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): August 7, 2025

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 2150
Los Angeles, California 90024
(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 August 7, 2025, Puma Biotechnology, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2025. 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 August 7, 2025.
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: August 7, 2025

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

News Release

Puma Biotechnology Reports Second Quarter Financial Results

LOS ANGELES, Calif., Aug. 7, 2025 - Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the second quarter ended June 30, 2025. Unless otherwise stated, all comparisons are for the second quarter 2025 compared to the second quarter 2024.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net in the second quarter of 2025 was $49.2 million, compared to product revenue, net of $44.4 million in the second quarter of 2024. Product revenue, net in the first six months of 2025 was $92.3 million, compared to $84.6 million in the first six months of 2024.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $5.9 million, or $0.12 per basic and diluted share, for the second quarter of 2025, compared to a net loss of $4.5 million, or $0.09 per share, for the second quarter of 2024. Net income for the first six months of 2025 was $8.8 million, or $0.18 per basic and diluted share, compared to a net loss of $9.3 million, or $0.19 per share, for the first six months of 2024.

Non-GAAP adjusted net income was $7.5 million, or $0.15 per basic and diluted share, for the second quarter of 2025, compared to a non-GAAP adjusted net loss of $2.5 million, or $0.05 per share, for the second quarter of 2024. Non-GAAP adjusted net income for the first six months of 2025 was $12.4 million, or $0.25 per basic and diluted share, compared to a non-GAAP adjusted net loss of $4.9 million, or $0.10 per share, for the first six months of 2024. Non-GAAP adjusted net income (loss) excludes stock-based compensation expense. For a reconciliation of GAAP net income (loss) to non-GAAP adjusted net income (loss) and GAAP net income (loss) per share to non-GAAP adjusted net income (loss) per share, please see the financial tables at the end of this news release.

Net cash provided by operating activities for the second quarter of 2025 was $14.1 million, compared to $1.0 million in the second quarter of 2024. Net cash provided by operating activities for the first six months of 2025 was $17.7 million, compared to net cash provided by operating activities of $12.3 million in the first six months of 2024. At June 30, 2025, Puma had cash, cash equivalents and marketable securities of $96.0 million, compared to cash, cash equivalents and marketable securities of $101.0 million at December 31, 2024.

"We are pleased to report both the growth in revenues in the second quarter as well as the positive net income for the quarter," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We are pleased to see the year over year growth being driven by NERLYNX® demand and we are also pleased with the progress in the clinical development of alisertib in both chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer and small cell lung cancer as well."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) presentation of interim 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 (Q4 2025) and (ii) presentation of additional interim data from the ALI-4201/ALISCA™-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer (Q4 2025)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX®, Puma's first commercial product, and royalty revenue. For the second quarter ended June 30, 2025, total revenue was $52.4 million, of which $49.2 million was net product revenue and $3.2 million was royalty revenue. This compares to total revenue for the second quarter of 2024 of $47.1 million, of which $44.4 million was net product revenue and $2.7 million was royalty revenue. For the first six months of 2025, total revenue was $98.4 million, of which $92.3 million was net product revenue and $6.1 million was royalty revenue. This compares to total revenue for the first six months of 2024 of $90.8 million, of which $84.6 million was net product revenue and $6.2 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $45.8 million for the second quarter of 2025, compared to $49.3 million for the second quarter of 2024. Operating costs and expenses in the first six months of 2025 were $87.8 million, compared to $95.3 million in the first six months of 2024.

Cost of Sales

Cost of sales was $12.3 million for the second quarter of 2025, compared to $10.7 million for the second quarter of 2024. Cost of sales was $22.9 million for the first six months of 2025, compared to $21.4 million for the first six months of 2024. The increase in the first six months of 2025 was due to higher royalty expense and product costs resulting from increased worldwide net sales.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $18.0 million for the second quarter of 2025, compared to $25.0 million for the second quarter of 2024. SG&A expenses for the first six months of 2025 were $35.6 million, compared to $46.7 million for the first six months of 2024. The $11.1 million year-over-year decrease for the first six months resulted primarily from legal fees associated with the AstraZeneca litigation in the prior year.

Research and Development Expenses

Research and development (R&D) expenses were $15.5 million for the second quarter of 2025, compared to $13.6 million for the second quarter of 2024. R&D expenses for the first six months of 2025 were $29.3 million, compared to $27.2 million for the first six months of 2024. The $2.1 million year-over-year increase for the first six months resulted primarily from increased alisertib study activity.

Total Other Income (Expenses)

Total other income/expenses were $0.4 million for the second quarter of 2025, compared to total other expenses of $2.0 million for the second quarter of 2024. Total other income/expenses were $1.2 million for the first six months of 2025, compared to total other expenses of $4.2 million for the first six months of 2024. The $3.0 million year-over-year decrease in other expenses for the first six months of 2025 was primarily due to a lower debt balance as we continue to pay down our principal.

Third Quarter and Full Year 2025 Financial Outlook

	Third Quarter 2025	Full Year 2025 (current)	Full Year 2025 (previous)
Net Product Revenue	**$46-$48 million**	**$192–$198 million**	**$192–$198 million**
Royalty Revenue	**$2-$3 million**	**$20–$24 million**	**$20–$24 million**
License Revenue	**$0 million**	**$0 million**	**$0 million**
Total Revenue	**$48-$51 million**	**$212–$222 million**	**$212–$222 million**
Net Income/(Loss)*	**$2-$4 million**	**$23–$28 million**	**$23–$28 million**
Gross to Net Adjustment	**22.5%–23.5%**	**21.5%–22.0%**	**20.5%–21.5%**

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

Conference Call

Puma Biotechnology will host a conference call to report its second quarter 2025 financial results and provide an update on Puma's business and outlook at 1:30 p.m. PT/4:30 p.m. ET on Thursday, August 7, 2025. 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.

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, dizziness, back pain, arthralgia, urinary tract infection, upper respiratory tract infection, abdominal distention, renal impairment, and muscle spasms.

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 third quarter and full year 2025. 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, 2024 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.

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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 June 30,		Six Months Ended June 30,	
	2025 (Unaudited)	2024 (Unaudited)	2025 (Unaudited)	2024 (Unaudited)
Revenues:				
Product revenue, net	$ 49.2	$ 44.4	$ 92.3	$ 84.6
Royalty revenue	3.2	2.7	6.1	6.2
Total revenue	52.4	47.1	98.4	90.8
Operating costs and expenses:				
Cost of sales	12.3	10.7	22.9	21.4
Selling, general and administrative	18.0	25.0	35.6	46.7
Research and development	15.5	13.6	29.3	27.2
Total operating costs and expenses	45.8	49.3	87.8	95.3
Income (loss) from operations	6.6	(2.2)	10.6	(4.5)
Other income (expenses):				
Interest income	1.0	1.2	2.0	2.2
Interest expense	(1.8)	(3.4)	(4.0)	(6.6)
Other income	0.4	0.2	0.8	0.2
Total other expenses, net	(0.4)	(2.0)	(1.2)	(4.2)
Net income (loss) before income taxes	6.2	(4.2)	9.4	(8.7)
Income tax expense	(0.3)	(0.3)	(0.6)	(0.6)
Net income (loss)	$ 5.9	$ (4.5)	$ 8.8	$ (9.3)
Net income (loss) per share of common stock—basic	$ 0.12	$ (0.09)	$ 0.18	$ (0.19)
Net income (loss) per share of common stock—diluted	$ 0.12	$ (0.09)	$ 0.18	$ (0.19)
Weighted-average shares of common stock outstanding—basic	49,700,217	48,292,414	49,648,246	48,240,835
Weighted-average shares of common stock outstanding—diluted	50,144,704	48,292,414	50,003,709	48,240,835

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

	June 30, 2025 (Unaudited)	December 31, 2024
Cash and cash equivalents	$ 54.7	$ 69.2
Marketable securities	41.4	31.7
Working capital	57.5	51.5
Current portion of long-term debt	34.0	45.3
Long-term debt	10.9	21.7
Stockholders' equity	104.7	92.1

	Six Months Ended June 30, 2025 (Unaudited)	Six Months Ended June 30, 2024 (Unaudited)
Cash provided by (used in):		
Operating activities	$ 17.7	$ 12.3
Investing activities	(9.7)	(18.4)
Financing activities	(22.5)	(11.3)
Net decrease in cash, cash equivalents and restricted cash	$ (14.5)	$ (17.4)

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 (loss) and net income (loss) per share calculated in accordance with GAAP and as adjusted to remove the impact of stock-based compensation expense. For the three months and six months ended June 30, 2025, stock-based compensation represented approximately 4.9% and 5.6% of operating expenses, respectively, and 5.3% and 6.0% for the same periods in 2024, in each case excluding cost of sales and acquired in-process research and development. 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 (Loss) to Non-GAAP Adjusted Net Income (Loss) and GAAP Net Income (Loss) Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended June 30,	
	2025	**2024**
GAAP net income (loss)	$ 5.9	$ (4.5)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	1.0	1.4
Research and development (2)	0.6	0.6
Non-GAAP adjusted net income (loss)	$ 7.5	$ (2.5)
GAAP net income (loss) per share—basic	$ 0.12	$ (0.09)
Adjustment to net income (loss) (as detailed above)	0.03	0.04
Non-GAAP adjusted basic net income (loss) per share	$ 0.15 (3)	$ (0.05) (4)
GAAP net income (loss) per share—diluted	$ 0.12	$ (0.09)
Adjustment to net income (loss) (as detailed above)	0.03	0.04
Non-GAAP adjusted diluted net income (loss) per share	$ 0.15 (5)	$ (0.05) (6)

	Six Months Ended June 30,	
	2025	**2024**
GAAP net income (loss)	$ 8.8	$ (9.3)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	2.2	2.8
Research and development (2)	1.4	1.6
Non-GAAP adjusted net income (loss)	$ 12.4	$ (4.9)
GAAP net income (loss) per share—basic	$ 0.18	$ (0.19)
Adjustment to net income (loss) (as detailed above)	0.07	0.09
Non-GAAP adjusted basic net income (loss) per share	$ 0.25 (3)	$ (0.10) (4)
GAAP net income (loss) per share—diluted	$ 0.18	$ (0.19)
Adjustment to net income (loss) (as detailed above)	0.07	0.09
Non-GAAP adjusted diluted net income (loss) per share	$ 0.25 (5)	$ (0.10) (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 49,700,217 and 49,648,246 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2025, respectively.
(4) Non-GAAP adjusted basic net loss per share was calculated based on 48,292,414 and 48,240,835 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2024, respectively.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 50,144,704 and 50,003,709 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2025, respectively.
(6) 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 and six months ended June 30, 2024, as these shares would be considered anti-dilutive.