Puma Biotechnology Reports Third Quarter 2019 Financial Results

November 6, 2019

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2019. Unless otherwise stated, all comparisons are for the third quarter 2019 compared to the third quarter 2018.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net NERLYNX revenue in the third quarter of 2019 was $53.5 million, compared to net NERLYNX revenue of $52.6 million in the third quarter of 2018. Net NERLYNX revenue in the first nine months of 2019 was $152.9 million, compared to net NERLYNX revenue of $139.4 million in the first nine months of 2018.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $16.9 million, or $0.44 per share, for the third quarter of 2019, compared to a net loss of $14.2 million, or $0.37 per share, for the third quarter of 2018. Net loss for the first nine months of 2019 was $64.4 million, or $1.67 per share, compared to $82.9 million, or $2.19 per share, for the first nine months of 2018.

Non-GAAP adjusted net loss was $4.7 million, or $0.12 per share, for the third quarter of 2019, compared to non-GAAP adjusted net income of $6.6 million, or $0.17 per basic share and $0.16 per diluted share, for the third quarter of 2018. Non-GAAP adjusted net loss for the first nine months of 2019 was $18.6 million, or $0.48 per share, compared to non-GAAP adjusted net loss of $14.5 million, or $0.38 per share, for the first nine months of 2018. Non-GAAP adjusted net loss excludes stock-based compensation expense. For a reconciliation of GAAP net loss to non-GAAP adjusted net loss and GAAP net loss per share to non-GAAP adjusted net loss per share, please see the financial tables at the end of this news release.

Net cash used in operating activities for the third quarter of 2019 was $7.3 million, compared to $7.3 million in the third quarter of 2018. Net cash provided by operating activities for the first nine months of 2019 was $20.8 million, compared to net cash used in operating activities of $31.2 million for the first nine months of 2018. At September 30, 2019, Puma had cash, cash equivalents and marketable securities of $110.4 million, compared to $165.4 million at December 31, 2018.

"In the third quarter of 2019 we were pleased to report that our supplemental New Drug Application for neratinib for the treatment of third-line HER2-positive metastatic breast cancer was accepted by the U.S. Food and Drug Administration," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "The FDA also granted Orphan Drug Designation for neratinib for the treatment of breast cancer patients with brain metastases during the quarter. In addition, we were pleased to report that NERLYNX was approved by Health Canada and ANMAT in Canada and Argentina, respectively, during the quarter."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 to 18 months: (i) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2019; (ii) reporting Phase II data from the SUMMIT basket trial of neratinib in HER2 nonamplified (HER2 negative) breast cancer patients with a HER2 mutation in the fourth quarter of 2019; (iii) receiving regulatory decisions for the extended adjuvant HER2-positive early stage breast cancer indication in additional countries; (iv) receiving a U.S. regulatory decision on neratinib in third-line HER2-positive metastatic breast cancer in the second quarter of 2020; and (v) 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 either the fourth quarter of 2020 or the first half of 2021."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product, license revenue and royalty revenue. For the third quarter of 2019, total revenue was $56.4 million, of which $53.5 million was net product revenue, $2.8 million was license revenue received from Puma's sub-licensees and $0.1 million was royalty revenue. This compares to total revenue of $62.6 million in the third quarter of 2018, of which $52.6 million was net product revenue and $10.0 million was license revenue received from one of Puma's sub-licensees. For the first nine months of 2019, total revenue was $209.3 million, of which $152.9 million was net product revenue, $56.2 million was license revenue received from Puma's sub-licensees and $0.2 million was royalty revenue. This compares to total revenue for the first nine months of 2018 of $179.9 million, of which $139.4 million was net product revenue and $40.5 million was license revenue.

Operating Costs and Expenses

Operating costs and expenses were $70.8 million for the third quarter of 2019, compared to $73.9 million for the third quarter of 2018. Operating costs and expenses for the first nine months of 2019 were $239.7 million, compared to $256.0 million for the first nine months of 2018.

Cost of Sales

Cost of sales was $9.4 million for the third quarter of 2019 and $26.7 million for the first nine months of 2019, compared to $9.0 million for the third quarter and $24.3 million for the first nine months of 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses (SG&A) were $31.4 million for the third quarter of 2019, compared to $28.5 million for the third quarter of 2018. SG&A expenses for the first nine months of 2019 were $110.4 million, compared to $105.2 million for the first nine months of 2018. The $5.2 million year-to-date increase resulted primarily from increases of approximately $10.4 million for professional fees, such as legal fees and marketing and commercial support, and $0.6 million for office and banking expenses. These were partially offset by decreases of approximately $4.0 million in employee stock-based compensation expense, $0.9 million in payroll and payroll-related expenses, and $0.9 million in travel and meeting-related expenses.

Research and Development Expenses

Research and development (R&D) expenses were $30.0 million for the third quarter of 2019, compared to $36.4 million for the third quarter of 2018. R&D expenses for the first nine months of 2019 were $102.6 million, compared to $126.5 million for the first nine months of 2018. The $23.9 million year-to-date decrease resulted primarily from decreases of approximately $18.5 million in stock-based compensation expense, $4.4 million for internal R&D, primarily related to payroll and payroll-related expenses, $0.8 million in clinical trial expenses, and $0.2 million in consulting and contractor expenses related to clinical research and regulatory activities.

Total Other Income (Expenses)

Total other expenses were $2.5 million for the third quarter and $34.0 million for the first nine months of 2019, compared to total other expenses of $2.9 million for the third quarter and $6.8 million for the first nine months of 2018. The $27.2 million year-to-date increase includes approximately $16.4 million related to a March 2019 jury verdict against Puma, $8.1 million in loss on debt extinguishment related to fees paid in connection with our debt refinancing in the second quarter of 2019 and a $3.5 million increase in net interest expense. These amounts were offset by other immaterial fluctuations.

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 2019 financial results and provide an update on the Company's business and outlook at 1:30 p.m. PST/4:30 p.m. EST on Wednesday, Nov. 6, 2019. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (international) at least 10 minutes prior to the start of the call and referencing 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 www.pumabiotechnology.com. A replay of the call will be available approximately one hour after completion of the call and will be archived on the company'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. 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 may 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 for the extended adjuvant treatment of adult patients with HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis 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 (≥ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, weight decreased and urinary tract infection.

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 or moderate CYP3A4 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.

The recommended dose of NERLYNX is 240 mg (six 40 mg tablets) given orally once daily with food, continuously for one year. Antidiarrheal prophylaxis should be initiated with the first dose of NERLYNX and continued during the first 2 months (56 days) of treatment and as needed thereafter.

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 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, 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, 2018. 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 September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 53.5	$ 52.6	$ 152.9	$ 139.4
License revenue	2.8	10.0	56.2	40.5
Royalty revenue	0.1	—	0.2	—
Total revenue	56.4	62.6	209.3	179.9
Operating costs and expenses:				
Cost of sales	9.4	9.0	26.7	24.3
Selling, general and administrative	31.4	28.5	110.4	105.2
Research and development	30.0	36.4	102.6	126.5
Total operating costs and expenses	70.8	73.9	239.7	256.0
Loss from operations	(14.4)	(11.3)	(30.4)	(76.1)

Other income (expenses):				
Interest income	0.6	0.6	2.4	1.1
Interest expense	(3.1)	(3.5)	(11.9)	(7.2)
Legal verdict expenses	—	—	(16.4)	—
Loss on debt extinguishment	—	—	(8.1)	—
Other expense	—	—	—	(0.7)
Total other expenses	(2.5)	(2.9)	(34.0)	(6.8)
Net loss	$ (16.9)	$ (14.2)	$ (64.4)	$ (82.9)
Net loss per common share—basic and diluted	$ (0.44)	$ (0.37)	$ (1.67)	$ (2.19)
Weighted-average common shares outstanding—basic and diluted	38,893,757	38,043,174	38,675,961	37,855,249

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

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 58.9	$ 108.4
Marketable securities	51.5	57.0
Working capital	62.8	135.9
Stockholders' equity	17.2	34.3

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Cash provided by (used in):		
Operating activities	$ 20.8	$ (31.2)
Investing activities	5.6	(60.2)
Financing activities	(67.1)	78.0
Decrease in cash and cash equivalents, and restricted cash	$ (40.7)	$ (13.4)

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 nine months ended September 30, 2019 stock-based compensation represented approximately 19.9% and 21.5% 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 September 30,	
	2019	**2018**
GAAP net loss	$ (16.9)	$ (14.2)

Adjustments:				
Stock-based compensation -				
Selling, general and administrative	5.6		9.4	(1)
Research and development	6.6		11.4	(2)
Non-GAAP adjusted net income (loss)	$ (4.7)		$ 6.6	
GAAP net loss per share—basic	$ (0.44)		$ (0.37)	
Adjustment to net loss (as detailed above)	0.32		0.54	
Non-GAAP adjusted basic net income (loss) per share	$ (0.12)		$ 0.17	(3)
GAAP net loss per share—diluted	$ (0.44)		$ (0.36)	
Adjustment to net loss (as detailed above)	0.32		0.52	
Non-GAAP adjusted diluted net income (loss) per share	$ (0.12)	(5)	$ 0.16	(6)

	Nine Months Ended September 30,		
	2019	**2018**	
GAAP net loss	$ (64.4)	$ (82.9)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	22.9	27.0	(1)
Research and development	22.9	41.4	(2)
Non-GAAP adjusted net loss	$ (18.6)	$ (14.5)	
GAAP net loss per share—basic and diluted	$ (1.67)	$ (2.19)	
Adjustment to net loss (as detailed above)	1.19	1.81	
Non-GAAP adjusted basic and diluted net loss per share	$ (0.48)	$ (0.38)	(4)

(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 per share was calculated based on 38,893,757 and 38,043,174 weighted-average shares of common stock outstanding for the three months ended September 30, 2019 and 2018, respectively.

(4) Non-GAAP adjusted basic net loss per share was calculated based on 38,675,961 and 37,855,249 weighted-average shares of common stock outstanding for the nine months ended September 30, 2019 and 2018, respectively.

(5) 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 September 30, 2019 as these shares would be considered anti-dilutive.

(6) Non-GAAP adjusted diluted net income per share was calculated based on 39,677,446 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended September 30, 2018.

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