Puma Biotechnology Reports Fourth Quarter and Full Year Financial Results

February 25, 2021

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

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net NERLYNX revenue in the fourth quarter of 2020 was $50.0 million, compared to $58.7 million in the fourth quarter of 2019. Net NERLYNX revenue for the full year 2020 was $196.7 million, compared to $211.6 million for the full year 2019.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of $15.0 million, or $0.38 per share, for the fourth quarter of 2020, compared to a net loss of $11.2 million, or $0.29 per share, for the fourth quarter of 2019. Net loss for the full year 2020 was $60.0 million, or $1.52 per share, compared to $75.6 million, or $1.95 per share, for the full year 2019.

Non-GAAP adjusted net loss was $5.5 million, or $0.14 per basic and diluted share, for the fourth quarter of 2020, compared to non-GAAP adjusted net income of $0.3 million, or $0.01 per basic and diluted share, for the fourth quarter of 2019. Non-GAAP adjusted net loss for the full year 2020 was $23.4 million, or $0.59 per share, compared to non-GAAP adjusted net loss of $18.3 million, or $0.47 per share, for the full year 2019. Non-GAAP adjusted net (loss) income excludes stock-based compensation expense. For a reconciliation of GAAP net loss to non-GAAP adjusted net (loss) income and GAAP net loss per share to non-GAAP adjusted net (loss) income per share, please see the financial tables at the end of this news release.

Net cash used in operating activities for the fourth quarter of 2020 was $5.6 million, compared to net cash provided by operating activities of $1.6 million for the fourth quarter of 2019. Net cash provided by operating activities for the full year 2020 was $0.8 million, compared to net cash provided by operating activities of $22.4 million for the full year 2019. At December 31, 2020, Puma had cash, cash equivalents, and marketable securities of $93.4 million, compared to $111.6 million at December 31, 2019.

"During the fourth quarter of 2020 Puma continued to be negatively impacted by the challenges of COVID-19; however, we were pleased to be able to achieve NERLYNX revenues that were within the previously stated guidance," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Our year concluded with a number of positive clinical milestones for the Company, including the publication of ExteNET data in *Clinical Breast Cancer,* a research collaboration with NCCN Oncology, the announcement of interim SUMMIT data in exon 18 mutated non-small cell lung cancer, and the presentation of neratinib data at the San Antonio Breast Cancer Symposium across multiple spotlight and traditional poster presentations. Although we anticipate that COVID-19 may continue to impact our operations in 2021, we remain focused on and committed to providing support to patients battling breast cancer."

Mr. Auerbach added, "We anticipate the following key milestones over the next 12 months: (i) completing enrollment in the randomized cohort in the Phase II SUMMIT trial of neratinib in hormone receptor positive breast cancer that has a HER2 mutation in the second quarter of 2021; (ii) reporting top line data from the randomized cohort in the Phase II SUMMIT trial of neratinib in hormone receptor positive breast cancer that has a HER2 mutation in 2021; (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 2021; (iv) reporting Phase II data from the SUMMIT trial of neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations in the second half of 2021; (v) 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 second half of 2021; (vi) conducting a meeting with the FDA to discuss the potential for an accelerated approval pathway for neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations who have been previously treated with an EGFR tyrosine kinase inhibitor in 2021; and (vii) receiving regulatory decisions for the extended adjuvant HER2-positive early stage breast cancer indication in additional countries in 2021."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, license revenue and royalty revenue. For the fourth quarter of 2020, total revenue was $52.6 million, of which $50.0 million was net product revenue and $2.6 million was royalty revenue from Puma's sub-licensees. This compares to total revenue of $62.9 million for the fourth quarter of 2019, of which $58.7 million was net product revenue, $4.0 million was license revenue, and $0.2 million was royalty revenue from Puma's sub-licensees. For the year ended December 31, 2020, total revenue was $225.1 million, of which $196.7 million was net product revenue, $22.7 million was license revenue, and $5.7 million was royalty revenue from Puma's sub-licensees. This compares to total revenue of $272.3 million for the year ended December 31, 2019, of which $211.6 million was net product revenue, $60.3 million was license revenue, and $0.4 million was royalty revenue from Puma's sub-licensees.

Operating Costs and Expenses

Total operating costs and expenses were $63.9 million for the fourth quarter of 2020, compared to $71.5 million for the fourth quarter of 2019. Total operating costs and expenses were $255.5 million for the full year 2020, compared to $311.3 million for the full year 2019.

Cost of Sales

Cost of sales was $10.9 million for the fourth quarter of 2020 and $39.4 million for the full year 2020, compared to $10.1 million for the fourth quarter of 2019 and $36.8 million for the full year 2019. The increase in cost of sales was primarily attributable to increased royalty expense due to the increase in royalty revenue and an increase in the amortization of the intangible asset related to the milestone payments made to Pfizer.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $28.8 million for the fourth quarter of 2020, compared to $31.2 million for the fourth quarter of 2019. Selling, general and administrative expenses for the full year 2020 were $118.4 million, compared to $141.6 million for the full year 2019. The $23.2 million year-over-year decrease resulted primarily from decreases in stock-based compensation expense of approximately $10.1 million, professional fees of approximately $6.1 million, travel and meeting costs of approximately $6.3 million, and impairment loss of approximately $1.2 million, offset by an increase in credit loss expense of $1.0 million.

Research and Development Expenses

Research and development expenses were $24.2 million for the fourth quarter of 2020, compared to $30.2 million for the fourth quarter of 2019. Research and development expenses for the full year 2020 were $97.7 million, compared to $132.9 million for the full year 2019. The $35.2 million year-over-year decrease resulted primarily from decreases in stock-based compensation expense of approximately $10.6 million, internal R&D expenses of approximately $0.9 million, clinical trial expenses of approximately $20.1 million, and consultant and contractor expenses of approximately $3.6 million.

Total Other Income (Expenses)

Total other expenses were $3.7 million for the fourth quarter of 2020, compared to total other expenses of $2.5 million for the fourth quarter of 2019. Total other expenses were $29.4 million for the full year 2020, compared to total other expenses of $36.5 million for the full year 2019. The $7.1 million year-over-year decrease resulted primarily from decreases in interest expense of approximately $0.9 million and debt extinguishment loss of approximately $8.1 million, offset by a decrease in interest income of approximately $2.3 million.

Conference Call

Puma Biotechnology will host a conference call to report its fourth quarter and full year 2020 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 25, 2021. 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. 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 ≥ 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) 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 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, 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.

(Financial Tables Follow)

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,	
	2020	2019	2020	2019
	(Unaudited)	(Unaudited)	(Unaudited)	
Revenues:				
Product revenue, net	$ 50.0	$ 58.7	$ 196.7	$ 211.6
License revenue	—	4.0	22.7	60.3
Royalty revenue	2.6	0.2	5.7	0.4
Total revenue	52.6	62.9	225.1	272.3
Operating costs and expenses:				
Cost of sales	10.9	10.1	39.4	36.8
Selling, general and administrative	28.8	31.2	118.4	141.6
Research and development	24.2	30.2	97.7	132.9
Total operating costs and expenses	63.9	71.5	255.5	311.3
Loss from operations	(11.3)	(8.6)	(30.4)	(39.0)
Other income (expenses):				
Interest income	—	0.5	0.5	2.8
Interest expense	(3.6)	(3.1)	(14.1)	(15.0)
Legal verdict expense	(0.2)	—	(16.2)	(16.4)
Loss on debt extinguishment	—	—	—	(8.1)
Other income	0.1	0.1	0.4	0.2
Total other expenses	(3.7)	(2.5)	(29.4)	(36.5)
Loss before income taxes	(15.0)	(11.1)	(59.8)	(75.5)
Income tax expense	-	(0.1)	(0.2)	(0.1)
Net loss	$ (15.0)	$ (11.2)	$ (60.0)	$ (75.6)
Net loss per share of common stock—basic and diluted	$ (0.38)	$ (0.29)	$ (1.52)	$ (1.95)
Weighted-average shares of common stock outstanding—basic and diluted	39,881,131	39,043,706	39,576,107	38,768,653

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

	December 31, 2020 (Unaudited)	December 31, 2019
Cash and cash equivalents	$ 85.3	$ 60.0
Marketable securities	8.1	51.6
Working capital	31.9	75.5
Stockholders' (deficit) equity	(6.0)	17.5

	Twelve Months Ended December 31, 2020 (Unaudited)	Twelve Months Ended December 31, 2019
Cash provided by (used in):		
Operating activities	$ 0.8	$ 22.4
Investing activities	23.3	5.2
Financing activities	0.1	(67.1)

Increase (decrease) in cash and cash equivalents, and restricted cash	$ 24.2	$ (39.5)

Use of Non-GAAP 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 stock-based compensation. For the three months and full year ended December 31, 2020, stock-based compensation represented approximately 17.9% and 16.9% of operating expenses, respectively, and 18.8% and 20.9%, 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 Loss to Non-GAAP Adjusted Net (Loss) Income and GAAP Net Loss Per Share to Non-GAAP Adjusted Net (Loss) Income Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended December 31,			
	2020		2019	
GAAP net loss	$ (15.0)		$ (11.2)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	4.3		5.0	(1)
Research and development	5.2		6.5	(2)
Non-GAAP adjusted net (loss) income	$ (5.5)		$ 0.3	
GAAP net loss per share—basic	$ (0.38)		$ (0.29)	
Adjustment to net loss (as detailed above)	0.24		0.30	
Non-GAAP adjusted basic net (loss) income per share	$ (0.14)		$ 0.01	(3)
GAAP net loss per share—diluted	$ (0.38)		$ (0.29)	
Adjustment to net loss (as detailed above)	0.24		0.30	
Non-GAAP adjusted diluted net (loss) income per share	$ (0.14)	(4)	$ 0.01	(5)

	Twelve Months Ended December 31,			
	2020		2019	
GAAP net loss	$ (60.0)		$ (75.6)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	17.8		27.9	(1)
Research and development	18.8		29.4	(2)
Non-GAAP adjusted net loss	$ (23.4)		$ (18.3)	
GAAP net loss per share—basic and diluted	$ (1.52)		$ (1.95)	
Adjustment to net loss (as detailed above)	0.93		1.48	
Non-GAAP adjusted net loss per share	$ (0.59)		$ (0.47)	(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) income per share was calculated based on 39,881,131 and 39,043,706 weighted-average shares of common stock outstanding for the three months ended December 31, 2020 and 2019, respectively.

(4) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in the non-GAAP adjusted diluted net loss per share for the three months ended December 31, 2020 as these shares would be considered anti-dilutive.

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

(6) Non-GAAP adjusted net loss per share was calculated based on 39,576,107 and 38,768,653 weighted-average shares of common stock outstanding for the years ended December 31, 2020 and 2019, respectively.

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