Puma Biotechnology Reports Second Quarter 2020 Financial Results

August 6, 2020

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the second quarter ended June 30, 2020. Unless otherwise stated, all comparisons are for the second quarter of 2020 compared to the second quarter of 2019.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net NERLYNX product revenue in the second quarter of 2020 was $48.8 million, compared to $53.8 million in the second quarter of 2019. Net NERLYNX product revenue in the first six months of 2020 was $97.4 million, compared to $99.4 million in the first six months of 2019.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of $3.4 million, or $0.09 per basic share and $0.08 per diluted share, for the second quarter of 2020, compared to a net loss of $37.4 million, or $0.97 per basic and diluted share, for the second quarter of 2019. Net loss for the first six months of 2020 was $13.5 million, or $0.34 per basic and diluted share, compared to a net loss of $47.5 million, or $1.23 per basic and diluted share, for the first six months of 2019.

Non-GAAP adjusted net income was $14.0 million, or $0.36 per basic share and $0.35 per diluted share, for the second quarter of 2020, compared to non-GAAP adjusted net loss of $22.0 million, or $0.57 per basic and diluted share, for the second quarter of 2019. Non-GAAP adjusted net income for the first six months of 2020 was $6.0 million, or $0.15 per basic and diluted share, compared to non-GAAP adjusted net loss of $13.9 million, or $0.36 per basic and diluted share, for the first six months of 2019. 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 a reconciliation of 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 second quarter of 2020 was $16.2 million, compared to $44.2 million for the second quarter of 2019. Net cash provided by operating activities for the first six months of 2020 was $4.7 million, compared to $28.1 million for the first six months of 2019. At June 30, 2020, Puma had cash, cash equivalents and marketable securities of $107.3 million, compared to $111.6 million at December 31, 2019.

"We are pleased to announce that despite the challenges presented by the COVID-19 situation as well as a significant inventory draw down by specialty pharmacies in the quarter, we were able to achieve NERLYNX revenues that were within the Company's previously stated second quarter guidance range," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Although we anticipate that COVID-19 may continue to impact our revenues going forward, we remain focused on and committed to providing support to patients battling breast cancer. The addition of Jeff Ludwig to our team as Chief Commercial Officer demonstrates our commitment to increasing the global success of NERLYNX. Maintaining the health and safety of our employees remains a priority for all of us at Puma, and we are pleased with the accomplishments made by our team as they adjusted to working remotely and responding to any COVID-related challenges."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) reporting Phase II data from the hormone receptor positive breast cancer cohort of the SUMMIT trial of neratinib in patients with HER2 mutations in the fourth quarter of 2020; (ii) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2020; (iii) reporting data from the Phase II TBCRC-022 trial of the combination of Kadcyla plus neratinib in patients with HER2 positive breast cancer with brain metastases who have previously been treated with Kadcyla in the first half of 2021; (iv) conducting a pre-NDA meeting with the FDA to discuss accelerated approval of neratinib in HER2 mutated hormone receptor positive breast cancer in the first half of 2021; and (v) receiving regulatory decisions for an extended adjuvant HER2-positive early stage breast cancer indication in additional countries."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product, license revenue, and royalty revenue. For the second quarter of 2020, total revenue was $70.6 million, of which $48.8 million was net product revenue, $20.7 million was license revenue received from Puma's sub-licensees, and $1.1 million was royalty revenue from Puma's sub-licensees. This compares to total revenue for the second quarter of 2019 of $53.9 million, of which $53.8 million was net product revenue and $0.1 million was royalty revenue from Puma's sub-licensees. For the first six months of 2020, total revenue was $121.8 million, of which $97.4 million was net product revenue, $22.7 million was license revenue received from Puma's sub-licensees, and $1.7 million was royalty revenue also from Puma's sub-licensees. This compares to total revenue for the first six months of 2019 of $153.0 million, of which $99.4 million was net product revenue, $53.5 million was license revenue received from Puma's sub-licensees, and $0.1 million was royalty revenue also from Puma's sub-licensees.

Operating Costs and Expenses

Total operating costs and expenses were $63.5 million for the second quarter of 2020, compared to $79.7 million for the second quarter of 2019. Operating costs and expenses in the first six months of 2020 were $128.9 million, compared to $168.9 million in the first six months of 2019.

Cost of Sales

Cost of sales was $9.4 million for the second quarter of 2020 and $18.5 million for the first six months of 2020, compared to $9.3 million for the second quarter of 2019 and $17.3 million for the first six months of 2019.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $29.4 million for the second quarter of 2020, compared to $33.5 million for the second quarter of 2019. SG&A expenses for the first six months of 2020 were $60.3 million, compared to $79.0 million for the first six months of 2019. The $18.7 million year-over-year decrease for the first six months resulted primarily from a decrease in stock-based compensation expense of approximately $7.9 million, a decrease in professional fees and expenses of approximately $7.7 million, a decrease in expenses associated with travel and meetings of approximately $2.5 million, and a decrease of approximately $0.4 million in payroll and payroll-related expenses.

Research and Development Expenses

Research and development (R&D) expenses were $24.7 million for the second quarter of 2020, compared to $36.9 million for the second quarter of 2019. R&D expenses for the first six months of 2020 were $50.1 million, compared to $72.6 million for the first six months of 2019. The $22.5 million year-over-year decrease for the first six months resulted primarily from a decrease in clinical trial expense of approximately $13.5 million, a decrease in employee stock-based compensation expense of approximately $6.1 million, and a decrease in consultant and contractors expenses of approximately $2.9 million primarily due to the close out of certain clinical trials.

Total Other Income (Expenses)

Total other expenses were $3.7 million for the second quarter of 2020 and $6.4 million for the first six months of 2020, compared to total other expenses of $11.6 million for the second quarter of 2019 and $31.6 million for the first six months of 2019. The $25.2 million year-over-year decrease for the first six months primarily resulted from a decrease in debt extinguishment loss of approximately $8.1 million, a decrease in legal verdict expense of approximately $16.2 million, and a decrease in interest expense of approximately $2.0 million, partially offset by a decrease in interest income of approximately $1.3 million.

Conference Call

Puma Biotechnology will host a conference call to report its second 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, August 6, 2020. 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 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 July 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 August 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 can be found at www.pumabiotechnology.com.

Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication

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 ≥ 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 H_2-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 H_2-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 other risk factors disclosed in Puma's Annual Report on Form 10-K for the year ended December 31, 2019, Puma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and subsequent reports filed by Puma with the Securities and Exchange Commission from time to time. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	$ 48.8	$ 53.8	$ 97.4	$ 99.4
License revenue	20.7	—	22.7	53.5
Royalty revenue	1.1	0.1	1.7	0.1
Total revenue	70.6	53.9	121.8	153.0
Operating costs and expenses:				
Cost of sales	9.4	9.3	18.5	17.3
Selling, general and administrative	29.4	33.5	60.3	79.0
Research and development	24.7	36.9	50.1	72.6
Total operating costs and expenses	63.5	79.7	128.9	168.9
Income (loss) from operations	7.1	(25.8)	(7.1)	(15.9)
Other income (expenses):				
Interest income	0.1	0.9	0.5	1.8
Interest expense	(3.8)	(4.4)	(6.9)	(8.9)
Legal verdict expense	(0.1)	—	(0.2)	(16.4)
Loss on debt extinguishment	—	(8.1)	—	(8.1)
Other income	0.1	—	0.2	—
Total other expenses	(3.7)	(11.6)	(6.4)	(31.6)
Net income (loss)	$ 3.4	$ (37.4)	$ (13.5)	$ (47.5)
Net income (loss) per share of common stock—basic	$ 0.09	$ (0.97)	$ (0.34)	$ (1.23)
Net income (loss) per share of common stock—diluted	$ 0.08	$ (0.97)	$ (0.34)	$ (1.23)
Weighted-average shares of common stock outstanding—basic	39,432,030	38,647,775	39,361,596	38,565,258
Weighted-average shares of common stock outstanding—diluted	39,997,571	38,647,775	39,361,596	38,565,258

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

	June 30, 2020 (Unaudited)	December 31, 2019
Cash and cash equivalents	$ 90.9	$ 60.0
Marketable securities	16.4	51.6
Working capital	64.7	75.5
Stockholders' equity	23.4	17.5

	Six Months Ended June 30, 2020 (Unaudited)	Six Months Ended June 30, 2019 (Unaudited)
Cash provided by (used in):		
Operating activities	$ 4.7	$ 28.1
Investing activities	25.1	(33.4)
Financing activities	-	(67.1)

Increase (decrease) in cash and cash equivalents, and restricted cash	$ 29.8	$ (72.4)

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 and six months ended June 30, 2020, stock-based compensation represented approximately 19.7% and 17.7% of operating expenses, respectively, and 21.9% and 22.2%, respectively, for the same periods in 2019, 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, 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 Income (Loss) Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended June 30,			
	2020		2019	
GAAP net income (loss)	$ 3.4		$ (37.4)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	4.7		7.4	(1)
Research and development	5.9		8.0	(2)
Non-GAAP adjusted net income (loss)	$ 14.0		$ (22.0)	
GAAP net income (loss) per share—basic	$ 0.09		$ (0.97)	
Adjustment to net income (loss) (as detailed above)	0.27		0.40	
Non-GAAP adjusted basic net income (loss) per share	$ 0.36	(3)	$ (0.57)	(4)
GAAP net income (loss) per share—diluted	$ 0.08		$ (0.97)	
Adjustment to net income (loss) (as detailed above)	0.27		0.40	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.35	(5)	$ (0.57)	(6)

	Six Months Ended June 30,			
	2020		2019	
GAAP net income (loss)	$ (13.5)		$ (47.5)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	9.4		17.3	(1)
Research and development	10.1		16.3	(2)
Non-GAAP adjusted net income (loss)	$ 6.0		$ (13.9)	
GAAP net income (loss) per share—basic	$ (0.34)		$ (1.23)	
Adjustment to net income (loss) (as detailed above)	0.49		0.87	
Non-GAAP adjusted basic net income (loss) per share	$ 0.15	(3)	$ (0.36)	(4)
GAAP net income (loss) per share—diluted	$ (0.34)		$ (1.23)	
Adjustment to net income (loss) (as detailed above)	0.49		0.87	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.15	(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 (loss) per share was calculated based on 39,432,030 and 39,361,596 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2020, respectively.

(4) Non-GAAP adjusted basic net income (loss) per share was calculated based on 38,647,775 and 38,565,258 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2019, respectively.

(5) Non-GAAP adjusted diluted net income per share was calculated based on 39,997,571 and 39,815,867 weighted-average shares of common stock outstanding for the three and six months ended June 30, 2020, respectively.

(6) 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 and six months ended June 30, 2019, as these shares would be considered anti-dilutive.

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