



Puma Biotechnology Reports Fourth Quarter and Full Year 2024 Financial Results

February 27, 2025

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2024. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2024 compared to the fourth quarter and full year 2023.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net for the fourth quarter of 2024 was \$54.4 million, compared to \$53.2 million in the fourth quarter of 2023. Product revenue, net for the full year 2024 was \$195.2 million, compared to \$203.1 million in 2023.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of \$19.3 million, or \$0.39 per basic and diluted share, for the fourth quarter of 2024, compared to net income of \$12.3 million, or \$0.26 per basic and diluted share, for the fourth quarter of 2023. Net income for full year 2024 was \$30.3 million, or \$0.62 per basic and diluted share, compared to net income of \$21.6 million, or \$0.46 per basic share and \$0.45 per diluted share, for full year 2023.

The fourth quarter 2024 net income of \$19.3 million, or \$0.39 per basic and diluted share includes a partial release of our valuation allowance that favorably impacted net income by \$7.1 million and favorably impacted earnings per share by \$0.15 per basic and diluted share. This compares to net income in the third quarter 2024 of \$20.3 million, or \$0.41 per basic and diluted share.

Non-GAAP adjusted net income was \$21.1 million, or \$0.43 per basic and diluted share, for the fourth quarter of 2024, compared to non-GAAP adjusted net income of \$14.8 million, or \$0.31 per basic and diluted share, for the fourth quarter of 2023. Non-GAAP adjusted net income for full year 2024 was \$38.5 million, or \$0.79 per basic and \$0.78 per diluted share, compared to non-GAAP adjusted net income of \$31.8 million, or \$0.68 per basic share and \$0.67 per diluted share, for full year 2023. 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 fourth quarter of 2024 was \$15.6 million, compared to net cash provided by operating activities of \$10.5 million for the fourth quarter of 2023. Net cash provided by operating activities for full year 2024 was \$38.9 million, compared to net cash provided by operating activities of \$27.0 million for full year 2023. At December 31, 2024, Puma had cash, cash equivalents, and marketable securities of approximately \$101 million, compared to cash, cash equivalents, and marketable securities of \$96 million at December 31, 2023.

"We are very pleased with our financial results for the fourth quarter of 2024, as well as for the full year 2024, and we are very pleased to be able to report positive net income for the third consecutive year, reflecting our strong execution and disciplined financial management," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "This execution was driven by both our continued commercial performance in the United States and abroad, as well as effective implementation of our planned initiatives to raise patient awareness and expand access channels. In addition, we are pleased to be able to initiate the ALI-1201/ALISCA™-Breast1 Phase II trial of alisertib in combination with endocrine treatment in patients with chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer in November, which is a significant step in our clinical development plan for alisertib."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) presentation of interim data from the Phase I trial of neratinib given in combination with trastuzumab deruxtecan in solid tumors with HER2 alterations (H1 2025); (ii) 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 (2025); and (iii) 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 (2025).

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, license revenue and royalty revenue. For the fourth quarter of 2024, total revenue was \$59.1 million, of which \$54.4 million was product revenue, net and \$4.7 million was royalty revenue. This compares to total revenue of \$72.2 million for the fourth quarter of 2023, of which \$53.2 million was product revenue, net and \$19.0 million was royalty revenue. For the year ended December 31, 2024, total revenue was \$230.5 million, of which \$195.2 million was product revenue, net and \$35.3 million was royalty revenue. This compares to total revenue in 2023 of \$235.6 million, of which \$203.1 million was product revenue, net and \$32.5 million was royalty revenue. Puma reported no license

revenue for the years ended December 31, 2024 and 2023.

Operating Costs and Expenses

Total operating costs and expenses were \$45.7 million for the fourth quarter of 2024, compared to \$57.4 million for the fourth quarter of 2023. Total operating costs and expenses were \$199.5 million for full year 2024, compared to \$203.0 million for full year 2023.

Cost of Sales

Cost of sales was \$13.9 million for the fourth quarter of 2024, compared to \$24.3 million for the fourth quarter of 2023. Cost of sales was \$64.4 million for full year 2024, compared to cost of sales of \$62.7 million for full year 2023. The \$1.7 million increase in full year 2024 was primarily due to the increase of product unit sales to our sub-licensees and the related cost of sales (primarily sales in China), partially offset by lower domestic sales.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were \$16.6 million for the fourth quarter of 2024, compared to \$20.2 million for the fourth quarter of 2023. SG&A expenses for full year 2024 were \$80.2 million, compared to \$89.9 million for full year 2023. The \$9.7 million decrease in SG&A expenses for full year 2024 compared to 2023 resulted primarily from a decrease in professional fees and expenses of approximately \$4.1 million, primarily due to a decrease in consultant and contractor expenses (primarily marketing related) of approximately \$2.7 million, a decrease in legal fees of approximately \$1.0 million, and a decrease in insurance and other expense of approximately \$0.4 million; a decrease in payroll and related costs of approximately \$1.9 million, primarily due to lower headcount, partially offset by annual salary increases; a decrease in provision for credit loss (recovery) of approximately \$1.4 million, due to an overdue receivable as of December 31, 2023 that was collected in 2024; a decrease in stock-based compensation expense of approximately \$1.3 million, primarily due to lower fair value on equity grants as a result of a lower market price for our common stock; and a decrease in loss on impairment of asset expense of \$0.6 million in connection with our decision to sublease a portion of our leased office space in 2023, which was recorded as an operating asset in accordance with ASC 842.

Research and Development Expenses

Research and development (R&D) expenses were \$15.2 million for the fourth quarter of 2024, compared to \$12.9 million for the fourth quarter of 2023. R&D expenses for full year 2024 were \$54.9 million, compared to \$50.4 million for full year 2023. The \$4.5 million increase in R&D expenses during full year 2024 compared to full year 2023 resulted from an increase in clinical trial expense of approximately \$3.5 million, primarily due to the procurement of our alisertib drug product, as well as increased alisertib study activity, partially offset by the achievement of fewer clinical milestones; an increase in internal R&D of approximately \$1.5 million, primarily due to higher compensation related to achieving company goals and one-time payroll and severance-related expenses; partially offset by a decrease in stock-based compensation of approximately \$0.7 million, primarily due to lower fair value on equity grants as a result of a lower market price for our common stock.

Total Other Income (Expenses)

Total other expenses were \$1.1 million for the fourth quarter of 2024, compared to total other expenses of \$2.0 million for the fourth quarter of 2023. Total other expenses were \$6.9 million for full year 2024, compared to \$9.9 million for full year 2023. The \$3.0 million decrease in other expenses in full year 2024 resulted primarily from a \$2.1 million increase in interest income, which reflected higher balances in cash equivalents and marketable securities, and a \$0.9 million decrease in interest expense, which was due to the pay down of debt in 2024, as well as ending imputed interest on \$8.0 million related to the final installment payment of the Eshelman litigation settlement paid in October 2024.

Deferred Income Tax Benefit

In the fourth quarter of 2024, Puma released a portion of its valuation allowance resulting in a non-cash, deferred tax income benefit of \$7.1 million. The valuation allowance was established to offset Puma's deferred tax assets, which are primarily related to its historical losses. This significantly increased Puma's net income for the fourth quarter and full year 2024.

First Quarter 2025 and Full Year 2025 Financial Outlook

	First Quarter 2025	Full Year 2025
Net Product Revenue	\$41–\$43 million	\$192–\$198 million
Royalty Revenue	\$1.5–\$2.5 million	\$20–\$24 million
License Revenue	\$0 million	\$0 million
Net Income/(Loss)*	\$(2)–\$0 million	\$23–\$28 million
Gross to Net Adjustment	22.5%–23.5%	20.5%–21.5%

*There are no tax valuation allowance adjustments included in the outlook above.

Conference Call

Puma Biotechnology will host a conference call to report its fourth quarter and full year 2024 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, February 27, 2025. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (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 approximately one hour 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-FDA-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 with 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 first 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
	(Unaudited)	(Unaudited)		
Revenues:				
Product revenue, net	\$ 54.4	\$ 53.2	195.2	203.1
Royalty revenue	4.7	19.0	35.3	32.5
Total revenue	59.1	72.2	230.5	235.6
Operating costs and expenses:				
Cost of sales	13.9	24.3	64.4	62.7
Selling, general and administrative	16.6	20.2	80.2	89.9
Research and development	15.2	12.9	54.9	50.4
Total operating costs and expenses	45.7	57.4	199.5	203.0
Income from operations	13.4	14.8	31.0	32.6
Other income (expenses):				
Interest income	1.2	0.7	4.7	2.6
Interest expense	(2.6)	(3.3)	(12.5)	(13.3)
Other income	0.2	0.6	0.9	0.8
Total other expenses	(1.2)	(2.0)	(6.9)	(9.9)
Net income before income taxes	12.2	12.8	24.1	22.7
Income tax expense	—	(0.5)	(0.9)	(1.1)
Deferred income tax benefit	7.1	—	7.1	—

Net income	\$ 19.3	\$ 12.3	\$ 30.3	\$ 21.6
Net income per share of common stock—basic	\$ 0.39	\$ 0.26	\$ 0.62	\$ 0.46
Net income per share of common stock—diluted	\$ 0.39	\$ 0.26	\$ 0.62	\$ 0.45
Weighted-average shares of common stock outstanding—basic	49,095,583	47,600,505	48,648,701	47,134,331
Weighted-average shares of common stock outstanding—diluted	49,408,877	48,040,118	49,100,433	47,550,852

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

	December 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 69.2	\$ 84.6
Marketable securities	\$ 31.7	\$ 11.4
Working capital	\$ 51.5	\$ 56.8
Short term debt	\$ 45.3	\$ 34.0
Long term debt	\$ 21.7	\$ 65.7
Stockholders' equity	\$ 92.1	\$ 53.4
	Twelve Months Ended December 31, 2024	Twelve Months Ended December 31, 2023 (Unaudited)
Cash provided by (used in):		
Operating activities	\$ 38.9	\$ 27.0
Investing activities	(20.4)	(19.1)
Financing activities	(33.9)	—
Increase (decrease) in cash and cash equivalents, and restricted cash	\$ (15.4)	\$ 7.9

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 twelve months ended December 31, 2024, stock-based compensation represented approximately 5.5% and 6.1% of total selling, general and administrative expense and research and development expense, respectively, and 7.4% and 7.3% for the same periods in 2023. 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 December 31,	
	2024	2023
GAAP net income	\$ 19.3	\$ 12.3
Adjustments:		

Stock-based compensation -		
Selling, general and administrative (1)	1.3	1.5
Research and development (2)	0.5	1.0
Non-GAAP adjusted net income	<u>\$ 21.1</u>	<u>\$ 14.8</u>
GAAP net income per share—basic	\$ 0.39	\$ 0.26
Adjustment to net income (as detailed above)	0.04	0.05
Non-GAAP adjusted basic net income per share	<u>\$ 0.43</u> (3)	<u>\$ 0.31</u> (3)
GAAP net income per share—diluted	\$ 0.39	\$ 0.26
Adjustment to net income (as detailed above)	0.04	0.05
Non-GAAP adjusted diluted net income per share	<u>\$ 0.43</u> (4)	<u>\$ 0.31</u> (4)

	Twelve Months Ended December 31,	
	2024	2023
GAAP net income	<u>\$ 30.3</u>	<u>\$ 21.6</u>
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	5.5	6.9
Research and development (2)	2.7	3.3
Non-GAAP adjusted net income	<u>\$ 38.5</u>	<u>\$ 31.8</u>
GAAP net income per share—basic	\$ 0.62	\$ 0.46
Adjustment to net income (as detailed above)	0.17	0.22
Non-GAAP adjusted basic net income per share	<u>\$ 0.79</u> (5)	<u>\$ 0.68</u> (5)
GAAP net income per share—diluted	\$ 0.62	\$ 0.45
Adjustment to net income (as detailed above)	0.16	0.22
Non-GAAP adjusted diluted net income per share	<u>\$ 0.78</u> (6)	<u>\$ 0.67</u> (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 49,095,583 and 47,600,505 weighted-average shares of common stock outstanding for the three months ended December 31, 2024 and 2023, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 49,408,877 and 48,040,118 weighted-average shares of common stock outstanding for the three months ended December 31, 2024 and 2023, respectively.

(5) Non-GAAP adjusted basic net income per share was calculated based on 48,648,701 and 47,134,331 weighted-average shares of common stock outstanding for the years ended December 31, 2024 and 2023, respectively.

(6) Non-GAAP adjusted diluted net income per share was calculated based on 49,100,433 and 47,550,852 weighted-average shares of common stock outstanding for the years ended December 31, 2024 and 2023, respectively.

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