News Release

Puma Biotechnology Reports Fourth Quarter and Full Year 2023 Financial Results

LOS ANGELES, Calif., Feb. 29, 2024 — Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2023. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2023 compared to the fourth quarter and full year 2022.

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net for the fourth quarter of 2023 was $53.2 million, compared to $53.7 million in the fourth quarter of 2022. Product revenue, net for the full year 2023 was $203.1 million, compared to $200.0 million in 2022.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $12.3 million, or $0.26 per basic and diluted share, for the fourth quarter of 2023, compared to a net loss of $5.6 million, or $0.12 per basic and diluted share, for the fourth quarter of 2022. Net income for full year 2023 was $21.6 million, or $0.46 per basic share and $0.45 per diluted share, compared to a net income of $2,000, or $0.00 per basic and diluted share, for full year 2022.

Non-GAAP adjusted net income was $14.8 million, or $0.31 per basic and diluted share, for the fourth quarter of 2023, compared to non-GAAP adjusted net loss of $3.0 million, or $0.07 per basic and diluted share, for the fourth quarter of 2022. Non-GAAP adjusted net income for full year 2023 was $31.8 million, or $0.68 per basic share and $0.67 per diluted share, compared to non-GAAP adjusted net income of $11.8 million, or $0.26 per basic and diluted share, for full year 2022. 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 fourth quarter of 2023 was $10.4 million, compared to $7.7 million for the fourth quarter of 2022. Net cash provided by operating activities for full year 2023 was $27.0 million, compared to net cash used in operating activities of $15.8 million for full year 2022. At December 31, 2023, Puma had cash, cash equivalents, and marketable securities of $96.0 million, compared to cash, cash equivalents, and marketable securities of $81.1 million at December 31, 2022.

"We are pleased to report positive net income for both the fourth quarter and full year 2023," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "NERLYNX sales in the fourth quarter were negatively impacted by the lower enrollments seen in Q3, as well as a higher than expected gross to net for the quarter. We have continued to reduce our internal expenses to account for this higher gross to net and lower Q3 enrollments, as we recognize our fiscal responsibility to continue to be net income positive in 2024. Puma also continues to execute on the clinical development of alisertib, and in February, we were pleased to initiate ALISertib in CAncer (ALISCA-Lung1), a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) presentation of biomarker studies from the randomized trial of alisertib plus fulvestrant versus alisertib alone in hormone receptor positive, HER2-negative breast cancer (H1 2024); (ii) updated data from the clinical trial of

alisertib in combination with osimertinib in patients with metastatic EGFR-mutant non small cell lung cancer who have developed osimertinib resistance (H1 2024); (iii) 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 (iv) 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 (H2 2024)."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, license revenue and royalty revenue. For the fourth quarter of 2023, total revenue was $72.2 million, of which $53.2 million was product revenue, net, and $19.0 million was royalty revenue. This compares to total revenue of $65.7 million for the fourth quarter of 2022, of which $53.7 million was product revenue, net, and $12.0 million was royalty revenue. For the year ended December 31, 2023, total revenue was $235.6 million, of which $203.1 million was product revenue, net, and $32.5 million was royalty revenue. This compares to total revenue in 2022 of $228.0 million, of which $200.0 million was product revenue, net, and $28.0 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $57.4 million for the fourth quarter of 2023, compared to $55.7 million for the fourth quarter of 2022. Total operating costs and expenses were $203.0 million for full year 2023, compared to $204.3 million for full year 2022.

Cost of Sales

Cost of sales was $24.3 million for the fourth quarter of 2023, compared to $16.8 million for the fourth quarter of 2022. Cost of sales was $62.7 million for full year 2023, compared to cost of sales of $55.1 million for full year 2022.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $20.2 million for the fourth quarter of 2023, compared to $25.1 million for the fourth quarter of 2022. SG&A expenses for full year 2023 were $89.9 million, essentially unchanged from $90.0 million for full year 2022. The slight increase includes an increase in payroll and related costs of approximately $3.5 million, primarily due to a one-time $2.0 million CARES Act credit in 2022, increased compensation of $1.5 million in 2023, and a $0.9 million credit loss reserve. These increases were offset by a decrease of $4.1 million in professional fees and expenses related to consultants and contractors, as well as lower insurance expenses and administrative costs.

Research and Development Expenses

Research and development (R&D) expenses were $12.9 million for the fourth quarter of 2023, compared to $13.8 million for the fourth quarter of 2022. R&D expenses for full year 2023 were $50.4 million, compared to $52.2 million for full year 2022. The $1.8 million decrease in R&D expenses during full year 2023 compared to full year 2022 resulted primarily from the reduction and closure of NERLYNX clinical trial sites of approximately $4.7 million, partially offset by an increase in internal R&D expenses of approximately $3.2 million, primarily due to a tax credit recorded during the year ended December 31, 2022 under the CARES Act, without a comparable tax credit in 2023.

Acquired In-Process Research and Development Expense

Puma recorded acquired in-process R&D expense related to an alisertib up-front payment of $7.0 million during the year ended December 31, 2022. No similar expenses were recorded in 2023.

Total Other Income (Expenses)

Total other expenses were $2.0 million for the fourth quarter of 2023, compared to $15.3 million for the fourth quarter of 2022. Total other expenses were $9.9 million for full year 2023, compared to $23.2 million for full year 2022. The $13.3 million decrease in other expenses in full year 2023 resulted primarily from legal verdict expenses recorded in 2022, with no similar accruals in 2023, as well as an increase in other income related to higher interest rates in 2023.

First Quarter 2024 and Full Year 2024 Financial Outlook

	First Quarter 2024	Full Year 2024
Net Product Revenue	$38 - $40 million	$183 - $190 million
Royalty Revenue	$2.5 - $3 million	$30 - $33 million
License Revenue	$0 million	$1 - $2 million
Net Income/(Loss)	$(10) - $(12) million	$12 - $15 million
Gross to Net Adjustment	23% - 24%	21.5% - 22.5%

Conference Call

Puma Biotechnology will host a conference call to discuss its fourth quarter and full year 2023 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, February 29, 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 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), PB272 (neratinib, intravenous) and PB357. 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.

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 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 SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)		
Revenues:				
Product revenue, net	$ 53.2	$ 53.7	203.1	$ 200.0
License revenue	—	—	—	—
Royalty revenue	19.0	12.0	32.5	28.0
Total revenue	72.2	65.7	235.6	228.0
Operating costs and expenses:				
Cost of sales	24.3	16.8	62.7	55.1
Selling, general and administrative	20.2	25.1	89.9	90.0
Research and development	12.9	13.8	50.4	52.2
Acquired in-process research and development	—	—	—	7.0
Total operating costs and expenses	57.4	55.7	203.0	204.3
Income from operations	14.8	10.0	32.6	23.7
Other income (expenses):				
Interest income	0.7	0.6	2.6	0.8
Interest expense	(3.3)	(3.3)	(13.3)	(11.5)
Legal verdict (expense) credit	—	(12.4)	—	(12.5)
Other income (expense)	0.6	(0.2)	0.8	—
Total other expenses	(2.0)	(15.3)	(9.9)	(23.2)
Net income (loss) before income taxes	12.8	(5.3)	22.7	0.5
Income tax expense	(0.5)	(0.3)	(1.1)	(0.5)
Net income (loss)	$ 12.3	$ (5.6)	$ 21.6	$ (0.0)
Net income (loss) per share of common stock—basic	$ 0.26	$ (0.12)	$ 0.46	$ 0.00
Net income (loss) per share of common stock—diluted	$ 0.26	$ (0.12)	$ 0.45	$ 0.00
Weighted-average shares of common stock outstanding—basic	47,600,505	45,814,185	47,134,331	44,674,501
Weighted-average shares of common stock outstanding—diluted	48,040,118	45,814,185	47,550,852	44,929,998

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

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 84.6	$ 76.2
Marketable securities	$ 11.4	$ 4.9
Working capital	$ 56.8	$ 56.8
Short term debt	$ 34.0	—
Long term debt	$ 65.7	$ 98.3
Stockholders' deficit	$ 53.4	$ 21.6

	Twelve Months Ended December 31, 2023	Twelve Months Ended December 31, 2022
Cash provided by (used in):		
Operating activities	$ 27.0	$ (15.8)
Investing activities	(19.1)	7.1
Financing activities	—	12.2
Increase (decrease) in cash and cash equivalents, and restricted cash	$ 7.9	$ 3.5

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 twelve months ended December 31, 2023, stock-based compensation represented approximately 7.4% and 7.3% of operating expenses, respectively, and 6.8% and 8.3% for the same periods in 2022, 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 SUBSIDIARIES
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 December 31,			
	2023		2022	
GAAP net income (loss)	$ 12.3		$ (5.6)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	1.5		1.8	(1)
Research and development	1.0		0.8	(2)
Non-GAAP adjusted net income (loss)	$ 14.8		$ (3.0)	
GAAP net income (loss) per share—basic	$ 0.26		$ (0.12)	
Adjustment to net income (loss) (as detailed above)	0.05		0.05	
Non-GAAP adjusted basic net income (loss) per share	$ 0.31	(3)	$ (0.07)	(3)
GAAP net income (loss) per share—diluted	$ 0.26		$ (0.12)	
Adjustment to net income (loss) (as detailed above)	0.05		0.05	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.31	(4)	$ (0.07)	(5)

	Twelve Months Ended December 31,			
	2023		2022	
GAAP net income (loss)	$ 21.6		$ 0.0	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	6.9		8.0	(1)
Research and development	3.3		3.8	(2)
Non-GAAP adjusted net income	$ 31.8		$ 11.8	
GAAP net income (loss) per share—basic	$ 0.46		$ 0.00	
Adjustment to net income (loss) (as detailed above)	0.22		0.26	
Non-GAAP adjusted basic net income per share	$ 0.68	(6)	$ 0.26	(6)
GAAP net income (loss) per share—diluted	$ 0.45		$ 0.00	
Adjustment to net income (loss) (as detailed above)	0.22		0.26	
Non-GAAP adjusted diluted net income per share	$ 0.67	(7)	$ 0.26	(7)

(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 (loss) per share was calculated based on 47,600,505 and 44,814,185 weighted-average shares of common stock outstanding for the three months ended December 31, 2023 and 2022, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 48,040,118 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended December 31, 2023.

(5) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in the non-GAAP adjusted diluted net loss as these shares would be considered anti-dilutive.

(6) Non-GAAP adjusted basic net income per share was calculated based on 47,134,331 and 44,674,501 weighted-average shares of common stock outstanding for the years ended December 31, 2023 and 2022, respectively.

(7) Non-GAAP adjusted diluted net income per share was calculated based on 47,550,852 and 44,929,998 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the years ended December 31, 2023 and 2022, respectively.