Puma Biotechnology Reports First Quarter Financial Results

May 2, 2024

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

Product revenue, net consists entirely of revenue from sales of NERLYNX®, Puma's first commercial product. Product revenue, net in the first quarter of 2024 was $40.3 million, compared to product revenue, net of $46.8 million in the first quarter of 2023.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $4.8 million, or $0.10 per basic and diluted share, for the first quarter of 2024, compared to net income of $1.4 million, or $0.03 per basic and diluted share, for the first quarter of 2023.

Non-GAAP adjusted net loss was $2.4 million, or $0.05 per basic and diluted share, for the first quarter of 2024, compared to non-GAAP adjusted net income of $4.2 million, or $0.09 per basic and diluted share, for the first quarter 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 first quarter of 2024 was $11.3 million, compared to $2.6 million in the first quarter of 2023. At March 31, 2024, Puma had cash, cash equivalents and marketable securities of $107.2 million, compared to cash, cash equivalents and marketable securities of $96.0 million at December 31, 2023.

"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," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We also look forward to presenting 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, as well as results from the biomarker studies of the randomized trial of alisertib plus fulvestrant versus alisertib alone in hormone receptor-positive, HER2-negative breast cancer at the American Society of Clinical Oncology (ASCO) Annual Meeting. We remain committed to our goal to clinically develop alisertib, while carefully managing our resources to achieve positive net income for this year."

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 (Q2 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 (Q2 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 (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 first quarter ended March 31, 2024, total revenue was $43.8 million, of which $40.3 million was net product revenue and $3.5 million was royalty revenue. This compares to total revenue of $52.8 million in the first quarter of 2023, of which $46.8 million was net product revenue and $6.0 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were $46.1 million for the first quarter of 2024, compared to $48.4 million for the first quarter of 2023.

Cost of Sales

Cost of sales was $10.7 million for the first quarter of 2024, compared to $13.2 million for the first quarter of 2023. The $2.5 million decrease resulted primarily from lower royalty expense reflecting decreased worldwide net sales.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $21.8 million for the first quarter of 2024, compared to $22.5 million for the first

quarter of 2023. The $0.7 million decrease resulted primarily from payroll-related expenses and stock-based compensation, partially offset by an increase in professional fees and expenses.

Research and Development Expenses

Research and development expenses were $13.6 million for the first quarter of 2024, compared to $12.7 million for the first quarter of 2023. The $0.9 million increase resulted primarily from an increase in clinical trial expense of approximately $1.0 million, due to a milestone payment associated with a neratinib clinical trial, partially offset by a decrease in neratinib-related consultant and contractors expense.

Total Other Income (Expenses)

Total other expenses were $2.3 million for the first quarter of 2024, compared to total other expenses of $2.8 million for the first quarter of 2023. The $0.5 million decrease resulted primarily from an increase in interest income, which resulted from higher interest rates and increased cash investments.

Second Quarter and Full Year 2024 Financial Outlook

	Second Quarter 2024	Full Year 2024
Net Product Revenue	**$43 -45 million**	**$183 - $190 million**
Royalty Revenue	**$2.5 - $3 million**	**$30 - $33 million**
License Revenue	**$0 million**	**$1 - $2 million**
Net Income/(Loss)	**$(6) - $(9) million**	**$12 - $15 million**
Gross to Net Adjustment	**22% - 23%**	**21.5% - 22.5%**

Conference Call

Puma Biotechnology will host a conference call to report its first quarter 2024 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, May 2, 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) 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 ≥ 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 second 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 March 31,

	2024	2023
	(Unaudited)	(Unaudited)
Revenues:		
Product revenue, net	$ 40.3	$ 46.8
License revenue	—	—
Royalty revenue	3.5	6.0
Total revenue	43.8	52.8
Operating costs and expenses:		
Cost of sales	10.7	13.2
Selling, general and administrative	21.8	22.5
Research and development	13.6	12.7
Total operating costs and expenses	46.1	48.4
(Loss) income from operations	(2.3)	4.4
Other expenses:		
Interest income	1.0	0.5
Interest expense	(3.4)	(3.3)
Other income	0.1	—
Total other expenses	(2.3)	(2.8)
Net (loss) income before income taxes	(4.6)	1.6
Income tax expense	(0.2)	(0.2)
Net (loss) income	$ (4.8)	$ 1.4
Net (loss) income per share of common stock—basic	$ (0.10)	$ 0.03
Net (loss) income per share of common stock—diluted	$ (0.10)	$ 0.03
Weighted-average shares of common stock outstanding—basic	48,189,256	46,636,083
Weighted-average shares of common stock outstanding—diluted	48,189,256	47,157,904

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

	March 31, 2024 (Unaudited)	December 31, 2023
Cash and cash equivalents	$ 76.8	$ 84.6
Marketable securities	30.4	11.4
Working capital	44.8	56.8
Long term debt	54.7	65.7
Stockholders' equity	51.0	53.4

	Three Months Ended March 31, 2024 (Unaudited)	Three Months Ended March 31, 2023 (Unaudited)
Cash provided by (used in):		
Operating activities	$ 11.3	$ 2.6
Investing activities	(19.1)	(17.4)
Financing activities	—	—
Increase (decrease) in cash and cash equivalents, and restricted cash	$ (7.8)	$ (14.8)

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 ended March 31, 2024 and 2023, stock-based compensation represented approximately 6.7% and 8.1% of operating expenses, respectively, 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 SUBSIDIARY
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
(in millions except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
GAAP net (loss) income	$ (4.8)	$ 1.4
Adjustments:		
Stock-based compensation -		
Selling, general and administrative (1)	1.5	2.0
Research and development (2)	0.9	0.8
Non-GAAP adjusted net (loss) income	$ (2.4)	$ 4.2
GAAP net (loss) income per share—basic	$ (0.10)	$ 0.03
Adjustment to net (loss) income (as detailed above)	0.05	0.06
Non-GAAP adjusted basic net (loss) income per share (3)	$ (0.05)	$ 0.09
GAAP net (loss) income per share—diluted	$ (0.10)	$ 0.03
Adjustment to net (loss) income (as detailed above)	0.05	0.06
Non-GAAP adjusted diluted net (loss) income per share (4)	$ (0.05)	$ 0.09

(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) income per share was calculated based on 48,189,256 and 46,636,083 weighted-average shares of common stock outstanding for the three months ended March 31, 2024 and 2023, respectively.
(4) Non-GAAP adjusted diluted net (loss) income per share was calculated based on 48,189,256 and 47,157,904 weighted-average shares of common stock outstanding for the years ended March 31, 2024 and 2023, respectively.

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