UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 5, 2026

PUMA BIOTECHNOLOGY, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	001-35703	77-0683487
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10880 Wilshire Boulevard, Suite 1700
Los Angeles, California90024
(Address of principal executive offices) (Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading symbol	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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2026, Puma Biotechnology, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2026. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 2.02, including the accompanying exhibit, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Item 2.02 shall not be incorporated by reference into any filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release dated November 5, 2026.
104	Cover Page Interactive Data File (formatted as inline XBRL).

SIGNATURE

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 hereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: November 5, 2026

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

News Release

Puma Biotechnology Reports Third Quarter 2026 Financial Results

- Third quarter U.S. NERLYNX sales driven by increased year-over-year demand
- Raising 2026 net income guidance

LOS ANGELES, Calif., Nov. 5, 2026 - Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2026. Unless otherwise stated, all comparisons are for the third quarter of 2026 compared to the third quarter of 2025.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net in the third quarter of 2026 was $54.1 million, compared to product revenue, net of $51.9 million in the third quarter of 2025. Product revenue, net in the first nine months of 2026 was $149.6 million, compared to $144.2 million in the first nine months of 2025.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $6.0 million, or $0.12 per basic share and $0.11 per diluted share, for the third quarter of 2026, compared to net income of $8.8 million, or $0.18 per basic share and $0.17 per diluted share, for the third quarter of 2025.

Net income for the first nine months of 2026 was $10.4 million, or $0.20 per basic and diluted share, compared to net income of $17.7 million, or $0.35 per basic and diluted share, for the first nine months of 2025.

Non-GAAP adjusted net income was $8.0 million, or $0.15 per basic and diluted share, for the third quarter of 2026, compared to non-GAAP adjusted net income of $10.5 million, or $0.21 per basic and diluted share, for the third quarter of 2025. Non-GAAP adjusted net income for the first nine months of 2026 was $16.3 million, or $0.32 per basic share and $0.31 per diluted share, compared to non-GAAP adjusted net income of $23.0 million, or $0.46 per basic and diluted share, for the first nine months of 2025. Non-GAAP adjusted net income excludes stock-based compensation expense. For a reconciliation of GAAP net income to non-GAAP adjusted net income and GAAP net income per share to non-GAAP adjusted net income per share, please see the financial tables at the end of this news release.

Net cash provided by operating activities for the third quarter of 2026 was $14.6 million, compared to $9.7 million in the third quarter of 2025. Net cash provided by operating activities for the first nine months of 2026 was $31.6 million, compared to net cash provided by operating activities of $27.4 million in the first nine months of 2025. At September 30, 2026, Puma had cash, cash equivalents and marketable securities of $108.5 million, compared to cash, cash equivalents and marketable securities of $97.5 million at December 31, 2025.

"Third quarter U.S. NERLYNX sales were positively impacted by increased year-over-year demand and were negatively impacted by higher than expected gross to net due to an increase in Medicaid and 340B sales, as well as a delay in sales to Puma's ex-U.S. commercial partners that shifted from the third quarter to the fourth quarter," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We continue to anticipate increased year-over-year demand for NERLYNX, while we continue to advance alisertib across our ALISCA® clinical development programs. During the quarter, we initiated ALISCA®-Lung2, a Phase II trial evaluating alisertib in combination with paclitaxel in patients with advanced small cell lung cancer, further expanding our clinical development program in this area, while we are continuing to enroll the ALISCA®-Breast1 and ALISCA®-Lung1 trials."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) presentation of updated data from ALISCA®-Breast1, a Phase II trial of alisertib in combination with endocrine treatment in patients with chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer (San Antonio Breast Cancer Symposium, December 2026); (ii) initiation of discussions with global regulatory agencies regarding the Phase III trial design for alisertib in combination with endocrine treatment in patients with chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer (H1 2027); (iii) continued

enrollment in ALISCA®-Breast1, a Phase II trial of alisertib in combination with endocrine treatment in patients with chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer to obtain more data in biomarker focused populations (H2 2026); (iv) continued enrollment of ALISCA®-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer and ALISCA®-Lung2, a Phase II trial evaluating alisertib in combination with paclitaxel in patients with advanced small cell lung cancer (Q4 2026); and (v) presentation of updated data from ALISCA®-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer (2027).”

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma’s first commercial product, and royalty revenue. For the third quarter ended September 30, 2026, total revenue was $55.1 million, of which $54.1 million was net product revenue and $1.0 million was royalty revenue. This compares to total revenue for the third quarter of 2025 of $54.5 million, of which $51.9 million was net product revenue and $2.6 million was royalty revenue. For the first nine months of 2026, total revenue was $156.4 million, of which $149.6 million was net product revenue and $6.8 million was royalty revenue. This compares to total revenue for the first nine months of 2025 of $152.9 million, of which $144.2 million was net product revenue and $8.7 million was royalty revenue. The third quarter and first nine months of 2026 included a $2.1 million reduction to royalty revenue as a change in accounting estimate, reflecting the receipt of new third-party market data confirming that the market share of generic versions of NERLYNX in China reached a specified threshold during the period.

Operating Costs and Expenses

Total operating costs and expenses were $49.8 million for the third quarter of 2026 , compared to $44.9 million for the third quarter of 2025. Operating costs and expenses in the first nine months of 2026 were $147.4 million, compared to $132.7 million in the first nine months of 2025. The year-to-date increases were primarily attributable to increases in R&D expenses and cost of sales.

Cost of Sales

Cost of sales was $15.2 million for the third quarter of 2026, compared to $12.2 million for the third quarter of 2025. Cost of sales was $38.1 million for the first nine months of 2026, compared to $35.0 million for the first nine months of 2025. The increases in cost of sales for the third quarter and first nine months of 2026 were due primarily to higher product sales to an international partner.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $16.3 million for the third quarter of 2026, compared to $16.8 million for the third quarter of 2025. SG&A expenses for the first nine months of 2026 were $52.3 million, compared to $52.5 million for the first nine months of 2025, and were virtually unchanged year over year.

Research and Development Expenses

Research and development (R&D) expenses were $18.3 million for the third quarter of 2026, compared to $15.9 million for the third quarter of 2025. R&D expenses for the first nine months of 2026 were $57.0 million, compared to $45.2 million for the first nine months of 2025. The $11.8 million year-over-year increase for the first nine months resulted primarily from an $8.9 million increase in clinical trial expense, reflecting increased alisertib study activity, and an increase of approximately $2.9 million in internal R&D expense, primarily due to increased employee compensation including the hiring of a new executive.

Total Other Income (Expenses)

Total other income was $0.9 million for the third quarter of 2026, compared to total other expenses of $0.4 million for the third quarter of 2025. Total other income was $2.0 million for the first nine months of 2026, compared to total other expenses of $1.5 million for the first nine months of 2025. The $3.5 million year-over-year increase in other income for the first nine months of 2026 resulted primarily from a decrease in interest expense, reflecting a lower debt balance, as Puma paid down its debt principal in May 2026, partially offset by the termination of subleases as of March 31, 2026 and unfavorable exchange rates on Euro-denominated transactions.

Fourth Quarter and Full Year 2026 Financial Outlook

	Fourth Quarter 2026	New Full Year 2026	Prior Full Year 2026
Net Product Revenue	**$56–$58 million**	**$206–$208 million**	**$205–$209 million**
Royalty Revenue	**$11–$12 million**	**$18–$19 million**	**$19–$22 million**
Total Revenue	**$67–$70 million**	**$224–$227 million**	**$224–$231 million**
Net Income*	**$10–$12 million**	**$20–$22 million**	**$17–$20 million**
Gross to Net Adjustment	**28%–29%**	**27.5%–28%**	**26.5%–27.5%**

*The outlook above does not include any potential adjustments for tax valuation allowance.

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 2026 financial results and provide an update on the Company's business and outlook at 1:30 p.m. PT/4:30 p.m. ET on Thursday, November 5, 2026. The call may be accessed by dialing (877) 709-8150 (domestic) or (201) 689-8354 (international). Please dial in at least 10 minutes in advance and inform the operator that you would like to join the "Puma Biotechnology Conference Call." A live webcast of the conference call and presentation slides may be accessed on the Investors section of the Puma Biotechnology website at https://www.pumabiotechnology.com. A replay of the call will be available shortly after completion of the call and will be archived on Puma's website for 90 days.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. Puma in-licensed the global development and commercialization rights to PB272 (neratinib, oral) in 2011. Neratinib, oral was approved by the U.S. Food and Drug Administration in 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. 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. NERLYNX was granted marketing authorization by the European Commission in 2018 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 completion of prior adjuvant trastuzumab-based therapy. NERLYNX® is a registered trademark of Puma Biotechnology, Inc.

In September 2022, Puma entered into an exclusive license agreement for the development and commercialization of the anti-cancer drug alisertib, a selective, small molecule, orally administered inhibitor of aurora kinase A. Initially, Puma intends to focus the development of alisertib on the treatment of small cell lung cancer and breast cancer. In February 2024, Puma initiated ALISCA®-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer. In November 2024, Puma initiated ALISCA®-Breast1, a Phase II clinical trial of alisertib in combination with endocrine therapy for the treatment of patients with HER2-negative, HR-positive metastatic breast cancer. In September 2026, Puma initiated ALISCA®-Lung2, a Phase II clinical trial of alisertib in combination with paclitaxel for the treatment of patients with advanced small cell lung cancer. ALISCA® is a registered trademark of Puma Biotechnology, Inc.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at https://www.NERLYNX.com or by calling 1-855-816-5421.

Further information about Puma Biotechnology may be found at https://www.pumabiotechnology.com.

INDICATIONS

NERLYNX® (neratinib) tablets, for oral use, is a kinase inhibitor indicated:

- As a single agent, for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
- 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.

Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea**: Manage diarrhea through either NERLYNX dose escalation or loperamide prophylaxis. If diarrhea occurs despite recommended prophylaxis, treat with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity**: Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.
- **Embryo-Fetal Toxicity**: NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common adverse reactions (reported in ≥ 5% of patients) were as follows:

- NERLYNX as a single agent: diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increased, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased, and urinary tract infection.
- NERLYNX in combination with capecitabine: diarrhea, nausea, vomiting, decreased appetite, constipation, fatigue/asthenia, weight decreased.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) or FDA at 1-800-332-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors. Separate NERLYNX by at least 2 hours before or 10 hours after H2-receptor antagonists. Or separate NERLYNX by at least 3 hours after antacids.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- P-gp and moderate CYP3A4 dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- Certain P-gp substrates: Monitor for adverse reactions of P-gp substrates for which minimal concentration change may lead to serious adverse reactions when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- Lactation: Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Puma's anticipated milestones and estimates of future financial results for the fourth quarter and full year 2026. All forward-looking statements involve risks and uncertainties that could cause Puma's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, any adverse impact on Puma's business or the global economy and financial markets, any changes in Puma's product candidates' regulatory approvals, results from Puma's clinical trials, any litigation involving Puma, any changes to Puma's in-licensed intellectual property and the risk factors disclosed in the periodic and current reports filed by Puma with the Securities and Exchange Commission from time to time, including Puma's Annual Report on Form 10-K for the year ended December 31, 2025 and subsequent filings. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

Contacts

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(Financial Tables Follow)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026 (Unaudited)	2025 (Unaudited)	2026 (Unaudited)	2025 (Unaudited)
Revenues:				
Product revenue, net	$ 54.1	$ 51.9	$ 149.6	$ 144.2
Royalty revenue	1.0	2.6	6.8	8.7
Total revenue	55.1	54.5	156.4	152.9
Operating costs and expenses:				
Cost of sales	15.2	12.2	38.1	35.0
Selling, general and administrative	16.3	16.8	52.3	52.5
Research and development	18.3	15.9	57.0	45.2
Total operating costs and expenses	49.8	44.9	147.4	132.7
Income from operations	5.3	9.6	9.0	20.2
Other income (expenses):				
Interest income	0.9	1.0	2.7	3.1
Interest expense	—	(1.5)	(0.9)	(5.5)
Other income	—	0.1	0.2	0.9
Total other income (expenses), net	0.9	(0.4)	2.0	(1.5)
Net income before income taxes	6.2	9.2	11.0	18.7
Income tax expense	(0.2)	(0.4)	(0.6)	(1.0)
Net income	$ 6.0	$ 8.8	$ 10.4	$ 17.7
Net income per share of common stock—basic	$ 0.12	$ 0.18	$ 0.20	$ 0.35
Net income per share of common stock—diluted	$ 0.11	$ 0.17	$ 0.20	$ 0.35
Weighted-average shares of common stock outstanding—basic	51,602,295	50,339,456	51,131,897	49,881,181
Weighted-average shares of common stock outstanding—diluted	53,116,836	50,929,893	52,605,014	50,334,553

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
LIQUIDITY AND CAPITAL RESOURCES
(in millions)

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 41.5	$ 29.6
Marketable securities	67.0	67.9
Working capital	105.7	81.4
Current portion of long-term debt	—	22.5
Stockholders' equity	146.6	130.3

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Cash provided by (used in):		
Operating activities	$ 31.6	$ 27.4
Investing activities	0.7	(9.2)
Financing activities	(22.5)	(33.9)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 9.8	$ (15.7)

Use of Non-GAAP Measures

In addition to operating results as calculated in accordance with GAAP, Puma uses certain non-GAAP financial measures when planning, monitoring and evaluating operational performance. The following table presents Puma's net income and net income per share calculated in accordance with GAAP and as adjusted to remove the impact of stock-based compensation expense. For the three months and nine months ended September 30, 2026, stock-based compensation represented approximately 5.8% and 5.4% of operating expenses, respectively, and 5.1% and 5.5% for the same periods in 2025, in each case excluding cost of sales. Puma's management believes that these non-GAAP financial measures are useful to enhance understanding of Puma's financial performance, are more indicative of its 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.

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
Reconciliation of GAAP Net Income to Non-GAAP Adjusted Net Income and
GAAP Net Income Per Share to Non-GAAP Adjusted Net Income Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended September 30,			
	2026		2025	
GAAP net income	$ 6.0		$ 8.8	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative [1]	1.3		1.1	
Research and development [2]	0.7		0.6	
Non-GAAP adjusted net income	$ 8.0		$ 10.5	
GAAP net income per share—basic	$ 0.12		$ 0.18	
Adjustment to net income (as detailed above)	0.03		0.03	
Non-GAAP adjusted basic net income per share	$ 0.15	(3)	$ 0.21	(4)
GAAP net income per share—diluted	$ 0.11		$ 0.17	
Adjustment to net income (as detailed above)	0.04		0.04	
Non-GAAP adjusted diluted net income per share	$ 0.15	(5)	$ 0.21	(6)

	Nine Months Ended September 30,			
	2026		2025	
GAAP net income	$ 10.4		$ 17.7	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative [1]	3.6		3.3	
Research and development [2]	2.3		2.0	
Non-GAAP adjusted net income	$ 16.3		$ 23.0	
GAAP net income per share—basic	$ 0.20		$ 0.35	
Adjustment to net income (as detailed above)	0.12		0.11	
Non-GAAP adjusted basic net income per share	$ 0.32	(3)	$ 0.46	(4)
GAAP net income per share—diluted	$ 0.20		$ 0.35	
Adjustment to net income (as detailed above)	0.11		0.11	
Non-GAAP adjusted diluted net income per share	$ 0.31	(5)	$ 0.46	(6)

(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 income per share was calculated based on 51,602,295 and 51,131,897 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2026, respectively.
(4) Non-GAAP adjusted basic net income per share was calculated based on 50,339,456 and 49,881,181 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2025, respectively.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 53,116,836 and 52,605,014 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2026, respectively.
(6) Non-GAAP adjusted diluted net income per share was calculated based on 50,929,893 and 50,334,553 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2025, respectively.