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Puma Biotechnology Reports Fourth Quarter and Full Year 2018 Financial Results

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2018. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2018, compared to the fourth quarter and full year 2017.

Product revenue, net consists entirely of sales revenue from NERLYNX, Puma's first commercial product. Net NERLYNX revenue in the fourth quarter of 2018 was \$61.1 million, compared to net NERLYNX revenue of \$20.1 million in the fourth quarter of 2017. Net NERLYNX revenue for the full year 2018 was \$200.5 million, compared to net NERLYNX revenue of \$26.2 million in 2017. Puma received approval from the U.S. Food and Drug Administration (FDA) for NERLYNX (neratinib) for the treatment of early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy on July 17, 2017, and the Company began shipment to wholesalers at the end of July 2017.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of \$30.7 million, or \$0.80 per share, for the fourth quarter of 2018, compared to a net loss of \$64.1 million, or \$1.71 per share, for the fourth quarter of 2017. Net loss for the full year 2018 was \$113.6 million, or \$2.99 per share, compared to \$292.0 million, or \$7.85 per share, for the full year 2017.

Non-GAAP adjusted net loss was \$12.2 million, or \$0.32 per share, for the fourth quarter of 2018, compared to non-GAAP adjusted net loss of \$38.6 million, or \$1.03 per share, for the fourth quarter of 2017. Non-GAAP adjusted net loss for the full year 2018 was \$26.7 million, or \$0.70 per share, compared to non-GAAP adjusted net loss of \$183.3 million, or \$4.93 per share, for the full year 2017. 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 fourth quarter of 2018 was \$7.1 million, compared to net cash used in operating activities of \$35.6 million for the fourth quarter of 2017. Net cash used in operating activities for the full year 2018 was \$24.1 million, compared to \$172.5 million for the full year 2017. At December 31, 2018, Puma had cash and cash equivalents of \$108.4 million and marketable securities of \$57.0 million, compared to cash and cash equivalents of \$81.7 million at December 31, 2017.

"2018 was a strong year for Puma as we continued to grow NERLYNX sales, expanded our global presence and made progress in expanding the potential indications for the drug," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "This was highlighted by the European Commission granting marketing authorization in Europe, additional licensing agreements designed to provide access to NERLYNX in China, Latin America, Israel and Canada, and announcing data from the Phase III NALA trial, Phase II CONTROL trial, and Phase II SUMMIT trials."

Mr. Auerbach added, "During 2019, we anticipate the following key milestones for Puma: (i) meeting with the FDA and the European Medicines Agency to discuss data from the Phase III trial in third-line metastatic breast cancer patients in the first half of 2019; (ii) meeting with the FDA to discuss the clinical development and regulatory strategy for the SUMMIT trial in the first half of 2019; (iii) announcing regulatory decisions on neratinib for the extended adjuvant HER2-positive early stage breast cancer indication in countries outside of the United States and Europe in the first half of 2019; (iv) presenting data from the Phase III trial in third-line HER2-positive metastatic breast cancer treatment (NALA) in the first half of 2019; (v) reporting additional data from the Phase II CONTROL trial in the first half of 2019; and (vi) reporting Phase II data from the SUMMIT basket trial of neratinib in patients with HER2 mutations in the first half of 2019."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product, and license revenue. For the fourth quarter ended December 31, 2018, total revenue was \$71.1 million, of which \$61.1 million was net NERLYNX revenue and \$10.0 million was license revenue. For the year ended December 31, 2018, total revenue was \$251.0 million, of which \$200.5 million was net NERLYNX revenue and \$50.5 million was license revenue received from Puma's sublicensees. This compares to total revenue of \$27.7 million in 2017, of which \$26.2 million was net NERLYNX revenue and \$1.5 million was license revenue.

Operating Costs and Expenses

Total operating costs and expenses were \$89.7 million for the fourth quarter of 2018, compared to \$85.2 million for the fourth quarter of 2017. Total operating costs and expenses were \$345.7 million for the full year 2018 compared to \$320.1 million for the full year 2017.

Cost of Sales:

Cost of sales was \$10.3 million for the fourth quarter and \$34.6 million for the full year 2018, compared to \$4.1 million for the fourth quarter and \$5.6 million for the full year 2017.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were \$41.0 million for the fourth quarter of 2018, compared to selling, general and administrative expenses of \$30.9 million for the fourth quarter of 2017. Selling, general and administrative expenses for full year 2018 were \$146.2 million, compared to \$106.7 million for full year 2017, an increase of approximately \$39.5 million. Increases in SG&A expenses for the full year 2018 primarily related to the hiring of a sales force and the commercial launch of NERLYNX, including approximately \$18.9 million in payroll and related expenses, \$8.2 million in travel and meetings, \$6.0 million in professional fees, such as marketing, market access and analytics, \$3.7 million in stock-based compensation and \$2.6 million in other expenses, such as software and facilities, to support overall corporate growth.

Research and Development Expenses:

Research and development expenses were \$38.4 million for the fourth quarter of 2018, compared to \$50.2 million for the fourth quarter of 2017. Research and development expenses for the full year 2018 were \$164.9 million, compared to \$207.8 million for the full year 2017. The decrease of \$42.9 million during the full year 2018 compared to the full year 2017 resulted primarily from decreases of approximately \$25.5 million in stock-based compensation, \$16.8 million in clinical trial expense, \$2.6 million in consultant and contractor expense, partially offset by increases of approximately \$2.0 million in R&D expenses primarily related to headcount additions in the medical affairs, quality assurance, regulatory affairs and pharmacovigilance.

Total Other Income (Expenses)

Total other expenses were \$12.1 million for the fourth quarter of 2018, compared to total other expenses of \$0.5 million for the fourth quarter of 2017. Total other expenses were \$18.9 million for the year ended December 31, 2018, compared to total other income of \$0.4 million for the year ended December 31, 2017. Other expense recorded in the fourth quarter of 2018 includes \$9.0 million that represents an initial estimate of potential amounts that may be owed to class action participants as a result of the February 2019 jury verdict in a class action lawsuit, *Hsu vs. Puma Biotechnology, Inc., et al.* The total amount of aggregate class-wide damages is uncertain and will be ascertained only after an extensive claims process and the exhaustion of any appeals. It is possible that the total damages will be higher than this estimate.

Conference Call

Puma will host a conference call to report its fourth quarter and full year 2018 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 28, 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. Puma 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 for the extended adjuvant treatment of hormone receptor-positive HER2-positive early stage breast cancer in September 2018. 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 \geq 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 ($\geq 5\%$) 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 3 hours after antacid dosing.
- 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.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and health care 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.

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.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Puma’s anticipated milestones for 2019 and initial estimate of damages to be paid to participants in a class-action lawsuit against Puma. 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, 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 SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)**

	Three Months Ended		Twelve Months Ended	
	December 31, (Unaudited)		December 31,	
	2018	2017	2018	2017
Revenues:				
Product revenue, net	\$ 61.1	\$ 20.1	\$ 200.5	\$ 26.2
License revenue	10.0	1.5	50.5	1.5
Total revenue	71.1	21.6	251.0	27.7
Operating costs and expenses:				
Cost of sales	10.3	4.1	34.6	5.6
Selling, general and administrative	41.0	30.9	146.2	106.7
Research and development	38.4	50.2	164.9	207.8
Total operating costs and expenses	89.7	85.2	345.7	320.1
Loss from operations	(18.6)	(63.6)	(94.7)	(292.4)

Other income (expenses):				
Interest income	0.7	0.2	1.8	1.2
Interest expense	(3.8)	(0.7)	(11.0)	(0.7)
Other expense	(9.0)	-	(9.7)	(0.1)
Total other income (expenses)	(12.1)	(0.5)	(18.9)	0.4
Net loss	\$ (30.7)	\$ (64.1)	\$ (113.6)	\$ (292.0)
Net loss per common share—basic and diluted	\$ (0.80)	\$ (1.71)	\$ (2.99)	\$ (7.85)
Weighted-average common shares outstanding—basic and diluted	38,201,056	37,534,410	37,942,411	37,169,678

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

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 108.4	\$ 81.7
Marketable securities	57.0	—
Working capital	135.9	48.1
Stockholders' equity	34.3	53.3
	Twelve Months Ended December 31, 2018	Twelve Months Ended December 31, 2017
Cash provided by (used in):		
Operating activities	\$ (24.1)	\$ (172.5)
Investing activities	(57.6)	(15.4)
Financing activities	108.4	75.1
Increase (decrease) in cash and cash equivalents, and restricted cash	\$ 26.7	\$ (112.8)

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 Puma'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 and twelve months ended December 31, 2018, stock-based compensation represented approximately 60.3% and 76.5% of net loss, respectively. 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 SUBSIDIARY
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 December 31,		
	2018	2017	
GAAP net loss	\$ (30.7)	\$ (64.1)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	7.9	8.2	(1)
Research and development	10.6	17.3	(2)
Non-GAAP adjusted net loss	\$ (12.2)	\$ (38.6)	
GAAP net loss per share - basic	\$ (0.80)	\$ (1.71)	
Adjustment to net loss (as detailed above)	0.48	0.68	
Non-GAAP adjusted net loss per share	\$ (0.32)	\$ (1.03)	(3)
	Twelve Months Ended December 31,		
	2018	2017	
GAAP net loss	\$ (113.6)	\$ (292.0)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	34.9	31.2	(1)
Research and development	52.0	77.5	(2)
Non-GAAP adjusted net loss	\$ (26.7)	\$ (183.3)	
GAAP net loss per share - basic and diluted	\$ (2.99)	\$ (7.85)	
Adjustment to net loss (as detailed above)	2.29	2.92	
Non-GAAP adjusted net loss per share	\$ (0.70)	\$ (4.93)	(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 38,201,056 and 37,534,410 weighted average shares of common stock outstanding for the three months ended December 31, 2018 and 2017, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 37,942,411 and 37,169,678 weighted average shares of common stock outstanding for the twelve months ended December 31, 2018 and 2017, respectively.

Language:

English

Contact:

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull or Alex Fudukidis, Russo Partners, +1-212-845-4271

david.schull@russopartnersllc.com

alex.fudukidis@russopartnersllc.com

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