidiary, and Athyrium, as Administrative Agent, and certain other investor parties (the "Note Purchase Agreement"), with an initial maturity date of July 23, 2026 (the "Athyrium Notes"). The Athyrium Notes were issued for face amount of $100.0 million net of an original issue discount of $1.5 million. The Athyrium Notes also require a 2.0% exit payment to be made on each payment of principal. The borrowings under the Athyrium Notes, together with cash on hand, were used to repay the Company's outstanding indebtedness, including the applicable exit and prepayment fees owed to lenders under its prior credit facility with Oxford. The Athyrium Notes are secured by substantially all of the Company's assets. The Company incurred $1.9 million of deferred financing costs with the initial borrowing of the Athyrium Notes.

Interest on the Athyrium Notes is calculated in part based on the Secured Overnight Financing Rate ("SOFR"), which replaced the "London Interbank Offering Rate" as the floating benchmark for interest rate calculations applicable to the Athyrium Notes pursuant to the terms of the Third Amendment to Note Purchase Agreement dated as of September 16, 2022 (the "Third Amendment"). The modification of the Note Purchase Agreement pursuant to the Third Amendment did not meet the requirements of a debt extinguishment under ASC Topic 470-50—*Debt Modifications and Exchanges* and no gain or loss was recognized. The Company performed a quantitative analysis and determined that the terms of the new debt and original debt instrument were not substantially different. Accordingly, the Third Amendment is accounted for as a debt modification.

Following the effectiveness of the Third Amendment, the Athyrium Notes bear interest at an annual rate equal to the sum of (a) eight percent (8.00%) plus (b) the lesser of (i) the sum of (x) three-month term SOFR for an interest period of three months plus (y) 0.26161% (26.161 basis points) and (ii) three and one-half of one percent (3.50%) per annum. Interest is payable quarterly on the last business day of March, June, September and December each year. In the second quarter of 2024, the Company began paying the principal payments required to be made quarterly at 11.11% of the original face amount. The remaining balance will be paid at maturity. Each principal payment also includes a 2.0% exit payment. Each quarterly principal payment approximates $11.1 million, and each quarterly exit fee payment approximates $0.2 million. As of March 31, 2026, the effective interest rate for the loan was 12.99%.

As of March 31, 2026, the Company may prepay the outstanding principal balance of the notes, in whole or in part, without premium or penalty.

The Athyrium Notes include affirmative and negative covenants applicable to the Company. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, and satisfy certain requirements regarding deposit accounts. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions. The Company is also required to maintain minimum cash balances and achieve certain minimum product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis. As of March 31, 2026, the Company was in compliance with such covenants.

As of March 31, 2026, the principal balance outstanding under the Athyrium Notes was $11.1 million and exit fees were $0.2 million, representing all of the Company's debt.

The future minimum principal and exit payments under the Athyrium Notes as of March 31, 2026 are as follows (in thousands):

	Amount
2026	11,342
Total	$ 11,342

Debt Issuance Costs and Discounts:

Debt issuance costs and discounts consist of the following (in thousands):

	March 31, 2026	December 31, 2025
Debt issuance costs and discounts (Athyrium Notes)	$ 5,410	$ 5,410
Less: accumulated amortization	(5,351)	(5,258)
Included in current portion of debt	$ 59	$ 152

Debt issuance costs and discounts are financing costs related to the Company's outstanding debt. Amortization of debt issuance costs is expensed using the effective interest method and is included in interest expense in the condensed consolidated statement of operations. For each of the three months ended March 31, 2026 and 2025, the Company recorded approximately $0.1 million and $0.2 million of interest expense, respectively.

Note 10—Stockholders' Equity:

Common Stock:

The Company did not issue any shares of common stock upon exercise of stock options during the three months ended March 31, 2026 and 2025. The Company issued 471,181 and 509,340 shares of common stock upon vesting of RSUs during the three months ended March 31, 2026 and 2025, respectively.

Authorized Shares:

The Company has 100,000,000 shares of stock authorized for issuance, all of which are common stock, par value $0.0001 per share.

Warrants:

In October 2011, the Company issued an anti-dilutive warrant to Alan H. Auerbach, the Company's founder and Chief Executive Officer (the "Auerbach Warrant"). The Auerbach Warrant was issued to provide Mr. Auerbach with the right to maintain ownership of at least 20% of the Company's common stock in the event that the Company raised capital through the sale of its securities in the future.

In connection with the closing of a public offering in October 2012, the exercise price and number of shares underlying the Auerbach Warrant were established and, accordingly, the final value of the Auerbach Warrant became fixed. Pursuant to the terms of the Auerbach Warrant, as amended in June 2021, Mr. Auerbach may exercise the Auerbach Warrant to acquire 2,116,250 shares of the Company's common stock at $16 per share until October 4, 2026.

The Board of Directors is submitting for stockholder approval a second amendment (the "Auerbach Warrant Amendment") to the Auerbach Warrant, as amended by the first amendment on April 1, 2021. The Auerbach Warrant Amendment was approved by the Company's Compensation Committee and Board of Directors on March 13, 2026 and March 20, 2026, respectively, and in each case, is subject to approval by the Company's stockholders at the Annual Meeting.

Stock Options and Restricted Stock Units:

The Company's 2011 Plan, as amended, was adopted by the Company's Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers, and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. On April 1, 2021, the Board of Directors adopted an amendment to the 2011 Plan to increase the number of shares of the Company's common stock reserved for issuance thereunder by 2,000,000 shares. The amendment was approved by the Company's stockholders on June 15, 2021. On June 18, 2024, the stockholders of the Company approved an amendment to the Company's 2011 Plan, increasing the number of authorized shares of the Company's common stock, par value $0.0001 per share, that may become issuable under the 2011 Plan by 3,000,000 shares and extending the period during which incentive stock options may be granted. As of March 31, 2026, a total of 17,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

All of the options awarded by the Company have been "plain vanilla options" as determined by the SEC Staff Accounting Bulletin 107—*Share Based Payment.* As of March 31, 2026, 5,201,704 shares of the Company's common stock are issuable upon the exercise of outstanding stock options and vesting of RSUs granted under the 2011 Plan and 2,174,925 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees and nonemployees was estimated using the Black-Scholes Option Pricing Method (see Note 2—Significant Accounting Policies) with the following weighted-average assumptions used during the three months ended March 31, 2026:

	2026	2025
Dividend yield	0.0%	0.0%
Expected volatility	74.1%	81.5%
Risk-free interest rate	3.7%	4.4%
Expected life in years	5.54	5.55

The Company's 2017 Plan, as amended, was adopted by the Company's Board of Directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and RSUs, as well as other forms of equity-based compensation, to employees as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. On July 15, 2021, the Board of Directors adopted an amendment to the 2017 Plan to increase the number of shares of the Company's common stock reserved for issuance thereunder by 1,000,000 shares. As of March 31, 2026, a total of 397,974 shares of the Company's common stock are issuable upon the exercise of outstanding stock options and vesting of RSUs granted under the 2017 Plan and 1,282,048 shares of the Company's common stock are available for future issuance under the 2017 Plan.

Stock-based compensation expense was as follows (in thousands):

	For the Three Months Ended March 31,	
	2026	2025
Stock-based compensation:		
Options:		
Selling, general, and administrative	$ 246	$ 311
Research and development	54	46
Restricted stock units:		
Selling, general, and administrative	893	925
Research and development	703	744
Total stock-based compensation expense	$ 1,896	$ 2,026

Activity with respect to options granted under the 2011 Plan and 2017 Plan is summarized as follows:

Stock Option Roll Forward:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	3,217,289	$ 16.13		
Granted	364,336	6.68		
Outstanding at March 31, 2026	3,581,625	$ 15.17	5.6	$ 4,193
Vested and expected to vest at March 31, 2026	3,581,625	$ 15.17	5.6	$ 4,193
Exercisable	3,004,142	$ 17.08	4.9	$ 3,424

At March 31, 2026, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $1.7 million, which is expected to be recognized over a weighted-average period of 1.7 years. At March 31, 2026, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $8.8 million, which is expected to be recognized over a weighted-average period of 1.7 years. The weighted-average grant date fair value of options granted during the three months ended March 31, 2026 and 2025 was $4.37 and $1.95 per share, respectively. The weighted-average grant date fair value of RSUs awarded during the three months ended March 31, 2026 and 2025 was $6.79 and $3.28 per share, respectively.

Restricted Stock Unit Roll Forward:

	Shares	Weighted- Average Grant-Date Fair Value
Nonvested shares at December 31, 2025	1,334,973	$ 3.89
Granted	1,158,025	$ 6.79
(Forfeited)	(3,764)	$ 3.35
(Vested)	(471,181)	$ 4.70
Nonvested shares at March 31, 2026	2,018,053	$ 5.37

Note 11—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer-matching contributions of approximately $0.6 million and $0.5 million for the three months ended March 31, 2026 and 2025, respectively.

Note 12—Commitments and Contingencies:

Contractual Obligations:

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which the Company cannot reasonably predict future payment. The Company's contractual obligations result primarily from obligations for various contract manufacturing organizations and clinical research organizations, which include potential payments the Company may be required to make under its agreements. The contracts also contain variable costs and milestones that are hard to predict as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under contract manufacturing organization ("CMO") and CRO agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations. Also, those agreements are cancelable upon written notice by the Company and, therefore, not long-term liabilities.

License Agreements:

Pfizer License Agreement

In August 2011, the Company entered into an agreement pursuant to which Pfizer agreed to grant it a worldwide license for the development, manufacture and commercialization of PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to Pfizer. Under the agreement, the Company is obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and to use commercially reasonable efforts to complete clinical trials and to achieve certain milestones as provided in a development plan. From the closing date of the agreement through December 31, 2011, Pfizer continued to conduct the existing clinical trials on behalf of the Company at Pfizer's sole expense. At the Company's request, Pfizer agreed to continue to perform certain services in support of the existing clinical trials at the Company's expense. These services would continue through the completion of the transitioned clinical trials. The license agreement "capped" the out-of-pocket expense the Company would incur to complete the then existing clinical trials. All agreed upon costs incurred by the Company above the "cost cap" would be reimbursed by Pfizer. The Company exceeded the "cost cap" during the fourth quarter of 2012. In accordance with the license agreement, the Company billed Pfizer for agreed upon costs above the "cost cap" until December 31, 2013.

On July 18, 2014, the Company entered into an amendment to the license agreement with Pfizer. The amendment amends the agreement to (1) reduce the royalty rate payable by the Company to Pfizer on sales of licensed products; (2) release Pfizer from its obligation to pay for certain out-of-pocket costs incurred or accrued on or after January 1, 2014 to complete certain ongoing clinical studies; and (3) provide that Pfizer and the Company will continue to cooperate to effect the transfer to the Company of certain records, regulatory filings, materials and inventory controlled by Pfizer as promptly as reasonably practicable.

As consideration for the license, the Company is required to make substantial payments upon the achievement of certain milestones totaling approximately $187.5 million if all such milestones are achieved. In connection with the FDA approval of NERLYNX in July of 2017, the Company triggered a one-time milestone payment pursuant to the agreement. In June 2020, the Company entered into a letter agreement (the "Letter Agreement") with Pfizer relating to the method of payment associated with a one-time milestone payment under the license agreement with Pfizer. The Letter Agreement permitted the Company to make the milestone payment in installments with the remaining amount payable to Pfizer (including interest). The milestone payment accrued interest at 6.25% per annum. The milestone payment including accrued interest of $1.8 million was paid in full in September 2021. In addition, the Company reached a commercial milestone by achieving aggregate worldwide net sales of $250.0 million in calendar year 2022, resulting in a payment to Pfizer of $12.5 million during the three months ended March 31, 2023. The Company capitalized the milestones as intangible assets and is amortizing the assets to cost of sales on a straight-line basis over the estimated useful life of the licensed patent through 2030. Should the Company commercialize any more of the compounds licensed from Pfizer or any products containing any of these compounds, the Company will be obligated to pay Pfizer annual royalties at a fixed rate in the low-to-mid teens of net sales of all such products, subject to certain reductions and offsets in some circumstances. The Company's royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (1) the last to expire licensed patent covering the applicable licensed product in such country, or (2) the earlier of generic competition for such licensed product reaching a certain level in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that the Company sub-licenses the rights granted to the Company under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required. The Company can terminate the license agreement at will, or for safety concerns, in each case upon specified advance notice.

Takeda License Agreement

In September 2022, the Company entered into an exclusive license agreement with Takeda to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of Aurora Kinase A. Under the terms of the exclusive license agreement, the Company will assume sole responsibility for the global development and commercialization of alisertib. Takeda received an upfront license fee of $7.0 million in October 2022 and is eligible to receive potential future milestone payments of up to $287.3 million upon the Company's achievement of certain regulatory and commercial milestones over the course of the exclusive license agreement, as well as tiered royalty payments for any net sales of alisertib. No milestones were achieved as of March 31, 2026.

Legal Proceedings:

The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded.

Legal Malpractice Suit

On September 17, 2020, the Company filed a lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented the Company in *Eshelman v. Puma Biotechnology, Inc., et al*. in the Superior Court of Mecklenburg County, North Carolina. The Company is alleging legal malpractice based on the defendants' negligent handling of the defense of the Company in *Eshelman v. Puma Biotechnology, Inc., et al*. The Company is seeking recovery of the entire amount awarded in *Eshelman v. Puma Biotechnology, Inc., et al*. and all legal fees and expenses incurred in appealing from the judgment and retrying the damages phase of the trial. On November 23, 2020, the defendant filed an answer to the complaint denying the allegations of negligence. On August 19, 2022, the Company filed a voluntary dismissal of the legal malpractice action, without prejudice, to allow the *Eshelman v. Puma Biotechnology, Inc., et al*. to conclude before proceedings. On June 2, 2023, the Company re-filed the lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented the Company in *Eshelman v. Puma Biotechnology, Inc., et al.* in the Superior Court of Mecklenburg County, North Carolina. On August 22, 2023, the defendants filed motions to dismiss the case. These motions were presented at a hearing on February 20, 2024. The Superior Court Judge granted the motions to dismiss on March 20, 2024. The Company appealed this ruling to the North Carolina Court of Appeals. On September 3, 2025, the Court of Appeals reversed the dismissal of the Company's claim for legal malpractice and remanded the case to the Superior Court for further proceedings. The defendants filed a petition for discretionary review of this decision by the North Carolina Supreme Court on October 8, 2025. The Supreme Court has not decided whether to accept the case for review.

Patent-Related Proceedings

AstraZeneca Litigation

On September 22, 2021, the Company filed suit against AstraZeneca Pharmaceuticals, LP, AstraZeneca AB, and AstraZeneca PLC for infringement of United States Patent Nos. 10,603,314 ("the '314 patent") and 10,596,162 ("the '162 patent") (*Puma Biotechnology, Inc. et al. v. AstraZeneca Pharmaceuticals LP et al*., 1:21CV01338 (D. Del. Sep. 22, 2021)). The Company's complaint alleges that AstraZeneca's commercial manufacture, use, offer for sale, sale, distribution, and/or importation of Tagrisso® (osimertinib) products for the treatment of gefitinib and/or erlotinib-resistant non-small cell lung cancer infringes the '314 and '162 patents. The Company is an exclusive licensee of the '314 and '162 patents under the Pfizer Agreement. Wyeth is a co-plaintiff. Plaintiffs seek a judgment that AstraZeneca's product infringes the asserted patents and an award of monetary damages in an amount to be proven at trial. AstraZeneca AB and AstraZeneca Pharmaceuticals LP filed an answer and counterclaims on November 5, 2021, including claims challenging the asserted patents as not infringed and/or invalid, and accusing plaintiffs of unclean hands and patent misuse. The parties stipulated to dismiss AstraZeneca PLC as a defendant and Pfizer as a Counterclaim Defendant on December 10, 2021, which the Court so ordered on December 13, 2021. The Company filed its answer to AstraZeneca's counterclaims on December 17, 2021, denying those claims. The case was reassigned to visiting Judge Matthew Kennelly of the Northern District of Illinois. A Markman Hearing was conducted on March 17, 2023, and the Court issued its claim construction decision on March 29, 2023. Fact discovery closed on May 19, 2023, and expert discovery closed on November 17, 2023. The Court denied the parties' respective motions for summary judgment and Daubert motions, other than to clarify that Plaintiffs' damages cannot extend to any time period before the asserted patents were issued. The Court granted AstraZeneca's motion to dismiss the Company as a Plaintiff on constitutional standing grounds but denied the motion to dismiss Wyeth as a Plaintiff on constitutional standing grounds. On April 29, 2024, the Court granted AstraZeneca's motion to dismiss AstraZeneca's counterclaims against the Company, which removed the Company from the case. Wyeth remained in the case as a Plaintiff and counterclaim defendant. Under the Company's worldwide exclusive license agreement with Pfizer, Inc. (the parent of Wyeth) as amended, the Company also maintains contractual rights to recover monetary damages in the AstraZeneca litigation, and those contractual rights are unaffected by the court's March 18, 2024 and April 29, 2024 orders. A jury trial was held May 13-17, 2024. The jury found in favor of Wyeth and against AstraZeneca. In particular, the jury found that use of Tagrisso® according to each of the three FDA-approved indications infringes the asserted claims of the '314 and '162 patents, and that AstraZeneca induces that infringement. The jury further rejected AstraZeneca's challenges to the validity of the patents, finding that they are not invalid. The jury awarded damages to Wyeth for past acts of infringement through December 31, 2023, in the amount of $107.5 million. A separate bench trial related to certain equitable claims and defenses raised by AstraZeneca was held before Judge Kennelly on June 20 and 25, 2024. On August 6, 2024, Judge Kennelly issued his ruling on the issues that were tried in the bench trial, finding for Wyeth and against AstraZeneca on all claims and defenses. The Court found that AstraZeneca had not proved its claim that Wyeth's asserted patents were invalid as indefinite, or that Wyeth had committed acts that would give rise to findings of unclean hands, implied waiver, or patent misuse. AstraZeneca filed a motion challenging the jury's verdict and requesting a new trial. Wyeth filed a motion requesting supplemental damages for past infringement from January 1, 2024, through the date of judgment; pre-and-post judgment interest, and ongoing royalties through the remaining term of the patents. Briefing on these motions from both sides was completed on July 16, 2024. On August 14, 2024, Judge Kennelly ruled on AstraZeneca's motion challenging the jury's verdict, granting it in part and denying it in part. The Court granted AstraZeneca's motion for judgment as a matter of law that the '314 and '162 patents are invalid under 35 U.S.C. § 112 for lacking enablement and adequate written description as to a particular claim limitation. In all other respects, the Court denied AstraZeneca's motion. The Court entered its final and appealable judgment accordingly. The Company respectfully disagrees with the Court's ruling regarding invalidity with respect to the particular claim limitation. Wyeth filed a notice of appeal on September 12, 2024, appealing the District Court's judgment as a matter of law, as well as other rulings and opinions of the Court adverse to Wyeth. On December 18, 2024, Wyeth filed its opening brief. On March 13, 2025, AstraZeneca filed its response brief. On March 20, 2025, non-parties Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC filed a motion for leave to file an amicus curiae brief in the

Federal Circuit. The motion was granted on May 16, 2025. On June 6, 2025, Wyeth filed its reply brief. Briefing on the appeal is now complete, and the Court has scheduled oral arguments for May 7, 2026.

Acebright China Litigation

On January 18, 2022, Shanghai Acebright Pharmaceuticals Group Co., Ltd. ("Acebright") filed an abbreviated new drug application ("ANDA") with the National Medical Products Administration in China ("NMPA") seeking approval to market a generic version of the Company's NERLYNX® (neratinib) tablet, 40mg in China. Acebright seeks approval prior to the expiration of three patents listed on the China Patent Information Registration Platform for Marketed Drugs ("Chinese Orange Book"), namely, Chinese Patent Nos. ZL201410082103.7, ZL201080060546.6, and ZL200880118789.3 (the "'789 patent" and collectively, the "NERLYNX® Patents"), alleging in a Type 4.2 patent declaration that its generic version of NERLYNX does not fall within the scope of the claims of NERLYNX® Patents listed in the Chinese Orange Book. The patent declaration of Acebright was published in the Chinese Orange Book on January 19, 2022. On March 2, 2022, the Company filed petitions with the China National Intellectual Property Administration ("CNIPA") and requested administrative determination that Acebright's generic neratinib tablet falls within the scope of the claims of NERLYNX® Patents listed in the Chinese Orange Book. The Company's request for administrative determination was accepted by CNIPA on March 18, 2022. The Company has notified NMPA of the acceptance of the request for administrative determination for NMPA to institute a stay of Acebright's ANDA for nine months. On July 11, 2022, CNIPA decided that claims 5 and 6 of Patent No. ZL200880118789.3 are not eligible for registration in the Chinese Orange Book on the ground that these two pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On September 9, 2022, CNIPA decided that the generic drug in Acebright's ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of Patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of Patent No. ZL201080060546.6. The three CNIPA administrative decisions on NERLYNX® Patents have lifted the stay of Acebright's ANDA by NMPA. The Company has appealed each CNIPA administrative decision in January 2023 at the Beijing Intellectual Property Court ("BJIPC"). The three appeals were accepted by BJIPC on February 20, 2023. The Company also filed three civil complaints based on the three NERLYNX® Patents against Acebright with the BJIPC in July 2022 and requested court determination that Acebright's generic neratinib tablet falls within the scope of the claims of NERLYNX® Patents. On May 6, 2023, the Company withdrew two civil lawsuits and two appeals in relation to Chinese Patent Nos. ZL201410082103.7 and ZL201080060546.6 at the BJIPC. On May 24, 2023, the BJIPC accepted the Company's withdrawal request. On July 24, 2023, the Company withdrew the one remaining civil lawsuit and one appeal in relation to Chinese Patent No. ZL200880118789.3 at the BJIPC. On August 15, 2023, the BJIPC accepted the Company's withdrawal request. On September 12, 2023, the NMPA approved Acebright's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20234141.

On December 28, 2023, the Company filed a civil lawsuit against Acebright for infringement of the '789 patent under Article 11 of the Chinese Patent Law before Jiangsu Nanjing Intermediate People's Court. The Company's complaint alleges that Acebright's offer for sale of a generic version of the Company's NERLYNX® product infringes the '789 patent. The Company seeks a judgment that Acebright's product infringes the '789 patent and Acebright's act of offer for sale shall be enjoined. On January 2, 2024, Jiangsu Nanjing Intermediate People's Court accepted the civil complaint. An oral hearing was held on June 19, 2024, during which the Company amended its complaint to allege that Acebright making, selling and offering to sell the generic version of NERLYNX® infringes the '789 patent. On July 24, 2024, the Company submitted a request to withdraw the lawsuit. On August 8, 2024, Jiangsu Nanjing Intermediate People's Court accepted the withdrawal request.

On September 27, 2024, the Company filed an additional patent infringement claim against Acebright at Jiangsu Nanjing Intermediate People's Court. On October 14, 2024, the Court accepted the complaint and designated case number (2024) Su 01 Min Chu 2192 to this case. On December 16, 2024, the Court conducted an evidence exchange hearing. On January 10, 2025, the Court conducted a hearing of party experts on the evaluation of evidence. On July 14, 2025, the Court conducted a hearing to examine evidence and debate merits of party arguments. On September 28, 2025, the Court issued a first-instance decision, deciding that Acebright's product does not fall within the scope of the patent-in-suit, and Acebright did not infringe the NERLYNX® Patents. The Court also decided that the Company's enforcement efforts were not malicious and did not amount to unfair competition.

Aosaikang China Litigation

On November 17, 2022, Jiangsu Aosaikang Pharmaceutical Co. Ltd. ("Aosaikang") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2202006. Aosaikang made Type 4.2 declarations against the four Orange Book Patents ZL201410082103.7, ZL201080060546.6, ZL200880118789.3 and ZL201710057547.9, alleging that its generic version of NERLYNX does not fall within the scope of the claims of the Orange Book patents. Aosaikang also alleged that Patents ZL200880118789.3 and ZL201710057547.9 are not eligible for Chinese Orange Book listing.

On December 28, 2022, the Company submitted four Article 76 petitions against the Aosaikang ANDA with the CNIPA and requested administrative determination that Aosaikang's generic neratinib tablet falls within the scope of the claims of the four Orange Book patents. On January 6, 2023, the CNIPA accepted the Company's request for administrative determination in relation to Patent Nos. ZL201410082103.7 and ZL201080060546.6. Also on January 6, 2023, the CNIPA declined to accept the Company's request for administrative determination in relation to Patent Nos. ZL200880118789.3 and ZL201710057547.9, alleging that the listed claims are not eligible for registration in the Chinese Orange Book on the ground that these pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On January 28, 2023, the Company requested the NMPA to institute a nine-month stay against Aosaikang ANDA starting from the CNIPA's acceptance of the Company's request for administrative determination. On June 2, 2023, CNIPA decided that the generic drug in Aosaikang's ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of Patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of Patent No. ZL201080060546.6. The two CNIPA administrative decisions on NERLYNX® Patents have lifted the stay of Aosaikang's ANDA by NMPA. On October 22, 2024, the NMPA approved Aosaikang's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20249180.

Convalife China Litigation

Convalife Pharmaceuticals (Shanghai) Co., Ltd ("Convalife") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2202095. On December 23, 2022, Convalife made Type 4.2 declarations against the four Orange Book Patents ZL201410082103.7, ZL201080060546.6, ZL200880118789.3 and ZL201710057547.9, alleging that its generic version of NERLYNX does not fall within the scope of the claims of the Orange Book patents. Convalife also alleged that Patents ZL200880118789.3 and ZL201710057547.9 are not eligible for Chinese Orange Book listing.

On February 1, 2023, the Company submitted four Article 76 petitions against the Convalife ANDA with the CNIPA and requested administrative determination that Convalife's generic neratinib tablet falls within the scope of the claims of the four Orange Book patents. On February 3, 2023, the CNIPA accepted the Company's request for administrative determination in relation to Patent Nos. ZL201410082103.7 and ZL201080060546.6. Also on February 3, 2023, the CNIPA declined to accept the Company's request for administrative determination in relation to Patent Nos. ZL200880118789.3 and ZL201710057547.9, alleging that the listed claims are not eligible for registration in the Chinese Orange Book on the ground that these pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On February 24, 2023, the Company requested the NMPA to institute a nine-month stay against Convalife ANDA starting from the CNIPA's acceptance of the Company's request for administrative determination. On June 2, 2023, CNIPA decided that the generic drug in Convalife's ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of Patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of Patent No. ZL201080060546.6. The two CNIPA administrative decisions on NERLYNX® Patents have lifted the stay of Convalife's ANDA by NMPA. On June 28, 2024, the NMPA approved Convalife's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20244222.

Kelun China Litigation

Hunan Kelun Pharmaceutical Co., Ltd. ("Kelun") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2300221. On January 28, 2023, Kelun made Type 4.2 declarations against the four Orange Book Patents ZL201410082103.7, ZL201080060546.6, ZL200880118789.3 and ZL201710057547.9, alleging that its generic version of NERLYNX does not fall within the scope of the claims of the Orange Book patents. Kelun also alleged that Patents ZL200880118789.3 and ZL201710057547.9 are not eligible for Chinese Orange Book listing.

On March 13, 2023, the Company submitted four Article 76 petitions against the Kelun ANDA with the CNIPA and requested administrative determination that Kelun's generic neratinib tablet falls within the scope of the claims of the four Orange Book patents. On March 21, 2023, the CNIPA declined to accept the Company's request for administrative determination in relation to Patent Nos. ZL200880118789.3 and ZL201710057547.9, alleging that the listed claims are not eligible for registration in the Chinese Orange Book on the ground that these pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On March 24, 2023, the CNIPA accepted the Company's request for administrative determination in relation to Patent Nos. ZL201410082103.7 and ZL201080060546.6. On April 17, 2023, the Company requested the NMPA to institute a nine-month stay against Kelun's ANDA starting from the CNIPA's acceptance of the Company's request for administrative determination. On September 14, 2023, the Company withdrew the two requests for administrative determination in relation to Chinese Patent Nos. ZL201410082103.7 and ZL201080060546.6 at the CNIPA. On September 25, 2023, the CNIPA accepted the Company's withdrawal request. On September 9, 2025, the NMPA approved Kelun's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20255337.

Demai Litigation

Zhengzhou Demai Pharmaceutical Co., Ltd ("Demai") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2402776. On August 26, 2024, Demai made a Type 4.2 declaration against Orange Book Patent ZL201410082103.7, alleging that its generic version of NERLYNX does not fall within the scope of the claims of this Orange Book patent. On September 30, 2024, the Company filed a lawsuit against Demai at the BJIPC based on Nerlynx Patent No. ZL201080060546.6 and on October 8, 2024, the Company filed a lawsuit against Demai at the BJIPC based on Nerlynx Patent No. ZL201410082103.7. On February 13, 2025, the Company withdrew the lawsuits from BJIPC, filed an Article 76 petition with the CNIPA against the Demai ANDA and requested administrative determination that Demai's generic neratinib maleate tablet falls within the scope of the claims of Nerlynx Patent No. ZL201080060546.6. On February 21, 2025, the CNIPA accepted the Company's petition and started examination. On March 18, 2025, the Company filed a request with the NMPA to set up a nine-month stay on Demai's ANDA. On November 4, 2025, the NMPA approved Demai's ANDA to market a generic version of Puma's NERLYNX® in China with the approval number of GuoYaoZhunZi H20255844.

Hexal European Patent Opposition

An opposition was filed by Hexal AG ("Hexal") on August 3, 2016 against European Patent No. EP2416774 which was licensed from Pfizer in 2011, and which claims neratinib for use in a method for treating HER-2/neu overexpressed/amplified cancer and improving IDFS, wherein the method comprises delivering neratinib therapy to HER-2/neu overexpressed/amplified cancer patients following the completion of at least one year of trastuzumab adjuvant therapy, and wherein the neratinib therapy comprises treating the cancer patients with neratinib for at least twelve months. An oral hearing was held on December 8, 2017, wherein the patent was maintained as granted. Following an appeal filed by Hexal, the Board of Appeal of the European Patent Office rejected the claims as granted and all pending auxiliary requests during the oral hearing of September 2, 2021. Before issuance of a decision, the Company withdrew approval of the text in which the patent was granted and all pending auxiliary requests, thereby revoking the patent and concluding the appeal. One European divisional application, namely EP15188350.1, was granted with the European patent number EP3000467 on March 1, 2023. Oppositions against EP3000467 were filed by Hexal on November 3, 2023, by Alfred E. Tiefenbacher (GmbH & Co. KG) on November 28, 2023 and by Generics (UK) Limited ("Generics") on December 1, 2023. EP3000467 is used as the basic patent for Supplementary Protection Certificate applications for the EMA-approved NERLYNX® product, 17 of which have been granted, three proceedings have been stayed, and 11 are in active prosecution. The patentee response to the notice of opposition was filed on April 15, 2024, following which, all three opponents filed additional arguments in reply to the patentee's submission. On February 6, 2025, the Company filed its response to the summons to attend oral proceedings, including six auxiliary requests. Alfred E. Tiefenbacher and Hexal filed their responses to the summons to oral proceedings on February 6 and 7, 2025, respectively. Hexal filed a further brief on March 19, 2025. Oral proceedings took place on April 9 and 10, 2025. EP3000467 was upheld as amended after the first instance hearing based on Auxiliary Request 1, which covers the EMA approved indication for NERLYNX® as an extended adjuvant therapy for treating early stage hormone receptor-positive HER-2-overexpressed/amplified breast cancer. Hexal filed an appeal on June 6, 2025, Generics filed an appeal on June 20, 2025 and Wyeth filed an appeal on June 30, 2025. On September 5, 2025, Wyeth filed its grounds of appeal, including nine auxiliary requests. On the same day, Hexal filed its grounds of appeal. Generics filed its grounds of appeal on September 4, 2025, and Alfred E. Tiefenbacher filed its grounds of appeal on September 1, 2025. On December 16, 2025, Alfred E. Tiefenbacher withdrew its appeal. Wyeth responded to the opponents' grounds of appeal on January 12, 2026. On March 2, 2026, Hexal withdrew its request for oral proceedings, but remains a party to the proceedings.

One European divisional application is pending in the same family, namely EP 23157078.8. A response to the European Search Opinion ("ESO") for this application was filed February 14, 2024. The first office action was issued on January 28, 2025 with a response to the first office action filed on July 22, 2025.

Note 13—Subsequent Event

On May 4, 2026, the Company paid $11.5 million to Athyrium Opportunities IV Co-Invest 1 LP, consisting of principal, interest and exit fees due under the 2021 Note Purchase Agreement. This payment was made ahead of the maturity date of July 23, 2026, reduces the principal balance outstanding under the Athyrium Notes to zero and terminates all remaining obligations of the Company under the 2021 Note Purchase Agreement, other than customary continuing indemnification obligations.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q, (this "Quarterly Report"). The following discussion should also be read in conjunction with our audited consolidated financial statements and the notes thereto and "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.

Unless otherwise provided in this Quarterly Report, references to the "Company," "we," "us," and "our" refer to Puma Biotechnology, Inc., a Delaware corporation, together with its wholly owned subsidiary.

Overview

We are a biopharmaceutical company that develops and commercializes innovative products to enhance cancer care and improve treatment outcomes for patients. We are currently commercializing NERLYNX, an oral version of neratinib, for the treatment of certain HER2-positive breast cancers. Additionally, in 2022, we in-licensed and became responsible for the global development and commercialization of alisertib. Alisertib is a selective, small-molecule inhibitor of Aurora Kinase A that is designed to disrupt mitosis leading to apoptosis of rapidly proliferating tumor cells that are dependent on Aurora Kinase A. Prior to our licensing alisertib from Takeda, alisertib was tested in over 1,300 patients who were treated across 22 company-sponsored trials resulting in a large, well-characterized clinical safety database. Based on information in this database, we believe alisertib has potential application in the treatment of a range of different cancer types, including hormone receptor-positive breast cancer, triple-negative breast cancer and small cell lung cancer. We intend to pursue development of alisertib initially in small cell lung cancer and hormone receptor-positive breast cancer.

NERLYNX is currently approved in the United States for two indications: the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy and for use in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

We currently market NERLYNX in the United States using our direct specialty sales force consisting of approximately 35 sales specialists as of December 31, 2025. Our sales specialists are supported by an experienced sales leadership team consisting of regional managers and directors, as well as a commercial team of experienced professionals in marketing, access and reimbursement, managed markets, marketing research, commercial operations and sales force planning and management. Outside the United States, we seek to enter into exclusive sub-license agreements with third parties to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved. As of March 31, 2026, NERLYNX has received approval for the treatment of certain patients with extended adjuvant or metastatic HER2-positive breast cancer in over 60 countries outside the United States. We are currently party to several sub-licenses in various regions outside the United States, including Europe (excluding Ukraine), Australia, Canada, China, Southeast Asia, Israel, South Korea, Russia and various countries and territories in Central America, South America, Africa and the Middle East.

In September 2022, we entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited ("Takeda") to license the worldwide research and development and commercial rights to alisertib. Alisertib is an investigational, reversible, ATP-competitive inhibitor that is designed to be highly selective for Aurora Kinase A. Inhibition of Aurora Kinase A can lead to disruption of mitotic spindle apparatus assembly, disruption of chromosome segregation, and inhibition of cell proliferation. In clinical trials to date, alisertib has shown single agent activity and activity in combination with other cancer drugs in the treatment of many different types of cancers, including hormone receptor-positive breast cancer, triple-negative breast cancer, small cell lung cancer and head and neck cancer. We initiated the ALISertib in CAncer (ALISCA™ -Lung1) Phase II trial (PUMA-ALI-4201) of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer in February 2024, and we commenced the ALISCA™ -Breast1 Phase II trial (PUMA-ALI-1201) in November 2024.

Under the terms of the exclusive license agreement, we assumed sole responsibility for the global development and commercialization of alisertib. We paid Takeda an upfront license fee of $7.0 million in October 2022, and it is eligible to receive potential future milestone payments of up to $287.3 million upon our achievement of certain regulatory and commercial milestones over the course of the exclusive license agreement, as well as tiered royalty payments for any net sales of alisertib. We recorded in-process research and development expense of $7.0 million during the year ended December 31, 2022 in connection with the upfront payment related to the asset acquisition. As of March 31, 2026, no milestones had been accrued as the underlying contingencies were not probable.

Our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials, building out of our corporate infrastructure and, since 2017, the commercial launch of NERLYNX. Going forward, we anticipate significant expenses as we continue to develop alisertib in 2026. Accordingly, our success depends not only on the safety and efficacy of our drug candidates, but also on our ability to finance product development. To date, our major sources of working capital have been proceeds from product and license revenue, public and private offerings of our common stock, and proceeds from debt financings. We intend to satisfy our near-term liquidity requirements through a combination of our existing cash and cash equivalents and marketable securities as of March 31, 2026, and proceeds that we expect to become available to us through product sales, royalties and sub-license milestone payments. However, this intention is based on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, the impact of commercialization efforts, acquisition of additional drug candidates and changes in regulation. Some of these developments have had and may continue to have an adverse effect on our revenue and thus could have an adverse effect on our ability to satisfy the minimum revenue and cash balance covenants contained in the Athyrium Notes.

Critical Accounting Policies

As of the date of the filing of this Quarterly Report, we believe there have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2026 from our accounting policies at December 31, 2025, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Summary of Income and Expenses

Product revenue, net:

Product revenue, net consists of revenue from sales of NERLYNX. We sell NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. We record revenue at the net sales price, which includes an estimate for variable consideration for which reserves are established. Variable consideration consists of trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates and other incentives.

Product revenue also consists of product sales under sub-license agreements to our sub-licensees, who then sell into their respective international territories.

License revenue:

License revenue consists of consideration earned for performance obligations satisfied pursuant to our sub-license agreements.

Royalty revenue:

Royalty revenue consists of consideration earned related to product sales made by our sub-licensees in their respective territories pursuant to our sub-license agreements.

Cost of sales:

Cost of sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NERLYNX. Cost of product sales also includes period costs related to royalty charges payable to Pfizer, the amortization of milestone payments made under our license agreement with Pfizer, certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances. Cost of sales includes applicable license termination fees.

Selling, general and administrative expenses:

Selling, general and administrative expenses ("SG&A expenses") consist primarily of salaries and payroll-related costs, stock-based compensation expense, professional fees, business insurance, rent, general legal activities, credit loss expense and other corporate expenses. We expense SG&A expenses as they are incurred.

Research and development expenses:

Research and development expenses ("R&D expenses") include costs associated with services provided by consultants who conduct and perform clinical services on our behalf and contract organizations for the manufacturing of clinical materials. During the three months ended March 31, 2026 and 2025, our R&D expenses consisted primarily of clinical research organization ("CRO fees"); fees paid to consultants; salaries and related personnel costs; and stock-based compensation. We expense our R&D expenses as they are incurred. Internal R&D expenses primarily consist of payroll-related costs and also include equipment costs, travel expenses and supplies.

Tariffs

We do not believe that tariffs imposed or proposed to be imposed by the United States, particularly with the EU and China, will have a material impact on our product costs or results of operations. However, shifts in trade policies in the United States and other countries have been rapidly evolving and are difficult to
predict. The ultimate impact of any announced or future tariffs will depend on various factors, including what tariffs are ultimately implemented, the timing of implementation and the amount, scope and nature of such tariffs and potential exclusions from the application of those tariffs.

On April 2, 2026, the U.S. government issued a proclamation under Section 232 of the Trade Expansion Act of 1962, imposing new tariffs on imported patented pharmaceutical products and APIs. Any potential impact of the proclamation on the Company is uncertain and under review.

Results of Operations

Three Months Ended March 31, 2026 Compared to Three Months Ended March 31, 2025

Total revenue:

Total revenue for the three months ended March 31, 2026 was approximately $44.8 million, compared to $46.0 million for the three months ended March 31, 2025. This decrease in total revenue was due to a decrease in product revenue, net of approximately $1.1 million and a slight decrease in royalty revenue.

Product revenue, net:

Product revenue, net was approximately $42.0 million for the three months ended March 31, 2026, compared to $43.1 million for the three months ended March 31, 2025. This decrease in product revenue, net, compared to the three months ended March 31, 2025, was primarily attributable to a greater deduction to gross revenue for variable consideration, primarily related to government chargebacks and payor mix, partially offset by an increase in selling price.

Royalty revenue:

Royalty revenue was approximately $2.9 million for each of the three months ended March 31, 2026 and 2025 as sales were relatively consistent to our international partners.

Cost of sales:

Cost of sales was approximately $10.4 million for the three months ended March 31, 2026, compared to approximately $10.6 million for the three months ended March 31, 2025. Cost of sales was relatively consistent year-over-year as sales of our product bottles were relatively consistent.

Selling, general and administrative expenses:

SG&A expenses were approximately $18.4 million for the three months ended March 31, 2026, compared to approximately $17.6 million for the three months ended March 31, 2025. SG&A expenses for the three months ended March 31, 2026 and 2025 were as follows:

Selling, general, and administrative expenses (in thousands)	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2026	**2025**	**2026/2025**	**2026/2025**
Payroll and related costs	$ 9,112	$ 8,240	$ 872	10.6%
Provision for credit loss	—	213	(213)	-100.0%
Professional fees and expenses	5,043	4,610	433	9.4%
Travel and meetings	1,366	1,391	(25)	-1.8%
Facilities and equipment costs	1,095	1,209	(114)	-9.4%
Stock-based compensation	1,139	1,235	(96)	-7.8%
Other	668	706	(38)	-5.4%
	$ 18,423	$ 17,604	$ 819	4.7%

SG&A expenses increased approximately $0.8 million the three months ended March 31, 2026, compared to the same period in 2025, primarily attributable to the following:

- an increase in payroll and related costs of $0.9 million due primarily to increases in employee compensation; and
- an increase in professional fees and expenses of approximately $0.4 million, primarily related to marketing and market access costs.

Partially offset by:

- a decrease in credit loss of approximately $0.2 million, primarily related to the payment history of a customer receivable.

Research and development expenses:

R&D expenses were approximately $19.8 million for the three months ended March 31, 2026, compared to approximately $13.9 million for the three months ended March 31, 2025. R&D expenses for the three months ended March 31, 2026 and 2025 were as follows:

Research and development expenses (in thousands)	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2026	**2025**	**2026/2025**	**2026/2025**
Clinical trial expense	$ 8,829	$ 3,632	$ 5,197	143.1%
Internal R&D	9,283	8,560	723	8.4%
Consultant and contractors	926	880	46	5.2%
Stock-based compensation	757	791	(34)	-4.3%
	$ 19,795	$ 13,863	$ 5,932	42.8%

R&D expenses increased by approximately $5.9 million for the three months ended March 31, 2026, compared to the same period in 2025, primarily attributable to the following:

- an increase in clinical trial expense of approximately $5.2 million, primarily due to increased alisertib study activity; and
- an increase in internal R&D expense of approximately $0.7 million, primarily due to increased employee compensation.

Other income (expenses):

Other income (expenses) (in thousands)	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2026	**2025**	**2026/2025**	**2026/2025**
Interest income	$ 1,002	$ 1,101	$ (99)	-9.0%
Interest expense	(731)	(2,177)	1,446	-66.4%
Other income	130	359	(229)	-63.8%
	$ 401	$ (717)	$ 1,118	-155.9%

Interest expense:

For the three months ended March 31, 2026 , we recognized approximately $0.7 million in interest expense, compared to approximately $2.2 million of interest expense for the three months ended March 31, 2025 . The decrease in interest expense was primarily related to a lower debt balance as we continue paying down our debt principal.

Other income:

For the three months ended March 31, 2026 , we recognized approximately $0.1 million in other income, compared to approximately $0.4 million of other income for the three months ended March 31, 2025 . The decrease in other income was primarily due to unfavorable exchange rates in Euro-denominated transactions.

Liquidity and Capital Resources

The following table, which summarizes our liquidity and capital resources as of March 31, 2026 and December 31, 2025 and for the three months ended March 31, 2026 and 2025, is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	As of March 31, 2026	As of December 31, 2025
Cash and cash equivalents	$ 36,193	$ 29,635
Marketable securities	$ 65,352	$ 67,893
Working capital	$ 82,522	$ 81,433
Current portion of long-term debt	$ 11,283	$ 22,523
Stockholders' equity	$ 128,416	$ 130,340

	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025
Cash provided by (used in):		
Operating activities	$ 15,416	$ 3,612
Investing activities	2,474	1,531
Financing activities	(11,332)	(11,332)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 6,558	$ (6,189)

Operating Activities:

Cash provided by operating activities for the three months ended March 31, 2026 was $15.4 million and consisted of net loss of approximately $3.8 million, adjusted for non-cash items of approximately $4.5 million, which included stock-based compensation of $1.9 million and depreciation and amortization of $2.6 million. Total changes in cash flows from operations were due to an increase in working capital, primarily related to a decrease in accounts receivable of $27.3 million, primarily due to royalty receipts related to China sales and an increase in accounts payable of $3.1 million, partially offset by decrease in accrued expenses and other of approximately $11.7 million related primarily to the payment of royalties, an increase in inventory of $3.2 million related to a receipt of raw material inventory, a decrease in operating lease assets and liabilities, net, of $0.6 million and a decrease of post-marketing commitment liability of $0.5 million.

Cash provided by operating activities for the three months ended March 31, 2025 was $3.6 million and consisted of net income of approximately $3.0 million, adjusted for non-cash items of approximately $5.0 million, which included stock-based compensation of $2.0 million, depreciation and amortization of $2.8 million and provision for credit loss of $0.2 million. Total changes in cash flows from operations were due to an increase in working capital, primarily related to a decrease in accrued expenses and other of approximately $9.9 million, a decrease in operating lease assets and liabilities, net, of $0.4 million and a decrease of post-marketing commitment liability of $0.4 million and an increase in prepaid and other expenses of $0.8 million, partially offset by a decrease in accounts receivable of approximately $6.6 million and an increase in accounts payable of $0.5 million.

Investing Activities:

Cash provided by investing activities for the three months ended March 31, 2026 was approximately $2.5 million, compared to net cash provided by investing activities of approximately $1.5 million for the same period in 2025. Cash provided by investing activities for the three months ended March 31, 2026 was primarily due to the maturity of available-for-sale securities of approximately $27.3 million, partially offset by the purchase of available-for-sale securities of approximately $24.9 million.

Cash provided by investing activities for the three months ended March 31, 2025 was approximately $1.5 million. Cash provided by investing activities was primarily due to maturity of available-for-sale securities of approximately $14.1 million, partially offset by the purchase of available-for-sale securities of approximately $12.5 million.

Financing Activities:

Cash used in financing activities for the three months ended March 31, 2026 and 2025 was approximately $11.3 million, including $11.1 million related to the payment of principal and $0.2 million related to exit fees, on our debt with Athyrium.

Athyrium Note Purchase Agreement:

We issued senior notes for an aggregate principal amount of $100.0 million pursuant to the note purchase agreement dated July 23, 2021 by us, and our subsidiary, and Athyrium, as Administrative Agent, and certain other investor parties (the "Note Purchase Agreement"), with an initial maturity date of July 23, 2026 (the "Athyrium Notes"). The Athyrium Notes were issued for face amount of $100.0 million, net of an original issue discount of $1.5 million. The Athyrium Notes also require a 2.0% exit payment to be made on each payment of principal. The borrowings under the Athyrium Notes, together with cash on hand, were used to repay our outstanding indebtedness, including the applicable exit and prepayment fees owed to lenders under our prior credit facility with Oxford. The Athyrium Notes are secured by substantially all of our assets. We incurred $1.9 million of deferred financing costs with the initial borrowing of the Athyrium Notes.

Interest on the Athyrium Notes was calculated in part based on the Secured Overnight Financing Rate ("SOFR"), which replaced the "London Interbank Offering Rate" as the floating benchmark for interest rate calculations applicable to the Athyrium Notes pursuant to the terms of the Third Amendment to the Note Purchase Agreement dated as of September 16, 2022 (the "Third Amendment").

Following the effectiveness of the Third Amendment, the Athyrium Notes bore interest at an annual rate equal to the sum of (a) eight percent (8.00%) plus (b) the lesser of (i) the sum of (x) three-month term SOFR for an interest period of three months plus (y) 0.26161% (26.161 basis points) and (ii) three and one-half of one percent (3.50%) per annum. Interest is payable quarterly on the last business day of March, June, September and December each year. As of March 31, 2026, the effective interest rate for the loan was 12.99%.

As of March 31, 2026, we may prepay the outstanding principal balance of the notes, in whole or in part, without premium or penalty.

As of March 31, 2026, the principal balance outstanding under the Athyrium Notes was $11.1 million and represented all of our debt. We were in compliance with all applicable covenants under the Athyrium Notes as of March 31, 2026.

On May 4, 2026, we paid $11.5 million under the Note Purchase Agreement, ahead of the scheduled maturity date of July 23, 2026. This payment reduced the principal balance outstanding under the Athyrium Notes to zero and terminated all of our remaining obligations under the Note Purchase Agreement, other than customary continuing indemnification obligations.

Current and Future Financing Needs:

We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our R&D efforts and our commercialization efforts.

We may choose to begin new R&D efforts, or we may choose to launch additional marketing efforts. For example, we in-licensed alisertib from Takeda in 2022 and assumed sole responsibility for its global development and commercialization. These efforts will require funding in addition to the cash and cash equivalents totaling approximately $36.2 million and approximately $65.4 million in marketable securities available at March 31, 2026. While our condensed consolidated financial statements have been prepared on a going concern basis, we may incur significant losses in the future and will need to generate significant revenue to sustain operations and successfully commercialize neratinib and develop alisertib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, our success in commercializing neratinib, our success in developing alisertib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. We believe that our existing cash and cash equivalents and marketable securities as of March 31, 2026, and proceeds that will become available to us through product sales and sub-license payments are sufficient to satisfy our operating cash and capital needs for at least one year after the filing of this Quarterly Report.

Non-GAAP Financial Measures

In addition to our operating results, as calculated in accordance with Generally Accepted Accounting Principles ("GAAP") we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net (loss) income and net (loss) income per share, as calculated in accordance with GAAP, as adjusted to remove the impact of stock-based compensation. For the three months ended March 31, 2026, stock-based compensation represented approximately 5.0% of our operating expenses, compared to 6.4% for the same respective period in 2025, in each case excluding cost of sales. Our management believes that these non-GAAP financial measures are useful to enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

Reconciliation of GAAP Net (Loss) Income to Non-GAAP Adjusted Net (Loss) Income and GAAP Net (Loss) Income Per Share to Non-GAAP Adjusted Net (Loss) Income Per Share (in thousands except share and per share data)

	For the Three Months Ended March 31,	
	2026	2025
GAAP net (loss) income	$ (3,753)	$ 2,974
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	1,139	1,236
Research and development (2)	757	790
Non-GAAP adjusted net (loss) income	$ (1,857)	$ 5,000
GAAP net (loss) income per share—basic	$ (0.07)	$ 0.06
Adjustment to net income (as detailed above)	0.03	0.04
Non-GAAP adjusted basic net (loss) income per share	$ (0.04)(3)	$ 0.10 (3)
GAAP net (loss) income per share—diluted	$ (0.07)	$ 0.06
Adjustment to net (loss) income (as detailed above)	0.03	0.04
Non-GAAP adjusted diluted net (loss) income per share	$ (0.04)(4)	$ 0.10 (5)

(1) To reflect a non-cash charge to operating expense for selling, general, and administrative stock-based compensation.
(2) To reflect a non-cash charge to operating expense for research and development stock-based compensation.
(3) Non-GAAP adjusted basic net (loss) income per share was calculated based on 50,845,130 and 49,595,697 weighted-average shares of common stock outstanding for the three months ended March 31, 2026 and 2025, respectively.
(4) Potentially dilutive common stock equivalents (stock options restricted stock units and warrants) were not included in this non-GAAP adjusted diluted net loss per share for the three months ended March 31, 2026, as these shares would be considered anti-dilutive.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 49,906,341 weighted-average shares of common stock outstanding for the three months ended March 31, 2025.

Off-Balance Sheet Arrangements

We do not have any "off-balance sheet arrangements," as defined by SEC regulations.

Contractual Obligations

There have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2025.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the cash equivalents to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. We invested our excess cash primarily in cash equivalents such as money market investments as of March 31, 2026. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Because of the short-term maturities of our cash equivalents, we do not believe that a 10% increase in interest rates would have a material effect on the realized value of our cash equivalents.

We also have interest rate exposure as a result of borrowings outstanding under the Athyrium Notes. As of March 31, 2026, the aggregate outstanding principal amount of the Athyrium Notes was $11.1 million. The Athyrium Notes bear interest at a rate per annum equal to the sum of 8.00% plus the adjusted three-month term SOFR and the lesser of (a) the sum of (i) three-month term SOFR and (ii) 0.26161% (26.161 basis points) and (b) three and one-half of one percent (3.50%) per annum. If overall interest rates had increased by one hundred basis points during the quarter ended March 31, 2026, our interest expense would have increased by $0.2 million.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2026. Based on that

evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of March 31, 2026.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended March 31, 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

Legal Malpractice Suit

On September 17, 2020, the Company filed a lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented the Company in *Eshelman v. Puma Biotechnology, Inc., et al*. in the Superior Court of Mecklenburg County, North Carolina. The Company is alleging legal malpractice based on the defendants' negligent handling of the defense of the Company in *Eshelman v. Puma Biotechnology, Inc., et al*. The Company is seeking recovery of the entire amount awarded in *Eshelman v. Puma Biotechnology, Inc., et al*. and all legal fees and expenses incurred in appealing from the judgment and retrying the damages phase of the trial. On November 23, 2020, the defendant filed an answer to the complaint denying the allegations of negligence. On August 19, 2022, the Company filed a voluntary dismissal of the legal malpractice action, without prejudice, to allow the *Eshelman v. Puma Biotechnology, Inc., et al*. to conclude before proceedings. On June 2, 2023, the Company re-filed the lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented the Company in *Eshelman v. Puma Biotechnology, Inc., et al.* in the Superior Court of Mecklenburg County, North Carolina. On August 22, 2023, the defendants filed motions to dismiss the case. These motions were presented at a hearing on February 20, 2024. The Superior Court Judge granted the motions to dismiss on March 20, 2024. The Company appealed this ruling to the North Carolina Court of Appeals. On September 3, 2025, the Court of Appeals reversed the dismissal of the Company's claim for legal malpractice and remanded the case to the Superior Court for further proceedings. The defendants filed a petition for discretionary review of this decision by the North Carolina Supreme Court on October 8, 2025. The Supreme Court has not decided whether to accept the case for review.

Patent-Related Proceedings

AstraZeneca Litigation

On September 22, 2021, the Company filed suit against AstraZeneca Pharmaceuticals, LP, AstraZeneca AB, and AstraZeneca PLC for infringement of United States Patent Nos. 10,603,314 ("the '314 patent") and 10,596,162 ("the '162 patent") (*Puma Biotechnology, Inc. et al. v. AstraZeneca Pharmaceuticals LP et al*., 1:21CV01338 (D. Del. Sep. 22, 2021)). The Company's complaint alleges that AstraZeneca's commercial manufacture, use, offer for sale, sale, distribution, and/or importation of Tagrisso® (osimertinib) products for the treatment of gefitinib and/or erlotinib-resistant non-small cell lung cancer infringes the '314 and '162 patents. The Company is an exclusive licensee of the '314 and '162 patents under the Pfizer Agreement. Wyeth is a co-plaintiff. Plaintiffs seek a judgment that AstraZeneca's product infringes the asserted patents and an award of monetary damages in an amount to be proven at trial. AstraZeneca AB and AstraZeneca Pharmaceuticals LP filed an answer and counterclaims on November 5, 2021, including claims challenging the asserted patents as not infringed and/or invalid, and accusing plaintiffs of unclean hands and patent misuse. The parties stipulated to dismiss AstraZeneca PLC as a defendant and Pfizer as a Counterclaim Defendant on December 10, 2021, which the Court so ordered on December 13, 2021. The Company filed its answer to AstraZeneca's counterclaims on December 17, 2021, denying those claims. The case was reassigned to visiting Judge Matthew Kennelly of the Northern District of Illinois. A Markman Hearing was conducted on March 17, 2023, and the Court issued its claim construction decision on March 29, 2023. Fact discovery closed on May 19, 2023, and expert discovery closed on November 17, 2023. The Court denied the parties' respective motions for summary judgment and Daubert motions, other than to clarify that Plaintiffs' damages cannot extend to any time period before the asserted patents were issued. The Court granted AstraZeneca's motion to dismiss the Company as a Plaintiff on constitutional standing grounds but denied the motion to dismiss Wyeth as a Plaintiff on constitutional standing grounds. On April 29, 2024, the Court granted AstraZeneca's motion to dismiss AstraZeneca's counterclaims against the Company, which removed the Company from the case. Wyeth remained in the case as a Plaintiff and counterclaim-defendant. Under the Company's worldwide exclusive license agreement with Pfizer, Inc. (the parent of Wyeth) as amended, the Company also maintains contractual rights to recover monetary damages in the AstraZeneca litigation, and those contractual rights are unaffected by the court's March 18, 2024 and April 29, 2024 orders. A jury trial was held May 13-17, 2024. The jury found in favor of Wyeth and against AstraZeneca. In particular, the jury found that use of Tagrisso® according to each of the three FDA-approved indications infringes the asserted claims of the '314 and '162 patents, and that AstraZeneca induces that infringement. The jury further rejected AstraZeneca's challenges to the validity of the patents, finding that they are not invalid. The jury awarded damages to Wyeth for past acts of infringement through December 31, 2023, in the amount of $107.5 million. A separate bench trial related to certain equitable claims and defenses raised by AstraZeneca was held before Judge Kennelly on June 20 and 25, 2024. On August 6, 2024, Judge Kennelly issued his ruling on the issues that were tried in the bench trial, finding for Wyeth and against AstraZeneca on all claims and defenses. The Court found that AstraZeneca had not proved its claim that Wyeth's asserted patents were invalid as indefinite, or that Wyeth had committed acts that would give rise to findings of unclean hands, implied waiver, or patent misuse. AstraZeneca filed a motion challenging the jury's verdict and requesting a new trial. Wyeth filed a motion requesting supplemental damages for past infringement from January 1, 2024, through the date of judgment; pre-and-post judgment interest, and ongoing royalties through the remaining term of the patents. Briefing on these motions from both sides was completed on July 16, 2024. On August 14, 2024, Judge Kennelly ruled on AstraZeneca's motion challenging the jury's verdict, granting it in part and denying it in part. The Court granted AstraZeneca's motion for judgment as a matter of law that the '314 and '162 patents are invalid under 35 U.S.C. § 112 for lacking enablement and adequate written description as to a particular claim limitation. In all other respects, the Court denied AstraZeneca's motion. The Court entered its final and appealable judgment accordingly. The Company respectfully disagrees with the Court's ruling regarding invalidity with respect to the particular claim limitation. Wyeth filed a notice of appeal on September 12, 2024, appealing the District Court's judgment as a matter of law, as well as other rulings and opinions of the Court adverse to Wyeth. On December 18, 2024, Wyeth filed its opening brief. On March 13, 2025, AstraZeneca filed its response brief. On March 20, 2025, non-parties Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC filed a motion for leave to file an amicus curiae brief in the Federal Circuit. The motion was granted on May 16, 2025. On June 6, 2025, Wyeth filed its reply brief. Briefing on the appeal is now complete, and the Court has scheduled oral arguments for May 7, 2026.

Acebright China Litigation

On January 18, 2022, Shanghai Acebright Pharmaceuticals Group Co., Ltd. ("Acebright") filed an abbreviated new drug application ("ANDA") with the National Medical Products Administration in China ("NMPA") seeking approval to market a generic version of the Company's NERLYNX® (neratinib) tablet, 40mg in China. Acebright seeks approval prior to the expiration of three patents listed on the China Patent Information Registration Platform for Marketed Drugs ("Chinese Orange Book"), namely, Chinese Patent Nos. ZL201410082103.7, ZL201080060546.6, and ZL200880118789.3 (the "'789 patent" and collectively, the "NERLYNX® Patents"), alleging in a Type 4.2 patent declaration that its generic version of NERLYNX does not fall within the scope of the claims of NERLYNX® Patents listed in the Chinese Orange Book. The patent declaration of Acebright was published in the Chinese Orange Book on January 19, 2022. On March 2, 2022, the Company filed petitions with the China National Intellectual Property Administration ("CNIPA") and requested administrative determination that Acebright's generic neratinib tablet falls within the scope of the claims of NERLYNX® Patents listed in the Chinese Orange Book. The Company's request for administrative determination was accepted by CNIPA on March 18, 2022. The Company has notified NMPA of the acceptance of the request for administrative determination for NMPA to institute a stay of Acebright's ANDA for nine months. On July 11, 2022, CNIPA decided that claims 5 and 6 of Patent No. ZL200880118789.3 are not eligible for registration in the Chinese Orange Book on the ground that these two pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On September 9, 2022, CNIPA decided that the generic drug in Acebright's ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of Patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of Patent No. ZL201080060546.6. The three CNIPA administrative decisions on NERLYNX® Patents have lifted the stay of Acebright's ANDA by NMPA. The Company has appealed each CNIPA administrative decision in January 2023 at the Beijing Intellectual Property Court ("BJIPC"). The three appeals were accepted by BJIPC on February 20, 2023. The Company also filed three civil complaints based on the three NERLYNX® Patents against Acebright with the BJIPC in July 2022 and requested court determination that Acebright's generic neratinib tablet falls within the scope of the claims of NERLYNX® Patents. On May 6, 2023, the Company withdrew two civil lawsuits and two appeals in relation to Chinese Patent Nos. ZL201410082103.7 and ZL201080060546.6 at the BJIPC. On May 24, 2023, the BJIPC accepted the Company's withdrawal request. On July 24, 2023, the Company withdrew the one remaining civil lawsuit and one appeal in relation to Chinese Patent No. ZL200880118789.3 at the BJIPC. On August 15, 2023, the BJIPC accepted the Company's withdrawal request. On September 12, 2023, the NMPA approved Acebright's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20234141.

On December 28, 2023, the Company filed a civil lawsuit against Acebright for infringement of the '789 patent under Article 11 of the Chinese Patent Law before Jiangsu Nanjing Intermediate People's Court. The Company's complaint alleges that Acebright's offer for sale of a generic version of the Company's NERLYNX® product infringes the '789 patent. The Company seeks a judgment that Acebright's product infringes the '789 patent and Acebright's act of offer for sale shall be enjoined. On January 2, 2024, Jiangsu Nanjing Intermediate People's Court accepted the civil complaint. An oral hearing was held on June 19, 2024, during which the Company amended its complaint to allege that Acebright making, selling and offering to sell the generic version of NERLYNX® infringes the '789 patent. On July 24, 2024, the Company submitted a request to withdraw the lawsuit. On August 8, 2024, Jiangsu Nanjing Intermediate People's Court accepted the withdrawal request.

On September 27, 2024, the Company filed an additional patent infringement claim against Acebright at Jiangsu Nanjing Intermediate People's Court. On October 14, 2024, the Court accepted the complaint and designated case number (2024) Su 01 Min Chu 2192 to this case. On December 16, 2024, the Court conducted an evidence exchange hearing. On January 10, 2025, the Court conducted a hearing of party experts on the evaluation of evidence. On July 14, 2025, the Court conducted a hearing to examine evidence and debate merits of party arguments. On September 28, 2025, the Court issued a first-instance decision, deciding that Acebright's product does not fall within the scope of the patent-in-suit, and Acebright did not infringe the NERLYNX® Patents. The Court also decided that the Company's enforcement efforts were not malicious and did not amount to unfair competition.

Aosaikang China Litigation

On November 17, 2022, Jiangsu Aosaikang Pharmaceutical Co. Ltd. ("Aosaikang") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2202006. Aosaikang made Type 4.2 declarations against the four Orange Book Patents ZL201410082103.7, ZL201080060546.6, ZL200880118789.3 and ZL201710057547.9, alleging that its generic version of NERLYNX does not fall within the scope of the claims of the Orange Book patents. Aosaikang also alleged that Patents ZL200880118789.3 and ZL201710057547.9 are not eligible for Chinese Orange Book listing.

On December 28, 2022, the Company submitted four Article 76 petitions against the Aosaikang ANDA with the CNIPA and requested administrative determination that Aosaikang's generic neratinib tablet falls within the scope of the claims of the four Orange Book patents. On January 6, 2023, the CNIPA accepted the Company's request for administrative determination in relation to Patent Nos. ZL201410082103.7 and ZL201080060546.6. Also on January 6, 2023, the CNIPA declined to accept the Company's request for administrative determination in relation to Patent Nos. ZL200880118789.3 and ZL201710057547.9, alleging that the listed claims are not eligible for registration in the Chinese Orange Book on the ground that these pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On January 28, 2023, the Company requested the NMPA to institute a nine-month stay against Aosaikang ANDA starting from the CNIPA's acceptance of the Company's request for administrative determination. On June 2, 2023, CNIPA decided that the generic drug in Aosaikang's ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of Patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of Patent No. ZL201080060546.6. The two CNIPA administrative decisions on NERLYNX® Patents have lifted the stay of Aosaikang's ANDA by NMPA. On October 22, 2024, the NMPA approved Aosaikang's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20249180.

Convalife China Litigation

Convalife Pharmaceuticals (Shanghai) Co., Ltd ("Convalife") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2202095. On December 23, 2022, Convalife made Type 4.2 declarations against the four Orange Book Patents ZL201410082103.7, ZL201080060546.6, ZL200880118789.3 and ZL201710057547.9, alleging that its generic version of NERLYNX does not fall within the scope of the claims of the Orange Book patents. Convalife also alleged that Patents ZL200880118789.3 and ZL201710057547.9 are not eligible for Chinese Orange Book listing.

On February 1, 2023, the Company submitted four Article 76 petitions against the Convalife ANDA with the CNIPA and requested administrative determination that Convalife's generic neratinib tablet falls within the scope of the claims of the four Orange Book patents. On February 3, 2023, the CNIPA accepted the Company's request for administrative determination in relation to Patent Nos. ZL201410082103.7 and ZL201080060546.6. Also on February 3, 2023, the CNIPA declined to accept the Company's request for administrative determination in relation to Patent Nos. ZL200880118789.3 and

ZL201710057547.9, alleging that the listed claims are not eligible for registration in the Chinese Orange Book on the ground that these pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On February 24, 2023, the Company requested the NMPA to institute a nine-month stay against Convalife ANDA starting from the CNIPA's acceptance of the Company's request for administrative determination. On June 2, 2023, CNIPA decided that the generic drug in Convalife's ANDA does not fall within the protection scope of claims 1, 3, 5 and 6 of Patent No. ZL201410082103.7 and claims 1-4, 7 and 9-13 of Patent No. ZL201080060546.6. The two CNIPA administrative decisions on NERLYNX® Patents have lifted the stay of Convalife's ANDA by NMPA. On June 28, 2024, the NMPA approved Convalife's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20244222.

Kelun China Litigation

Hunan Kelun Pharmaceutical Co., Ltd. ("Kelun") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2300221. On January 28, 2023, Kelun made Type 4.2 declarations against the four Orange Book Patents ZL201410082103.7, ZL201080060546.6, ZL200880118789.3 and ZL201710057547.9, alleging that its generic version of NERLYNX does not fall within the scope of the claims of the Orange Book patents. Kelun also alleged that Patents ZL200880118789.3 and ZL201710057547.9 are not eligible for Chinese Orange Book listing.

On March 13, 2023, the Company submitted four Article 76 petitions against the Kelun ANDA with the CNIPA and requested administrative determination that Kelun's generic neratinib tablet falls within the scope of the claims of the four Orange Book patents. On March 21, 2023, the CNIPA declined to accept the Company's request for administrative determination in relation to Patent Nos. ZL200880118789.3 and ZL201710057547.9, alleging that the listed claims are not eligible for registration in the Chinese Orange Book on the ground that these pharmaceutical method-of-use claims fall within the scope of "patents of crystalline forms," which are not eligible for listing in the Chinese Orange Book. On March 24, 2023, the CNIPA accepted the Company's request for administrative determination in relation to Patent Nos. ZL201410082103.7 and ZL201080060546.6. On April 17, 2023, the Company requested the NMPA to institute a nine-month stay against Kelun's ANDA starting from the CNIPA's acceptance of the Company's request for administrative determination. On September 14, 2023, the Company withdrew the two requests for administrative determination in relation to Chinese Patent Nos. ZL201410082103.7 and ZL201080060546.6 at the CNIPA. On September 25, 2023, the CNIPA accepted the Company's withdrawal request. On September 9, 2025, the NMPA approved Kelun's ANDA to market a generic version of the Company's NERLYNX® in China with the approval number of GuoYaoZhunZi H20255337.

Demai Litigation

Zhengzhou Demai Pharmaceutical Co., Ltd ("Demai") filed an ANDA with NMPA in China seeking approval to market a generic version of the Company's NERLYNX®. The ANDA application No. is CYHS2402776. On August 26, 2024, Demai made a Type 4.2 declaration against Orange Book Patent ZL201410082103.7, alleging that its generic version of NERLYNX does not fall within the scope of the claims of this Orange Book patent. On September 30, 2024, the Company filed a lawsuit against Demai at the BJIPC based on Nerlynx Patent No. ZL201080060546.6 and on October 8, 2024, the Company filed a lawsuit against Demai at the BJIPC based on Nerlynx Patent No. ZL201410082103.7. On February 13, 2025, the Company withdrew the lawsuits from BJIPC, filed an Article 76 petition with the CNIPA against the Demai ANDA and requested administrative determination that Demai's generic neratinib maleate tablet falls within the scope of the claims of Nerlynx Patent No. ZL201080060546.6. On February 21, 2025, the CNIPA accepted the Company's petition and started examination. On March 18, 2025, the Company filed a request with the NMPA to set up a nine-month stay on Demai's ANDA. On November 4, 2025, the NMPA approved Demai's ANDA to market a generic version of Puma's NERLYNX® in China with the approval number of GuoYaoZhunZi H20255844.

Hexal European Patent Opposition

An opposition was filed by Hexal AG ("Hexal") on August 3, 2016 against European Patent No. EP2416774 which was licensed from Pfizer in 2011, and which claims neratinib for use in a method for treating HER-2/neu overexpressed/amplified cancer and improving IDFS, wherein the method comprises delivering neratinib therapy to HER-2/neu overexpressed/amplified cancer patients following the completion of at least one year of trastuzumab adjuvant therapy, and wherein the neratinib therapy comprises treating the cancer patients with neratinib for at least twelve months. An oral hearing was held on December 8, 2017, wherein the patent was maintained as granted. Following an appeal filed by Hexal, the Board of Appeal of the European Patent Office rejected the claims as granted and all pending auxiliary requests during the oral hearing of September 2, 2021. Before issuance of a decision, we withdrew approval of the text in which the patent was granted and all pending auxiliary requests, thereby revoking the patent and concluding the appeal. One European divisional application, namely EP15188350.1, was granted with the European patent number EP3000467 on March 1, 2023. Oppositions against EP3000467 were filed by Hexal on November 3, 2023, by Alfred E. Tiefenbacher (GmbH & Co. KG) on November 28, 2023 and by Generics (UK) Limited ("Generics") on December 1, 2023. EP3000467 is used as the basic patent for Supplementary Protection Certificate applications for the EMA-approved NERLYNX® product, 17 of which have been granted, three proceedings have been stayed, and 11 are in active prosecution. The patentee response to the notice of opposition was filed on April 15, 2024, following which, all three opponents filed additional arguments in reply to the patentee's submission. On February 6, 2025, the Company filed its response to the summons to attend oral proceedings, including six auxiliary requests. Alfred E. Tiefenbacher and Hexal filed their responses to the summons to oral proceedings on February 6 and 7, 2025, respectively. Hexal filed a further brief on March 19, 2025. Oral proceedings took place on April 9 and 10, 2025. EP3000467 was upheld as amended after the first instance hearing based on Auxiliary Request 1, which covers the EMA approved indication for NERLYNX® as an extended adjuvant therapy for treating early stage hormone receptor-positive HER-2-overexpressed/amplified breast cancer. Hexal filed an appeal on June 6, 2025, Generics filed an appeal on June 20, 2025 and Wyeth filed an appeal on June 30, 2025. On September 5, 2025, Wyeth filed its grounds of appeal, including nine auxiliary requests. On the same day, Hexal filed its grounds of appeal. Generics filed its grounds of appeal on September 4, 2025, and Alfred E. Tiefenbacher filed its grounds of appeal on September 1, 2025. On December 16, 2025, Alfred E. Tiefenbacher withdrew its appeal. Wyeth responded to the opponents' grounds of appeal on January 12, 2026. On March 2, 2026, Hexal withdrew its request for oral proceedings, but remains a party to the proceedings.

One European divisional application is pending in the same family, namely EP 23157078.8. A response to the European Search Opinion (ESO) for this application was filed February 14, 2024. The first office action was issued on January 28, 2025 with a response to the first office action filed on July 22, 2025.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2025, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report. Except as described below, there has been no material change in our risk factors subsequent to the filing of our prior reports referenced above. However, the risks described in our reports are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Trading Plans

During the three months ended March 31, 2026, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. EXHIBITS

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016, and incorporated herein by reference)
3.2	Fifth Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 24, 2025, and incorporated herein by reference)
10.1+	Ninth Amendment to Note Purchase Agreement and Firth Amendment to Disclosure Letter, dated April 16, 2026 by and between the Company and Athyrium Opportunities IV Co-Invest 1 LP, as Administrative Agent
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026
32.1++	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	Inline 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
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Linkbase Document
104+	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\+ Filed herewith
++ Furnished herewith

SIGNATURES

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

PUMA BIOTECHNOLOGY, INC.

Date: May 7, 2026

By: /s/ Alan H. Auerbach
Alan H. Auerbach
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 7, 2026

By: /s/ Maximo F. Nougues
Maximo Nougues
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1
Execution Version

NINTH AMENDMENT TO NOTE PURCHASE AGREEMENT
AND FIFTH AMENDMENT TO DISCLOSURE LETTER

This NINTH AMENDMENT TO NOTE PURCHASE AGREEMENT AND FIFTH AMENDMENT TO DISCLOSURE LETTER (this "Agreement"), dated as of April 16, 2026, is entered into by and among PUMA BIOTECHNOLOGY, INC., a Delaware corporation (the "Issuer"), the Guarantors party hereto, the Purchasers party hereto and ATHYRIUM OPPORTUNITIES IV CO-INVEST 1 LP, as the Administrative Agent. All capitalized terms used herein and not otherwise defined herein shall have the meanings given to such terms in the Note Purchase Agreement (as defined below).

RECITALS

WHEREAS, the Issuer, the Guarantors, the Purchasers and the Administrative Agent entered into that certain Note Purchase Agreement dated as of July 23, 2021 (as amended or modified from time to time, the "Note Purchase Agreement");

WHEREAS, the Credit Parties have requested that the Note Purchase Agreement and the Disclosure Letter be amended as set forth below, subject to the terms and conditions specified in this Agreement; and

WHEREAS, the parties hereto are willing to amend the Note Purchase Agreement and the Disclosure Letter, subject to the terms and conditions specified in this Agreement.

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

1. Amendments. The Note Purchase Agreement and the Disclosure Letter are hereby amended as follows:

(a) The definition of "Qualified Equity Issuance" in Section 1.01 of the Note Purchase Agreement is hereby amended by replacing the text "April 30, 2026" with the text "July 23, 2026".

(b) Section 7.23 of the Note Purchase Agreement is hereby amended by replacing each occurrence of the text "April 30, 2026" with the text "July 23, 2026".

(c) Schedule 1.01(c) to the Disclosure Letter is hereby amended by replacing the text "April 30, 2026" with the text "July 23, 2026".

2. Condition Precedent. This Agreement shall be effective as of the date hereof upon satisfaction of each of the following conditions:

(a) the Administrative Agent shall have received counterparts of this Agreement duly executed by the Issuer, the Guarantors, the Purchasers and the Administrative Agent; and

(b) the Issuer shall have paid all reasonable and documented out-of-pocket expenses incurred by the Administrative Agent and its Affiliates prior to the date hereof (including the reasonable fees, charges and disbursements of outside counsel for the Administrative Agent), in each case, to the extent required under Section 11.04 of the Note Purchase Agreement and invoiced at least three Business Days prior to the date hereof.

3. Reaffirmation of Representations and Warranties; No Default. The Issuer and each other Credit Party represents and warrants to the Administrative Agent and each Purchaser that after giving effect to this Agreement (a) the representations and warranties of the Issuer and each other Credit Party contained in Article VI of the Note Purchase Agreement or any other Note Document, or which are contained in any document furnished at any time under or in connection therewith, are true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) on and as of the date hereof, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date, and except that for purposes of this Section 3, the representations and warranties contained in clauses (a) and (b) of Section 6.05 of the Note Purchase Agreement shall be deemed to refer to the most recent statements furnished pursuant to clauses (a) and (b) of Section 7.01 of the Note Purchase Agreement, respectively, and (b) no Default or Event of Default exists.

4. Miscellaneous.

(a) The Note Purchase Agreement and the obligations of the Credit Parties thereunder and under the other Note Documents, are hereby ratified and confirmed and shall remain in full force and effect according to their terms.

(b) Sections 11.14 and 11.15 of the Note Purchase Agreement are incorporated herein by reference and shall apply, *mutatis mutandis*, to this Agreement as if fully set forth herein.

(c) As a material part of the consideration for the Administrative Agent and the Purchasers entering into this Agreement, the Credit Parties agree that the Administrative Agent, the Purchasers, each of their respective Affiliates and each of the foregoing Persons' respective officers, managers, members, directors, advisors, sub-advisors, partners, agents and employees, and their respective successors and assigns (hereinafter all of the above collectively referred to as the "Purchaser Group"), are irrevocably and unconditionally released, discharged and acquitted from any and all actions, causes of action, claims, demands, damages and liabilities of whatever kind or nature, in law or in equity, now known or unknown, suspected or unsuspected to the extent that any of the foregoing arises from any action or failure to act under or otherwise arising in connection with the Note Documents, in each case arising on or prior to the date hereof, except to the extent such actions, causes of action, claims, demands, damages and liabilities result from the gross negligence or willful misconduct of any of the Purchaser Group as determined by a court of competent jurisdiction in a final and nonappealable judgment.

(d) This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be an original, but all of which shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

(e) **THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK.**

[Signature pages follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first above written.

ISSUER:

PUMA BIOTECHNOLOGY, INC.,
a Delaware corporation

By:/s/ Alan Auerbach
Name: Alan Auerbach
Title: Chief Executive Officer

ADMINISTRATIVE AGENT:

ATHYRIUM OPPORTUNITIES
IV CO-INVEST 1 LP, a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES ASSOCIATES IV CO-INVEST LLC

By:/s/ Rashida Adams
Name: Rashida Adams
Title: Authorized Signatory

PURCHASERS:

ATHYRIUM OPPORTUNITIES
IV CO-INVEST 1 LP, a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES ASSOCIATES IV CO-INVEST LLC

By:/s/ Rashida Adams
Name: Rashida Adams
Title: Authorized Signatory

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alan H. Auerbach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2026;

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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2026

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Maximo F. Nougues, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2026;

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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2026

/s/ Maximo F. Nougues
Maximo F. Nougues
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2026, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Executive Officer

I, Alan H. Auerbach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2026, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: May 7, 2026

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2026, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Maximo F. Nougues, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2026, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: May 7, 2026

/s/ Maximo F. Nougues
Maximo F. Nougues
Principal Financial and Accounting Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.