Puma Biotechnology Reports Fourth Quarter and Full Year Financial Results

February 20, 2020

LOS ANGELES--(BUSINESS WIRE)-- Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2019. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2019, compared to the fourth quarter and full year 2018.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net product revenue in the fourth quarter of 2019 was $58.7 million, compared to net product revenue of $61.1 million in the fourth quarter of 2018. Net product revenue for the full year 2019 was $211.6 million, compared to net product revenue of $200.5 million for the full year 2018.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $11.2 million, or $0.29 per share, for the fourth quarter of 2019, compared to a net loss of $30.7 million, or $0.80 per share, for the fourth quarter of 2018. Net loss for the full year 2019 was $75.6 million, or $1.95 per share, compared to $113.6 million, or $2.99 per share, for the full year 2018.

Non-GAAP adjusted net income was $0.3 million, or $0.01 per share, for the fourth quarter of 2019, compared to non-GAAP adjusted net loss of $12.2 million, or $0.32 per share, for the fourth quarter of 2018. Non-GAAP adjusted net loss for the full year 2019 was $18.3 million, or $0.47 per share, compared to non-GAAP adjusted net loss of $26.7 million, or $0.70 per share, for the full year 2018. 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 provided by operating activities for the fourth quarter of 2019 was $1.6 million, compared to net cash provided by operating activities of $7.1 million for the fourth quarter of 2018. Net cash provided by operating activities for the full year 2019 was $22.4 million, compared to net cash used in operating activities of $24.1 million for the full year 2018. At December 31, 2019, Puma had cash, cash equivalents and marketable securities of $111.6 million, compared to $165.4 million at December 31, 2018.

"During 2019, Puma made broad strides to increase global commercial access to NERLYNX by HER2-positive breast cancer patients, as well as to expand the label and potential therapeutic indications of NERLYNX," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Our year concluded with a label expansion to address NERLYNX side effects, registration approval in Hong Kong and marketing approval in Singapore for NERLYNX, an expanded license agreement with Pierre Fabre, as well as several clinical data presentations at SABCS. We believe these regulatory, commercial, partnering and clinical milestones position Puma for improved results in 2020 and beyond."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) modifying the SUMMIT basket trial to expand the HER2-mutated breast cancer cohort in the first quarter of 2020; (ii) receiving a [U.S.] regulatory decision on neratinib in third-line HER2-positive metastatic breast cancer in the second quarter of 2020; (iii) 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 fourth quarter of 2020; (iv) reporting Phase II data from the HER-positive breast and cervical cancer cohorts from the SUMMIT trial of neratinib in patients with HER2 mutations in the fourth quarter of 2020; (v) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2020; and (vi) 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 fourth quarter of 2019, total revenue was $62.9 million, of which $58.7 million was net product revenue, $4.0 million was license revenue received from Puma's sub-licensees, and $0.2 million was royalty revenue. This compares to total revenue of $71.1 million in the fourth quarter of 2018, of which $61.1 million was net product revenue and $10.0 million was license revenue received from Puma's sub-licensees. For the year ended December 31, 2019, total revenue was $272.3 million, of which $211.6 million was net product revenue, $60.3 million was license revenue received from Puma's sub-licensees and $0.4 million was royalty revenue. This compares to total revenue of $251.0 million for the year ended December 31, 2018, of which $200.5 million was net product revenue and $50.5 million was license revenue received from Puma's sub-licensees.

Operating Costs and Expenses

Total operating costs and expenses were $71.6 million for the fourth quarter of 2019, compared to $89.7 million for the fourth quarter of 2018. Total operating costs and expenses were $311.4 million for the full year 2019 compared to $345.7 million for the

full year 2018.

Cost of Sales

Cost of sales was $10.1 million for the fourth quarter of 2019 and $36.8 million for the full year 2019, compared to $10.3 million for the fourth quarter of 2018 and $34.6 million for the full year 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $31.3 million for the fourth quarter of 2019, compared to $41.0 million for the fourth quarter of 2018. Selling, general and administrative expenses for the full year 2019 were $141.7 million, compared to $146.2 million for full year 2018, a decrease of approximately $4.5 million. The decrease in SG&A expenses for the full year 2019 primarily related to decreases in stock-based compensation expense of approximately $7.0 million, and payroll and related costs of approximately $1.3 million. These decreases were partially offset by an increase in professional fees and expenses of approximately $2.7 million and an impairment loss of approximately $1.2 million.

Research and Development Expenses

Research and development expenses were $30.2 million for the fourth quarter of 2019, compared to $38.4 million for the fourth quarter of 2018. Research and development expenses for the full year 2019 were $132.9 million, compared to $164.9 million for the full year 2018. The decrease of approximately $32.0 million for the full year 2019 resulted primarily from decreases in stock-based compensation expense of approximately $22.6 million, internal R&D expense of approximately $4.7 million, clinical trial expenses of approximately $4.2 million, and consultant and contractor costs of approximately $0.5 million.

Total Other Income (Expenses)

Total other expenses were $2.5 million for the fourth quarter of 2019, compared to $12.1 million for the fourth quarter of 2018. Total other expenses were $36.5 million for the year ended December 31, 2019, compared to $18.9 million for the year ended December 31, 2018. The increase of $17.6 million during the full year 2019 compared to the full year 2018 primarily resulted from an increase in debt extinguishment loss of approximately $8.1 million, an increase in legal verdict expense of approximately $7.4 million, and an increase in interest expense of approximately $4.0 million, partially offset by an increase in interest and other income of approximately $1.9 million.

Conference Call

Puma Biotechnology will host a conference call to report its fourth quarter and full year 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 Thursday, February 20, 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 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-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. 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 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, once filed, Puma's Annual Report on Form 10-K for the year ended December 31, 2019. 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 December 31,		Twelve Months Ended December 31,	
	2019 (Unaudited)	2018 (Unaudited)	2019 (Unaudited)	2018
Revenues:				
Product revenue, net	$ 58.7	$ 61.1	$ 211.6	$ 200.5
License revenue	4.0	10.0	60.3	50.5
Royalty revenue	0.2	—	0.4	—
Total revenue	62.9	71.1	272.3	251.0
Operating costs and expenses:				
Cost of sales	10.1	10.3	36.8	34.6
Selling, general and administrative	31.3	41.0	141.7	146.2

Research and development	30.2	38.4	132.9	164.9
Total operating costs and expenses	71.6	89.7	311.4	345.7
Loss from operations	(8.7)	(18.6)	(39.1)	(94.7)
Other income (expenses):				
Interest income	0.5	0.7	2.8	1.8
Interest expense	(3.1)	(3.8)	(15.0)	(11.0)
Legal verdict expenses	—	(9.0)	(16.4)	(9.0)
Loss on debt extinguishment	—	—	(8.1)	—
Other income (expense)	0.1	—	0.2	(0.7)
Total other expenses	(2.5)	(12.1)	(36.5)	(18.9)
Net loss	$ (11.2)	$ (30.7)	$ (75.6)	$ (113.6)
Net loss per common share—basic and diluted	$ (0.29)	$ (0.80)	$ (1.95)	$ (2.99)
Weighted-average common shares outstanding—basic and diluted	39,043,706	38,201,056	38,768,653	37,942,411

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

	December 31, 2019 (Unaudited)	December 31, 2018
Cash and cash equivalents	$ 60.0	$ 108.4
Marketable securities	51.6	57.0
Working capital	66.6	135.9
Stockholders' equity	17.5	34.3

	Twelve Months Ended December 31, 2019 (Unaudited)	Twelve Months Ended December 31, 2018
Cash provided by (used in):		
Operating activities	$ 22.4	$ (24.1)
Investing activities	5.2	(57.6)
Financing activities	(67.1)	108.4
Increase (decrease) in cash and cash equivalents, and restricted cash	$ (39.5)	$ 26.7

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 twelve months ended December 31, 2019 stock-based compensation represented approximately 18.7% and 20.9% 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 Net Income (Loss) Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended December 31,			
	2019		2018	
GAAP net loss	$ (11.2)		$ (30.7)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	5.0		7.9	(1)
Research and development	6.5		10.6	(2)
Non-GAAP adjusted net income (loss)	$ 0.3		$ (12.2)	
GAAP net loss per share—basic	$ (0.29)		$ (0.80)	
Adjustment to net loss (as detailed above)	0.30		0.48	
Non-GAAP adjusted basic net income (loss) per share	$ 0.01		$ (0.32)	(3)
GAAP net loss per share—diluted	$ (0.29)		$ (0.80)	
Adjustment to net loss (as detailed above)	0.30		0.48	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.01	(4)	$ (0.32)	(5)

	Twelve Months Ended December 31,			
	2019		2018	
GAAP net loss	$ (75.6)		$ (113.6)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	27.9		34.9	(1)
Research and development	29.4		52.0	(2)
Non-GAAP adjusted net loss	$ (18.3)		$ (26.7)	
GAAP net loss per share—basic and diluted	$ (1.95)		$ (2.99)	
Adjustment to net loss (as detailed above)	1.48		2.29	
Non-GAAP adjusted net loss per share	$ (0.47)		$ (0.70)	(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 loss per share was calculated based on 39,043,706 and 38,201,056 weighted-average shares of common stock outstanding for the three months ended December 31, 2019 and 2018, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 39,240,704 weighted-average shares of common stock outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units, and warrants) for the three months ended December 31, 2019.

(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 December 31, 2018 as these shares would be considered anti-dilutive.

(6) Non-GAAP adjusted net loss per share was calculated based on 38,768,653 and 37,942,411 weighted-average shares of common stock outstanding for the years ended December 31, 2019 and 2018, respectively.

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