Puma Biotechnology Reports Third Quarter 2023 Financial Results

November 2, 2023

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2023. Unless otherwise stated, all comparisons are for the third quarter of 2023 compared to the third quarter of 2022.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Product revenue, net in the third quarter of 2023 was $51.6 million, compared to $54.3 million in the third quarter of 2022. Product revenue, net in the first nine months of 2023 was $149.9 million, compared to $146.3 million in the first nine months of 2022.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $5.8 million, or $0.12 per basic and diluted share, for the third quarter of 2023, compared to a net loss of $0.4 million, or $0.01 per basic and diluted share, for the third quarter of 2022. Net income for the first nine months of 2023 was $9.3 million, or $0.20 per basic and diluted share, compared to a net income of $5.6 million, or $0.13 per basic and diluted share, for the first nine months of 2022.

Non-GAAP adjusted net income was $8.3 million, or $0.18 per basic share and $0.17 per diluted share, for the third quarter of 2023, compared to $2.5 million, or $0.05 per basic and diluted share, for the third quarter of 2022. Non-GAAP adjusted net income for the first nine months of 2023 was $17.1 million, or $0.36 per basic and diluted share, compared to non-GAAP adjusted net income of $14.8 million, or $0.33 per basic and diluted share, for the first nine months of 2022. Non-GAAP adjusted net income excludes stock-based compensation expenses. For a reconciliation of GAAP net income (loss) to non-GAAP adjusted net income and GAAP net income (loss) 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 2023 was $10.7 million, compared to net cash provided by operating activities of $17.3 million in the third quarter of 2022. Net cash provided by operating activities for the first nine months of 2023 was $16.6 million, compared to net cash used in operating activities of $23.5 million in the first nine months of 2022. On September 30, 2023, Puma had cash, cash equivalents, and marketable securities of $85.0 million, compared to cash, cash equivalents, and marketable securities of $81.1 million at December 31, 2022.

"We are pleased to report both positive net income and positive cash flow for the third quarter of 2023," said Alan H. Auerbach, Chairman, Chief Executive Officer, and President of Puma. "In addition, we were pleased to report the FDA's acceptance of our IND for alisertib and their granting of Orphan Drug Designation to alisertib for the treatment of small cell lung cancer, and we look forward to advancing the clinical development of alisertib in this indication."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) initiating a Phase II clinical trial of alisertib in small cell lung cancer (Q4 2023); (ii) conducting a meeting with the FDA to discuss the clinical development and registration pathway for alisertib in hormone receptor positive, HER2-negative breast cancer (Q4 2023); and (iii) initiating a Phase II clinical trial of alisertib in hormone receptor positive, HER2-negative breast cancer (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 third quarter of 2023, total revenue was $56.1 million, of which $51.6 million was product revenue, net and $4.5 million was royalty revenue. This compares to total revenue of $57.1 million in the third quarter of 2022, of which $54.3 million was product revenue, net and $2.8 million was royalty revenue. For the first nine months of 2023, total revenue was $163.5 million, of which $149.9 million was product revenue, net and $13.6 million was royalty revenue. This compares to total revenue of $162.4 million for the first nine months of 2022, of which $146.3 million was product revenue, net, and $16.1 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $47.5 million for the third quarter of 2023, compared to $54.7 million for the third quarter of 2022. Operating costs and expenses in the first nine months of 2023 were $145.7 million, compared to $148.7 million in the first nine months of 2022.

Cost of Sales

Cost of sales was $13.3 million for the third quarter of 2023, compared to $12.5 million for the third quarter of 2022. Cost of sales was $38.4 million for the first nine months of 2023, compared to $38.3 million for the first nine months of 2022. The year-to-date decrease was due to lower royalty expense related primarily to the timing of sales made in China by Puma's sub-licensee, partially

offset by increased intangible amortization related to the $12.5 million paid to Pfizer for meeting a commercial sales milestone as of December 31, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $22.8 million for the third quarter of 2023, compared to $24.0 million for the third quarter of 2022. SG&A expenses for the first nine months of 2023 were $69.7 million, compared to $64.9 million for the first nine months of 2022. The $4.8 million increase in SG&A expenses for the first nine months of 2023 compared to the first nine months of 2022 resulted from an increase in payroll and related costs of approximately $4.9 million, primarily related to a $2.0 million tax credit under the CARES Act recorded in the second quarter of 2022, salary increases beginning in the first quarter of 2023 and lower turnover during the nine months ended September 30, 2023.

Research and Development Expenses

Research and development (R&D) expenses were $11.4 million for the third quarter of 2023, compared to $11.2 million for the third quarter of 2022. R&D expenses for the first nine months of 2023 were $37.6 million, compared to $38.5 million for the first nine months of 2022. The $0.9 million year-over-year decrease in R&D expenses resulted primarily from a decrease in clinical trial expense of approximately $3.5 million, primarily due to the reduction and closure of clinical trial sites with respect to NERLYNX, partially offset by increases in internal R&D of approximately $3.4 million, due primarily to a $1.8 million tax credit related to the CARES Act recorded during the period ended September 30, 2022, as well as an increase in payroll-related expenses beginning in 2023.

Total Other Income (Expenses)

Total other expenses were $2.6 million for the third quarter of 2023, compared to $2.7 million for the third quarter of 2022. Total other expenses were $8.0 million for the first nine months of 2023, compared to $7.9 million for the first nine months of 2022. The $0.1 million increase for the first nine months of 2023 reflects higher interest rates on our outstanding notes as well as imputed interest on a legal settlement, largely offset by increased interest income.

Fourth Quarter and Full Year 2023 Financial Outlook

	Fourth Quarter 2023	**Full Year 2023**
Product Revenue, Net	$56 million - $59 million	$206 million - $209 million
Royalty Revenue	$16 million - $19 million	$30 million - $32 million
Net Income	$13 million - $16 million	$22 million - $25 million
Gross to Net Adjustment	15.5% - 16.5%	17.5% - 18.0%

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 2023 financial results and provide an update on the Company's business and outlook at 1:30 p.m. PDT/4:30 p.m. EDT on Thursday, November 2, 2023. 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), 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.

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 fourth quarter and full year 2023. 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, 2022 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	$ 51.6	$ 54.3	$ 149.9	$ 146.3
License revenue	—	—	—	—
Royalty revenue	4.5	2.8	13.6	16.1
Total revenue	56.1	57.1	163.5	162.4
Operating costs and expenses:				
Cost of sales	13.3	12.5	38.4	38.3
Selling, general and administrative	22.8	24.0	69.7	64.9
Research and development	11.4	11.2	37.6	38.5
Acquired in-process research and development	—	7.0	—	7.0
Total operating costs and expenses	47.5	54.7	145.7	148.7
Income from operations	8.6	2.4	17.8	13.7
Other income (expenses):				
Interest income	0.7	0.2	1.9	0.3
Interest expense	(3.3)	(2.9)	(10.0)	(8.3)
Legal verdict expense	—	—	—	(0.1)
Other income	—	—	0.1	0.2
Total other expenses, net	(2.6)	(2.7)	(8.0)	(7.9)
Net income (loss) before income taxes	$ 6.0	$ (0.3)	$ 9.8	$ 5.8
Income tax expense	(0.2)	(0.1)	(0.5)	(0.2)
Net income (loss)	$ 5.8	$ (0.4)	$ 9.3	$ 5.6
Net income (loss) per share of common stock—basic	$ 0.12	$ (0.01)	$ 0.20	$ 0.13
Net income (loss) per share of common stock—diluted	$ 0.12	$ (0.01)	$ 0.20	$ 0.13
Weighted-average shares of common stock outstanding —basic	47,520,338	45,567,739	46,977,127	44,290,432
Weighted-average shares of common stock outstanding —diluted	47,819,234	45,567,739	47,397,209	44,464,682

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

	September 30, 2023 (Unaudited)	December 31, 2022
Cash and cash equivalents	$ 81.8	$ 76.2
Marketable securities	3.2	4.9
Working capital	58.0	56.8
Short term debt	22.7	—
Long term debt	76.6	98.3
Stockholders' equity	38.7	21.6

	Nine Months Ended September 30, 2023 (Unaudited)	Nine Months Ended September 30, 2022 (Unaudited)
Cash provided by (used in):		

Operating activities	$ 16.6	$ (23.5)
Investing activities	(11.0)	19.0
Financing activities	—	9.8
Increase in cash and cash equivalents, and restricted cash	$ 5.6	$ 5.3

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 the Company'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, 2023, stock-based compensation represented approximately 7.4% and 7.3% of total selling, general and administrative expense and research and development expense, respectively and 8.2% and 8.9% for the same periods in 2022. 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 and
GAAP Net Income (loss) Per Share to Non-GAAP Adjusted Net Income Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended September 30,			
	2023		2022	
GAAP net income (loss)	$ 5.8		$ (0.4)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	1.8		2.0	
Research and development (2)	0.8		0.9	
Non-GAAP adjusted net income	$ 8.3		$ 2.5	
GAAP net income (loss) per share—basic	$ 0.12		$ (0.01)	
Adjustment to net income (as detailed above)	0.06		0.06	
Non-GAAP adjusted basic net income per share	$ 0.18	(3)	$ 0.05	(4)
GAAP net income (loss) per share—diluted	$ 0.12		$ (0.01)	
Adjustment to net income (as detailed above)	0.05		0.06	
Non-GAAP adjusted diluted net income per share	$ 0.17	(5)	$ 0.05	(6)

	Nine Months Ended September 30,			
	2023		2022	
GAAP net income	$ 9.3		$ 5.6	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative (1)	5.4		6.2	
Research and development (2)	2.4		3.0	
Non-GAAP adjusted net income	$ 17.1		$ 14.8	
GAAP net income per share—basic	$ 0.20		$ 0.13	
Adjustment to net income (as detailed above)	0.16		0.20	
Non-GAAP adjusted basic net income per share	$ 0.36	(3)	$ 0.33	(4)
GAAP net income per share—diluted	$ 0.20		$ 0.13	
Adjustment to net income (as detailed above)	0.16		0.20	
Non-GAAP adjusted diluted net income per share	$ 0.36	(5)	$ 0.33	(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 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.
(4) Non-GAAP adjusted basic net income per share was calculated based on 45,567,739 and 44,290,432 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2022, respectively.
(5) 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.
(6) Non-GAAP adjusted diluted net income per share was calculated based on 45,797,841 and 44,464,682 weighted-average shares of common stock outstanding for the three and nine months ended September 30, 2022, respectively.

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com
David Schull, Russo Partners, +1 212 845 4200
david.schull@russopartnersllc.com

Source: Puma Biotechnology, Inc.