Puma Biotechnology Reports Second Quarter 2019 Financial Results

August 8, 2019

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

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net NERLYNX revenue in the second quarter of 2019 was $53.8 million, compared to net NERLYNX revenue of $50.8 million in the second quarter of 2018. Net NERLYNX revenue in the first six months of 2019 was $99.4 million, compared to net NERLYNX revenue of $86.8 million in the first six months of 2018.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $37.4 million, or $0.97 per share, for the second quarter of 2019, compared to a net loss of $44.3 million, or $1.17 per share, for the second quarter of 2018. Net loss for the first six months of 2019 was $47.5 million, or $1.23 per share, compared to a net loss of $68.7 million, or $1.82 per share, for the first six months of 2018.

Non-GAAP adjusted net loss was $22.0 million, or $0.57 per share for the second quarter of 2019, compared to non-GAAP adjusted net loss of $22.2 million, or $0.59 per share for the second quarter of 2018. Non-GAAP adjusted net loss for the first six months of 2019 was $13.9 million, or $0.36 per share, compared to non-GAAP adjusted net loss of $21.2 million, or $0.56 per share, for the first six 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 provided by operating activities for the second quarter of 2019 was $44.2 million, compared to net cash used in operating activities of $17.6 million in the second quarter of 2018. Net cash provided by operating activities for the first six months of 2019 was $28.1 million, compared to net cash used in operating activities of $23.9 million in the first six months of 2018. At June 30, 2019, Puma had cash, cash equivalents, and marketable securities of $117.7 million, compared to cash, cash equivalents and marketable securities of $165.4 million at December 31, 2018. The reduction in cash, cash equivalents and marketable securities in the second quarter was the result of the previously disclosed repayment of the $155 million outstanding loan using cash on hand and $100 million in new borrowings from an amended and restated loan agreement in June 2019.

"The second quarter of 2019 included the achievement of several key milestones for Puma," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "This included sequential NERLYNX sales growth and the expansion of our global presence with NERLYNX with our European licensing agreement with Pierre Fabre. We saw the achievement of additional key milestones in July with the filing of the new drug application for neratinib in the metastatic breast cancer indication and obtaining approval for NERLYNX in the extended adjuvant indication from Health Canada."

Mr. Auerbach added, "We anticipate the following key milestones during the remainder of 2019: (i) meeting with the FDA to discuss the clinical development and regulatory strategy for the SUMMIT trial in the third quarter of 2019; (ii) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2019; and (iii) receiving regulatory decisions for the 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 ended June 30, 2019, total revenue was $53.9 million, of which $53.8 million was net NERLYNX revenue and $0.1 million was royalty revenue received from Puma's sub-licensees. This compares to total revenue of $50.8 million in the second quarter of 2018, all of which was net product revenue. For the first six months of 2019, total revenue was $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. This compares to total revenue for the first six months of 2018 of $117.3 million, of which $86.8 million was net product revenue and $30.5 million was license revenue.

Operating Costs and Expenses

Total operating costs and expenses were $79.7 million in the second quarter of 2019, compared to $92.2 million in the second quarter of 2018. Operating costs and expenses in the first six months of 2019 were $168.9 million, compared to $182.1 million in the first six months of 2018.

Cost of Sales:

Cost of sales was $9.3 million for the second quarter of 2019 and $17.3 million for the first six months of 2019, compared to $8.8 million for the second quarter of 2018 and $15.2 for the first six months of 2018.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses (SG&A) were $33.5 million for the second quarter of 2019, compared to $40.1 million for the second quarter of 2018. SG&A expenses for the first six months of 2019 were $79.0 million, compared to $76.7 million for the first six months of 2018. The approximately $2.3 million year-to-date increase resulted primarily from increases of approximately $2.9 million for professional fees, such as legal fees and marketing and commercial support, $0.6 million in office and banking expenses, and $0.4 million in payroll and payroll-related expenses. These were partially offset by decreases of approximately $1.4 million in travel and meeting-related expenses and $0.2 million related to stock-based compensation expense.

Research and Development Expenses:

Research and development (R&D) expenses were $36.9 million for the second quarter of 2019, compared to $43.3 million for the second quarter of 2018. R&D expenses for the first six months of 2019 were $72.6 million, compared to $90.2 million for the first six months of 2018. The $17.6 million year-to-date decrease resulted primarily from decreases of approximately $13.8 million for stock-based compensation, $3.5 million for internal R&D primarily related to payroll and payroll-related expenses, and $0.5 million in consulting fees related to clinical trials.

Total Other Income (Expenses)

Total other expenses were $11.6 million for the second quarter and $31.6 million for the first six months of 2019, compared to total other expenses of $2.9 million for the second quarter and $3.9 million for the first six months of 2018. The increase in other expenses recorded in the first six months of 2019 primarily included $16.4 million related to a March 2019 jury verdict against Puma and $8.1 million related to the debt refinancing.

Conference Call

Puma Biotechnology will host a conference call to report its second quarter 2019 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 8, 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 http://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. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the FDA 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 September 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 for the extended adjuvant treatment of adult patients with early stage 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, epistaxis, 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 (PPI) and H2-receptor antagonists. 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.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Puma's anticipated milestones for 2019. All forward-looking statements involve risks and uncertainties that could cause the 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, 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 June 30, (Unaudited)		Six Months Ended June 30, (Unaudited)	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 53.8	$ 50.8	$ 99.4	$ 86.8
License revenue	—	—	53.5	30.5
Royalty revenue	0.1	—	0.1	—
Total revenue	53.9	50.8	153.0	117.3
Operating costs and expenses:				
Cost of sales	9.3	8.8	17.3	15.2
Selling, general and administrative	33.5	40.1	79.0	76.7
Research and development	36.9	43.3	72.6	90.2
Total operating costs and expenses	79.7	92.2	168.9	182.1
Loss from operations	(25.8)	(41.4)	(15.9)	(64.8)
Other income (expenses):				
Interest income	0.9	0.3	1.8	0.5
Interest expense	(4.4)	(2.6)	(8.9)	(3.7)
Legal verdict expenses	—	—	(16.4)	—
Loss on debt extinguishment	(8.1)	—	(8.1)	—
Other expense	—	(0.6)	—	(0.7)
Total other expenses	(11.6)	(2.9)	(31.6)	(3.9)
Net loss	$ (37.4)	$ (44.3)	$ (47.5)	$ (68.7)

Net loss per common share—basic and diluted	$ (0.97)	$ (1.17)	$ (1.23)	$ (1.82)
Weighted-average common shares outstanding—basic and diluted	38,647,775	37,819,767	38,565,258	37,759,729

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

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 27.2	$ 108.4
Marketable securities	90.5	57.0
Working capital	65.9	135.9
Stockholders' equity	21.8	34.3

	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
Cash provided by (used in):		
Operating activities	$ 28.1	$ (23.9)
Investing activities	(33.4)	(38.8)
Financing activities	(67.1)	76.9
Increase (decrease) in cash and cash equivalents, and restricted cash	$ (72.4)	$ 14.2

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, 2019, stock-based compensation represented approximately 21.9% and 22.1% 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 Loss and GAAP Net Loss Per Share to Non-GAAP Adjusted Loss Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended June 30,		
	2019	2018	
GAAP net loss	$ (37.4)	$ (44.3)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	7.4	8.5	(1)
Research and development	8.0	13.6	(2)
Non-GAAP adjusted net loss	$ (22.0)	$ (22.2)	
GAAP net loss per share - basic and diluted	$ (0.97)	$ (1.17)	
Adjustment to net loss (as detailed above)	0.40	0.58	

Non-GAAP adjusted net loss per share	$ (0.57)	$ (0.59)	(3)

	Six Months Ended June 30,		
	2019	2018	
GAAP net loss	$ (47.5)	$ (68.7)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	17.3	17.5	(1)
Research and development	16.3	30.0	(2)
Non-GAAP adjusted net loss	$ (13.9)	$ (21.2)	
GAAP net loss per share - basic and diluted	$ (1.23)	$ (1.82)	
Adjustment to net loss (as detailed above)	0.87	1.26	
Non-GAAP adjusted net loss per share	$ (0.36)	$ (0.56)	(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 net loss per share was calculated based on 38,647,775 and 37,819,767 weighted-average shares of common stock outstanding for the three months ended June 30, 2019 and 2018, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 38,565,258 and 37,759,729 weighted-average shares of common stock outstanding for the six months ended June 30, 2019 and 2018, respectively.

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