News Release

Puma Biotechnology Reports Third Quarter 2024 Financial Results

LOS ANGELES, Calif., Nov. 7, 2024 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2024. Unless otherwise stated, all comparisons are for the third quarter of 2024 compared to the third quarter of 2023.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Product revenue, net in the third quarter of 2024 was $56.1 million, compared to $51.6 million in the third quarter of 2023. Product revenue, net in the first nine months of 2024 was $140.8 million, compared to $149.9 million in the first nine months of 2023.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $20.3 million, or $0.41 per basic and diluted share, for the third quarter of 2024, compared to a net income of $5.8 million, or $0.12 per basic and diluted share, for the third quarter of 2023. Net income for the first nine months of 2024 was $11.0 million, or $0.23 per basic share and $0.22 per diluted share, compared to net income of $9.3 million, or $0.20 per basic and diluted share, for the first nine months of 2023.

Non-GAAP adjusted net income was $22.4 million, or $0.46 per basic share and $0.45 per diluted share, for the third quarter of 2024, compared to $8.3 million, or $0.18 per basic share and $0.17 per diluted share, for the third quarter of 2023. Non-GAAP adjusted net income for the first nine months of 2024 was $17.5 million, or $0.36 per basic and diluted share, compared to non-GAAP adjusted net income of $17.1 million, or $0.36 per basic and diluted share, for the first nine months of 2023. Non-GAAP adjusted net income excludes stock-based compensation expenses. 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 2024 was $11.0 million, compared to $10.7 million in the third quarter of 2023. Net cash provided by operating activities for the first nine months of 2024 was $23.3 million, compared to net cash provided by operating activities of $16.6 million in the first nine months of 2023. On September 30, 2024, Puma had cash, cash equivalents and marketable securities of approximately $97 million, compared to cash, cash equivalents, and marketable securities of approximately $96 million at December 31, 2023.

"We are pleased to announce both positive net income and positive operating cash flow for the third quarter of 2024," said Alan H. Auerbach, Chairman, Chief Executive Officer, and President of Puma. "In addition to our focus on the commercialization of NERLYNX, we are also continuing to make progress with the clinical development of alisertib for patients with extensive stage small cell lung cancer and patients with chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) initiation of ALI-1201/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); (ii) presentation of interim data from 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); and (iii) 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)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product and royalty revenue. For the third quarter of 2024, total revenue was $80.5 million, of which $56.1 million was product revenue, net and $24.4 million was royalty revenue. This compares to total revenue of $56.1 million in the third quarter of 2023, of which $51.6 million was product revenue, net and $4.5 million was royalty revenue. For the first nine months of 2024, total revenue was $171.4 million, of which $140.8 million was product revenue, net and $30.6 million was royalty revenue. This compares to total revenue of $163.5 million for the first nine months of 2023, of which $149.9 million was product revenue, net, and $13.6 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $58.4 million for the third quarter of 2024, compared to $47.5 million for the third quarter of 2023. Operating costs and expenses in the first nine months of 2024 were $153.8 million, compared to $145.7 million in the first nine months of 2023.

Cost of Sales

Cost of sales was $29.1 million for the third quarter of 2024, compared to $13.3 million for the third quarter of 2023. Cost of sales was $50.5 million for the first nine months of 2024, compared to $38.4 million for the first nine months of 2023. The increase was primarily due to royalty expense related to the timing of sales made in China by our sub-licensee and an increase in units shipped to China.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $16.8 million for the third quarter of 2024, compared to $22.8 million for the third quarter of 2023. SG&A expenses for the first nine months of 2024 were $63.5 million, compared to $69.7 million for the first nine months of 2023. The $6.2 million decrease in SG&A expenses for the first nine months of 2024 compared to the first nine months of 2023 resulted from a decrease in payroll and related costs of approximately $2.4 million, primarily due to lower headcount, partially offset by annual salary increases; and a decrease in professional fees and expenses of approximately $1.2 million, primarily due to decreases of approximately $3.2 million in marketing expenses and $0.4 million in insurance and other expenses. These decreases were partially offset by an increase of approximately $2.3 million in legal fees; a decrease in stock-based compensation expense of approximately $1.1 million, primarily due to lower headcount; a decrease in provision for credit loss of $0.6 million, due to a customer payment on an overdue receivable; and a decrease in loss on impairment of asset expense of approximately $0.6 million in connection with our decision to sublease a portion of our office space in 2023.

Research and Development Expenses

Research and development (R&D) expenses were $12.5 million for the third quarter of 2024, compared to $11.4 million for the third quarter of 2023. R&D expenses for the first nine months of 2024 were $39.8 million, compared to $37.6 million for the first nine months of 2023. The $2.2 million year-over-year increase in R&D expenses resulted primarily from an increase in clinical trial expenses of approximately $1.8 million, primarily due to the procurement of alisertib drug product and increased alisertib study activity, partially offset by fewer clinical milestones being achieved, and an increase in internal R&D expenses of approximately $0.8 million, primarily due to one-time payroll and severance related expenses.

Total Other Income (Expenses)

Total other expenses were $1.5 million for the third quarter of 2024, compared to $2.6 million for the third quarter of 2023. Total other expenses of $5.7 million for the first nine months of 2024 were down from $8.0

million for the first nine months of 2023 due primarily to an increase in interest income.

Fourth Quarter and Full Year 2024 Financial Outlook

	Fourth Quarter 2024	Full Year 2024 (previous)	Full Year 2024 (new)
Net Product Revenue	**$46–$48 million**	**$183–$190 million**	**$187–$190 million**
Royalty Revenue	**$3.5–$5 million**	**$30–$34 million**	**$34–$36 million**
License Revenue	**$1–$2 million**	**$1–$2 million**	**$1–$2 million**
Net Income	**$4–$6 million**	**$12–$15 million**	**$15–$17 million**
Gross to Net Adjustment	**21%–22%**	**21%–22%**	**20.5%–21.5%**

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 2024 financial results and provide an update on Puma's business and outlook at 1:30 p.m. PST/4:30 p.m. EST on Thursday, November 7, 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™-Lung 1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive-stage small cell lung cancer.

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 fourth 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.

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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,	
	2024	2023	2024	2023
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	$ 56.1	$ 51.6	$ 140.8	$ 149.9
Royalty revenue	24.4	4.5	30.6	13.6
Total revenue	80.5	56.1	171.4	163.5
Operating costs and expenses:				
Cost of sales	29.1	13.3	50.5	38.4
Selling, general and administrative	16.8	22.8	63.5	69.7
Research and development	12.5	11.4	39.8	37.6
Total operating costs and expenses	58.4	47.5	153.8	145.7
Income from operations	22.1	8.6	17.6	17.8
Other income (expenses):				
Interest income	1.3	0.7	3.5	1.9
Interest expense	(3.1)	(3.3)	(9.8)	(10.0)
Legal verdict expense	—	—	—	—
Other income	0.3	—	0.6	0.1
Total other expenses, net	(1.5)	(2.6)	(5.7)	(8.0)
Net income before income taxes	$ 20.6	$ 6.0	$ 11.9	$ 9.8
Income tax expense	(0.3)	(0.2)	(0.9)	(0.5)
Net income	$ 20.3	$ 5.8	$ 11.0	$ 9.3
Net income per share of common stock—basic	$ 0.41	$ 0.12	$ 0.23	$ 0.20
Net income per share of common stock—diluted	$ 0.41	$ 0.12	$ 0.22	$ 0.20
Weighted-average shares of common stock outstanding—basic	49,008,464	47,520,338	48,498,579	46,977,127
Weighted-average shares of common stock outstanding—diluted	49,173,361	47,819,234	49,025,103	47,397,209

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

	September 30, 2024 (Unaudited)	December 31, 2023
Cash and cash equivalents	$ 67.3	$ 84.6
Marketable securities	29.5	11.4
Working capital	46.4	56.8
Long term debt	32.7	65.7
Stockholders' equity	71.1	53.4

	Nine Months Ended September 30, 2024 (Unaudited)	Nine Months Ended September 30, 2023 (Unaudited)
Cash provided by (used in):		
Operating activities	$ 23.3	$ 16.6
Investing activities	(18.1)	(11.0)
Financing activities	(22.5)	—
(Decrease) increase in cash and cash equivalents, and restricted cash	$ (17.3)	$ 5.6

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, 2024, stock-based compensation represented approximately 7.0% and 6.3% 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 September 30,			
	2024		2023	
GAAP net income	$ 20.3		$ 5.8	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	1.5		1.8	
Research and development (2)	0.6		0.8	
Non-GAAP adjusted net income	$ 22.4		$ 8.3	
GAAP net income per share—basic	$ 0.41		$ 0.12	
Adjustment to net income (as detailed above)	0.05		0.06	
Non-GAAP adjusted basic net income per share	$ 0.46	(3)	$ 0.18	(4)
GAAP net income per share—diluted	$ 0.41		$ 0.12	
Adjustment to net income (as detailed above)	0.04		0.05	
Non-GAAP adjusted diluted net income per share	$ 0.45	(5)	$ 0.17	(6)

	Nine Months Ended September 30,			
	2024		2023	
GAAP net income	$ 11.0		$ 9.3	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	4.3		5.4	
Research and development (2)	2.2		2.4	
Non-GAAP adjusted net income	$ 17.5		$ 17.1	
GAAP net income per share—basic	$ 0.23		$ 0.20	
Adjustment to net income (as detailed above)	0.13		0.16	
Non-GAAP adjusted basic net income per share	$ 0.36	(3)	$ 0.36	(4)
GAAP net income per share—diluted	$ 0.41		$ 0.20	
Adjustment to net income (as detailed above)	(0.05)		0.16	
Non-GAAP adjusted diluted net income per share	$ 0.36	(5)	$ 0.36	(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 49,008,464 and 48,498,579 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2024, respectively.

(4) Non-GAAP adjusted basic net income per share was calculated based on 47,520,338 and 46,977,127 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2023, respectively.

(5) Non-GAAP adjusted diluted net income per share was calculated based on 49,173,361 and 49,025,103 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2024, respectively.

(6) Non-GAAP adjusted diluted net income per share was calculated based on 47,819,234 and 47,397,209 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2023, respectively.