



Puma Biotechnology Reports First Quarter 2020 Financial Results

May 7, 2020

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the first quarter ended March 31, 2020. Unless otherwise stated, all comparisons are for the first quarter of 2020 compared to the first quarter of 2019.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net product revenue in the first quarter of 2020 was \$48.6 million, compared to net product revenue of \$45.6 million in the first quarter of 2019.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of \$16.9 million, or \$0.43 per share, for the first quarter of 2020, compared to a net loss of \$10.1 million, or \$0.26 per share, for the first quarter of 2019.

Non-GAAP adjusted net loss was \$8.0 million, or \$0.20 per share, for the first quarter of 2020, compared to non-GAAP adjusted net income of \$8.1 million, or \$0.21 per basic share and \$0.20 per diluted share, for the first quarter of 2019. Non-GAAP adjusted net income (loss) excludes stock-based compensation expense. For a reconciliation of GAAP net loss to non-GAAP adjusted net income (loss) and GAAP net 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 used in operating activities for the first quarter of 2020 was \$11.5 million, compared to \$16.1 million used in the first quarter of 2019. At March 31, 2020, Puma had cash, cash equivalents and marketable securities of \$100.6 million, compared to cash, cash equivalents and marketable securities of \$111.6 million at December 31, 2019.

"We remain focused on providing a significant impact to cancer patients in need. The earlier-than-expected approval of the sNDA of NERLYNX in combination with capecitabine to treat adult patients with HER2-positive metastatic breast cancer who have received two or more prior anti HER2-based regimens in the metastatic setting is an important step toward this goal," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Our global partners also are working hard to bring the drug to market in their respective territories, thereby increasing global access to NERLYNX. Earlier today, we announced that our licensing partner CANbridge Pharmaceuticals received marketing approval of NERLYNX in mainland China. In addition, we are closely monitoring the changing COVID-19 situation. We are pleased to announce that we maintain a significant stock of NERLYNX and do not anticipate any disruption of supply to existing or new patients."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) conducting a pre-NDA meeting with the FDA to discuss accelerated approval of neratinib in HER2 mutated hormone receptor positive breast cancer and HER2 mutated cervical cancer in the first quarter of 2021; (ii) reporting Phase II data from the HER-positive breast and cervical cancer cohort from the SUMMIT trial of neratinib in patients with HER2 mutations in the fourth quarter of 2020; (iii) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2020; and (iv) receiving regulatory decisions for an extended adjuvant HER2-positive early stage breast cancer indication in additional countries."

Revenue

Total revenue consists of net product revenue from sales of NERLYNX, Puma's first commercial product, license revenue and royalty revenue. For the first quarter of 2020, total revenue was \$51.2 million, of which \$48.6 million was net product revenue, \$2.0 million was license revenue from a Puma sub-licensee and \$0.6 million was royalty revenue. This compares to total revenue of \$99.1 million in the first quarter of 2019, of which \$45.6 million was net product revenue and \$53.5 million was license revenue from Puma's sub-licensees.

Operating Costs and Expenses

Total operating costs and expenses were \$65.5 million for the first quarter of 2020, compared to \$89.2 million for the first quarter of 2019.

Cost of Sales

Cost of sales was \$9.1 million for the first quarter of 2020, compared to \$8.0 million for the first quarter of 2019.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$30.9 million for the first quarter of 2020, compared to selling, general and administrative expenses of \$45.5 million for the first quarter of 2019. The \$14.6 million decrease resulted primarily from decreases

in professional fees and expenses of approximately \$8.7 million, stock-based compensation expense of approximately \$5.2 million, payroll and payroll-related expenses of approximately \$0.6 million, and travel and meetings of approximately \$0.3 million. These decreases were partially offset by an increase in training expenses and compliance fees of approximately \$0.2 million.

Research and Development Expenses

Research and development expenses were \$25.5 million for the first quarter of 2020, compared to \$35.7 million for the first quarter of 2019. The \$10.2 million decrease resulted primarily from decreases in clinical trial expense of approximately \$4.9 million, stock-based compensation expense of approximately \$4.0 million, and consultant and contractors expenses of approximately \$1.4 million.

Total Other Income (Expenses)

Total other expenses were \$2.6 million for the first quarter of 2020, compared to total other expenses of \$20.0 million for the first quarter of 2019. The \$17.4 million decrease resulted primarily from decreases in legal verdict expense of approximately \$16.3 million and interest expense of approximately \$1.5 million. These decreases were partially offset by a decrease in interest income of approximately \$0.5 million.

Conference Call

Puma Biotechnology will host a conference call to report its first quarter 2020 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 7, 2020. The call may be accessed by dialing 1-866-548-4713 (domestic) or 1-323-794-2093 (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 <http://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-licenses 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.

Further information about Puma Biotechnology may be found at www.pumabiotechnology.com.

IMPORTANT SAFETY INFORMATION

NERLYNX® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX 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.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea. 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) and www.NERLYNX.com 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. When patients require gastric acid reducing agents, use an H₂-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after H₂-receptor antagonists.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- Moderate CYP3A4 and P-glycoprotein (P-gp) dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- **Lactation:** Advise women not to breastfeed.

Please see [Full Prescribing Information](#) for additional safety information.

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 www.NERLYNX.com or 1-855-816-5421.

Forward-Looking Statements

This news release includes forward-looking statements, including statements regarding Puma's anticipated milestones. 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, generally, from the global COVID-19 pandemic, 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, 2019 and, once filed, Puma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. 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 SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS (in millions except share and per share data)

	Three Months Ended	
	March 31,	
	2020	2019
	(Unaudited)	(Unaudited)
Revenues:		
Product revenue, net	\$ 48.6	\$ 45.6
License revenue	2.0	53.5
Royalty revenue	0.6	—
Total revenue	51.2	99.1
Operating costs and expenses:		
Cost of sales	9.1	8.0
Selling, general and administrative	30.9	45.5
Research and development	25.5	35.7
Total operating costs and expenses	65.5	89.2

Profit (loss) from operations	(14.3)	9.9
Other income (expenses):		
Interest income	0.4	0.9
Interest expense	(3.0)	(4.5)
Legal verdict expense	(0.1)	(16.4)
Other income (expense)	0.1	—
Total other expenses	(2.6)	(20.0)
Net loss	<u>\$ (16.9)</u>	<u>\$ (10.1)</u>
Net loss per common share—basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.26)</u>
Weighted-average common shares outstanding—basic and diluted	<u>39,291,162</u>	<u>38,481,824</u>

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

	March 31, 2020 (Unaudited)	December 31, 2019
Cash and cash equivalents	\$ 83.4	\$ 60.0
Marketable securities	17.2	51.6
Working capital	68.2	75.5
Stockholders' equity	9.4	17.5

	Three Months Ended March 31, 2020 (Unaudited)	Three Months Ended March 31, 2019 (Unaudited)
Cash provided by (used in):		
Operating activities	\$ (11.5)	\$ (16.1)
Investing activities	34.3	(44.6)
Financing activities	—	1.1
Increase (decrease) in cash and cash equivalents, and restricted cash	<u>\$ 22.8</u>	<u>\$ (59.6)</u>

Non-GAAP Financial 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 loss and net loss per share calculated in accordance with GAAP and as adjusted to remove the impact of employee stock-based compensation. For the three months ended March 31, 2020 and 2019, stock-based compensation represented approximately 15.8% and 22.4% of operating expenses, respectively, in each case excluding cost of sales. Puma's management believes that these non-GAAP financial measures are useful to enhance understanding of Puma's financial performance, and 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 Loss to Non-GAAP Adjusted Net Income (Loss) and
GAAP Net Loss Per Share to Non-GAAP Adjusted Income (Loss) Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2020	2019
GAAP net loss	<u>\$ (16.9)</u>	<u>\$ (10.1)</u>

Adjustments:		
Stock-based compensation -		
Selling, general and administrative	4.7	9.9 (1)
Research and development	4.2	8.3 (2)
Non-GAAP adjusted net income (loss)	<u>\$ (8.0)</u>	<u>\$ 8.1</u>
GAAP net loss per share—basic	\$ (0.43)	\$ (0.26)
Adjustment to net loss (as detailed above)	0.23	0.47
Non-GAAP adjusted basic net income (loss) per share	<u>\$ (0.20)</u>	<u>\$ 0.21 (3)</u>
GAAP net loss per share—diluted	\$ (0.43)	\$ (0.26)
Adjustment to net loss (as detailed above)	0.23	0.46
Non-GAAP adjusted diluted net income (loss) per share	<u>\$ (0.20) (4)</u>	<u>\$ 0.20 (5)</u>

(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 39,291,162 and 38,481,824 weighted-average shares of common stock outstanding for the three months ended March 31, 2020 and 2019, respectively.

(4) 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 months ended March 31, 2020 as these shares would be considered anti-dilutive.

(5) Non-GAAP adjusted diluted net income per share was calculated based on 39,281,714 weighted-average shares of common stock outstanding for the three months ended March 31, 2019.

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