



Puma Biotechnology Reports Second Quarter Financial Results

August 1, 2024

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the second quarter ended June 30, 2024. Unless otherwise stated, all comparisons are for the second quarter 2024 compared to the second quarter 2023.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net in the second quarter of 2024 was \$44.4 million, compared to product revenue, net of \$51.6 million in the second quarter of 2023. Product revenue, net in the first six months of 2024 was \$84.6 million, compared to \$98.3 million in the first six months of 2023.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of \$4.5 million, or \$0.09 per share, for the second quarter of 2024, compared to net income of \$2.1 million, or \$0.05 per basic and diluted share, for the second quarter of 2023. Net loss for the first six months of 2024 was \$9.3 million, or \$0.19 per share, compared to net income of \$3.5 million, or \$0.08 per basic share and \$0.07 per diluted share, for the first six months of 2023.

Non-GAAP adjusted net loss was \$2.5 million, or \$0.05 per share, for the second quarter of 2024, compared to non-GAAP adjusted net income of \$4.6 million, or \$0.10 per basic and diluted share, for the second quarter of 2023. Non-GAAP adjusted net loss for the first six months of 2024 was \$4.9 million, or \$0.10 per share, compared to non-GAAP adjusted net income of \$8.8 million, or \$0.19 per basic and diluted share, for the first six months of 2023. Non-GAAP adjusted net (loss) income excludes stock-based compensation expense. For a 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, please see the financial tables at the end of this news release.

Net cash provided by operating activities for the second quarter of 2024 was \$1.0 million, compared to \$3.3 million in the second quarter of 2023. Net cash provided by operating activities for the first six months of 2024 was \$12.3 million, compared to net cash provided by operating activities of \$5.9 million in the first six months of 2023. At June 30, 2024, Puma had cash, cash equivalents and marketable securities of \$96.8 million, compared to cash, cash equivalents and marketable securities of \$96.0 million at December 31, 2023.

Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma, said, "We were pleased to see promising efficacy signals from the Phase I/Ib study of alisertib in combination with osimertinib in advanced osimertinib-resistant EGFR-mutated lung cancer, which was presented at the 2024 Annual Meeting of the American Society of Clinical Oncology. The trial has been amended such that future enrollment will be limited to patients who are tp53 wild type and we look forward to further studying this combination in this biomarker directed cohort of patients. In addition, the biomarker analysis from the Phase II randomized clinical trial of alisertib alone vs. alisertib + fulvestrant for the treatment of patients with endocrine and CDK4/6 inhibitor (CDK 4/6i) resistant, human epidermal growth factor receptor 2-negative (HER2-negative), hormone receptor-positive metastatic breast cancer, presented at the same conference, may provide clarity into the subset of patients who may derive the greatest benefit from treatment with alisertib."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) initiation of 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 2024) and (ii) interim data from ALISCA™-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer (Q4 2024)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX®, Puma's first commercial product, license revenue from Puma's sub-licensees and royalty revenue. For the second quarter ended June 30, 2024, total revenue was \$47.1 million, of which \$44.4 million was net product revenue and \$2.7 million was royalty revenue. This compares to total revenue for the second quarter of 2023 of \$54.6 million, of which \$51.6 million was net product revenue and \$3.0 million was royalty revenue. For the first six months of 2024, total revenue was \$90.8 million, of which \$84.6 million was net product revenue and \$6.2 million was royalty revenue. This compares to total revenue for the first six months of 2023 of \$107.3 million, of which \$98.3 million was net product revenue and \$9.0 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were \$49.3 million for the second quarter of 2024, compared to \$49.7 million for the second quarter of 2023. Operating costs and expenses in the first six months of 2024 were \$95.3 million, compared to \$98.0 million in the

first six months of 2023.

Cost of Sales

Cost of sales was \$10.7 million for the second quarter of 2024, compared to \$11.9 million for the second quarter of 2023. Cost of sales was \$21.4 million for the first six months of 2024, compared to \$25.1 million for the first six months of 2023. The \$3.7 million decrease in the first six months of 2024 resulted primarily from lower royalty expense resulting from decreased worldwide net sales.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were \$25.0 million for the second quarter of 2024, compared to \$24.4 million for the second quarter of 2023. SG&A expenses for the first six months of 2024 were \$46.7 million, compared to \$46.8 million for the first six months of 2023. The decrease was primarily due to lower payroll costs related to lower headcount and recruiting related expenses, a decrease in credit losses due to collection on an overdue receivable, a decrease in stock-based compensation expense and a decrease in marketing costs, partially offset by an increase in legal fees.

Research and Development Expenses

Research and development (R&D) expenses were \$13.6 million for the second quarter of 2024, compared to \$13.4 million for the second quarter of 2023. R&D expenses for the first six months of 2024 were \$27.2 million, compared to \$26.1 million for the first six months of 2023. The \$1.1 million year-over-year increase for the first six months resulted primarily from an increase in clinical trial expenses related to alisertib drug product procurement, as well as a one-time payroll-related expense.

Total Other Income (Expenses)

Total other expenses were \$2.0 million for the second quarter of 2024, compared to \$2.6 million for the second quarter of 2023. Total other expenses were \$4.2 million for the first six months of 2024, compared to \$5.4 million for the first six months of 2023. The \$1.2 million year-over-year decrease in other expenses for the first six months of 2024 resulted primarily from higher interest income associated with higher interest rates in the current year.

Third Quarter and Full Year 2024 Financial Outlook

	Third Quarter 2024	Full Year 2024
Net Product Revenue	\$50 - \$53 million	\$183 - \$190 million
Royalty Revenue	\$20 - \$22 million	\$30 - \$33 million
License Revenue	\$0 million	\$1 - \$2 million
Net Income	\$11 - \$13 million	\$12 - \$15 million
Gross to Net Adjustment	18.5% - 19.5%	21% - 22%

Conference Call

Puma Biotechnology will host a conference call to report its second quarter 2024 financial results and provide an update on Puma's business and outlook at 1:30 p.m. PDT/4:30 p.m. EDT on Thursday, August 1, 2024. 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 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.

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 $\geq 5\%$ 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 third quarter and full year 2024. 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, 2023 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		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	\$ 44.4	\$ 51.6	\$ 84.6	\$ 98.3
Royalty revenue	2.7	3.0	6.2	9.0
Total revenue	47.1	54.6	90.8	107.3
Operating costs and expenses:				
Cost of sales	10.7	11.9	21.4	25.1
Selling, general and administrative	25.0	24.4	46.7	46.8
Research and development	13.6	13.4	27.2	26.1
Total operating costs and expenses	49.3	49.7	95.3	98.0
(Loss) income from operations	(2.2)	4.9	(4.5)	9.3
Other income (expenses):				
Interest income	1.2	0.7	2.2	1.2
Interest expense	(3.4)	(3.4)	(6.6)	(6.6)
Other income	0.2	0.1	0.2	—
Total other expenses	(2.0)	(2.6)	(4.2)	(5.4)
Net (loss) income before income taxes	\$ (4.2)	\$ 2.3	\$ (8.7)	\$ 3.9
Income tax expense	(0.3)	(0.2)	(0.6)	(0.4)
Net (loss) income	\$ (4.5)	\$ 2.1	\$ (9.3)	\$ 3.5
Net (loss) income per share of common stock—basic	\$ (0.09)	\$ 0.05	\$ (0.19)	\$ 0.08
Net (loss) income per share of common stock—diluted	\$ (0.09)	\$ 0.05	\$ (0.19)	\$ 0.07
Weighted-average shares of common stock outstanding—basic	48,292,414	46,759,062	48,240,835	46,697,912
Weighted-average shares of common stock outstanding—diluted	48,292,414	47,201,185	48,240,835	47,172,752

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

	June 30, 2024 (Unaudited)	December 31, 2023
Cash and cash equivalents	\$ 67.1	\$ 84.6
Marketable securities	29.7	11.4
Working capital	33.4	56.8
Long term debt	43.7	65.7
Stockholders' equity	48.5	53.4

GAAP net (loss) income per share—basic	\$	(0.19)	\$	0.08
Adjustment to net (loss) income (as detailed above)		0.09		0.11
Non-GAAP adjusted basic net (loss) income per share	\$	(0.10)	\$	0.19
		(3)		(4)
GAAP net (loss) income per share—diluted	\$	(0.19)	\$	0.07
Adjustment to net (loss) income (as detailed above)		0.09		0.12
Non-GAAP adjusted diluted net (loss) income per share	\$	(0.10)	\$	0.19
		(5)		(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 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.

(4) Non-GAAP adjusted basic net income per share was calculated based on 46,759,062 and 46,697,912 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2023, respectively.

(5) 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.

(6) Non-GAAP adjusted diluted net income per share was calculated based on 47,201,185 and 47,172,752 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2023, respectively.

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull or Olipriya Das, Russo Partners, +1 212 845 4200

david.schull@russopartnersllc.com

olipriya.das@russopartnersllc.com

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