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Puma Biotechnology Reports Third Quarter 2017 Financial Results

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LOS ANGELES

Results include the initial sales of NERLYNX[®] in the U.S.

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter and nine months ended September 30, 2017. Unless otherwise stated, all comparisons are for the third quarter and nine months of 2017 compared to the third quarter and nine months of 2016.

On July 17, 2017, Puma Biotechnology 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, and began shipments to wholesalers at the end of July 2017. In the third quarter of 2017, the Company reported net revenue from initial sales of NERLYNX of approximately \$6.1 million.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$77.2 million, or \$2.07 per share, for the third quarter of 2017, compared to a net loss applicable to common stock of \$65.8 million, or \$2.02 per share, for the third quarter of 2016. Net loss applicable to common stock for the first nine months of 2017 was \$227.9 million, or \$6.15 per share, compared to \$203.4 million, or \$6.26 per share, for the first nine months of 2016.

Non-GAAP adjusted net loss was \$50.7 million, or \$1.36 per share, for the third quarter of 2017, compared to non-GAAP adjusted net loss of \$36.0 million, or \$1.11 per share, for the third quarter of 2016. Non-GAAP adjusted net loss for the nine months ended September 30, 2017 was \$144.7 million, or \$3.90 per share, compared to non-GAAP adjusted net loss of \$115.4 million, or \$3.55 per share, for the nine months ended September 30, 2016. Non-GAAP adjusted net loss excludes stock-based compensation expense, which represents a significant portion of overall expense and has no impact on the cash position of the Company. 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 2017 was \$54.9 million. Net cash used in operating activities for the nine months ended September 30, 2017 was \$136.9 million. At September 30, 2017, Puma had cash and cash equivalents of \$79.7 million and marketable securities of \$26.6 million, compared to cash and cash equivalents of \$194.5 million and marketable securities of \$35.0 million at December 31, 2016.

Effective October 31, 2017, Puma entered into a credit facility with Silicon Valley Bank and Oxford Finance for a term loan of up to \$100 million, subject to funding in two tranches. The Company received gross proceeds of \$50 million from the first tranche of the credit facility upon closing on October 31, 2017 and intends to use the funds for general corporate purposes and to further support NERLYNX commercial initiatives. The second tranche of \$50 million may be drawn at the Company's option and is subject to the achievement of certain milestones. The loan will mature on October 31, 2022.

"With the U.S. approval and launch of NERLYNX in the third quarter, we began providing early stage HER2-positive breast cancer patients with an additional option to reduce their risk of disease recurrence," said Puma Chief Executive Officer and President Alan H. Auerbach. "We are pleased with the feedback that we have received from patients, prescribers and payors during the initial launch and we look forward to continuing to execute our commercial activities throughout 2017 and beyond.

"Looking forward, we anticipate the following milestones: (i) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2017; (ii) receiving a regulatory opinion from the Committee for Medicinal Products for Human Use (CHMP) for neratinib in extended adjuvant HER2-positive early stage breast cancer in the first quarter of 2018; and (iii) reporting Phase III trial results in third-line HER2-positive metastatic breast cancer patients in the first half of 2018."

Product Revenue

Net revenue consists of sales of NERLYNX, Puma's first and only commercial product to date. The FDA approved NERLYNX in July 2017 and the Company commenced shipment to wholesalers in late July. For the three and nine months ended September 30, 2017, net revenue was approximately \$6.1 million.

Operating Expenses

Operating expenses were \$83.5 million for the third quarter of 2017, compared to \$66.0 million for the third quarter of 2016.

Operating expenses for the nine months ended September 30, 2017 were \$234.9 million, compared to \$203.7 million for the nine months ended September 30, 2016.

Cost of Sales:

Cost of sales was \$1.5 million for the third quarter and nine months ended September 30, 2017. The Company had no product sales prior to the third quarter of 2017.

Selling, General and Administrative Expenses:

Selling, general and administrative (SG&A) expenses were \$32.5 million for the third quarter of 2017, compared to \$14.0 million for the third quarter of 2016. SG&A expenses for the nine months ended September 30, 2017 were \$75.8 million, compared to \$37.3 million for the nine months ended September 30, 2016. The \$38.5 million increase during the first nine months of 2017, compared to the first nine months of 2016, resulted primarily from increases of approximately \$24.2 million for professional fees and expenses, \$8.2 million in payroll and related costs, \$3.2 million for stock-based compensation, \$2.4 million for other expenses such as travel and related costs to support the commercial launch of NERLYNX, and \$0.4 million for facility and equipment costs. These increases reflect overall corporate growth.

Research and Development Expenses:

Research and development (R&D) expenses were \$49.5 million for the third quarter of 2017, compared to \$52.0 million for the third quarter of 2016. R&D expenses for the nine months ended September 30, 2017 were \$157.6 million, compared to \$166.4 million for the nine months ended September 30, 2016. The approximately \$8.8 million decrease during the first nine months of 2017, compared to the first nine months of 2016, resulted primarily from decreases of approximately \$5.0 million due to a decrease in regulatory submission activity, decreased preclinical study activities and decreased drug supply manufacturing logistics, and \$8.0 million for stock-based compensation, partially offset by increases during the first nine months of 2017, compared to the first nine months of 2016, of approximately \$2.2 million for internal clinical development, internal regulatory affairs and quality assurance and internal chemical manufacturing, and \$2.0 million for consultants and contractors.

Conference Call

Puma Biotechnology will host a conference call to report its third quarter 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, November 9, 2017. 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. NERLYNX[®] (neratinib, oral) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

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 \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.

Forward-Looking Statements

This press release and the webcast of the presentation contain forward-looking statements, including statements regarding the benefits of NERLYNX and neratinib, the Company's clinical trials and the announcement of data relative to those trials. All forward-looking statements involve risks and uncertainties that could cause the Company'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 the Company with the Securities and Exchange Commission from time to time, including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company 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 September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2017	2016	2017	2016
Revenue, net	\$ 6.1	\$ -	\$ 6.1	\$ -
Operating expenses:				
Cost of sales	1.5	-	1.5	-
Selling, general and administrative	32.5	14.0	75.8	37.3
Research and development	49.5	52.0	157.6	166.4
Totals	83.5	66.0	234.9	203.7
Loss from operations	(77.4)	(66.0)	(228.8)	(203.7)
Other income (expenses):				
Interest income	0.3	0.2	1.0	0.7
Other income (expense)	(0.1)	-	(0.1)	(0.4)
Totals	0.2	0.2	0.9	0.3
Net loss	\$ (77.2)	\$ (65.8)	\$ (227.9)	\$ (203.4)
Net loss per common share—basic and diluted	\$ (2.07)	\$ (2.02)	\$ (6.15)	\$ (6.26)
Weighted-average common shares outstanding—basic and diluted	37,214,002	32,497,168	37,046,765	32,489,584

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

LIQUIDITY AND CAPITAL RESOURCES

(in millions, unaudited)

	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 79.7	\$ 194.5
Marketable securities	26.6	35.0
Working capital	22.3	199.0
Stockholders' equity	79.2	209.8
	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Cash provided by (used in):		
Operating activities	\$ (136.9)	\$ (100.7)
Investing activities	8.1	121.4
Financing activities	14.0	0.3
Increase (decrease) in cash and cash equivalents	\$ (114.8)	\$ 21.0

Non-GAAP Financial Measures

In addition to operating results as calculated in accordance with generally accepted accounting principles, or GAAP, the Company 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 and nine months ended September 30, 2017, stock-based compensation represented approximately 34.3% and 36.5% of net loss, respectively. Although net loss is important to measure financial performance, the Company currently places an emphasis on cash burn and, more specifically, cash used in operations. Stock-based compensation appears in GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows. Due to its noncash nature, the Company believes these non-GAAP measures enhance understanding of financial performance, are more indicative of 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 Net Loss Per Share

(in millions except share and per share data)

(Unaudited)

	Three Months Ended September 30,	
	2017	2016
GAAP net loss	\$ (77.2)	\$ (65.8)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative	8.3	7.7
Research and development	18.2	22.1
Non-GAAP adjusted net loss	\$ (50.7)	\$ (36.0)

GAAP net loss per share - basic and diluted	\$	(2.07)	\$	(2.02)	
Adjustment to net loss (as detailed above)		0.71		0.91	
Non-GAAP adjusted net loss per share	\$	(1.36)	\$	(1.11)	(3)

Nine Months Ended September 30,

	2017	2016	
GAAP net loss	\$ (227.9)	\$ (203.4)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	23.0	19.7	(1)
Research and development	60.2	68.3	(2)
Non-GAAP adjusted net loss	\$ (144.7)	\$ (115.4)	
GAAP net loss per share - basic and diluted	\$ (6.15)	\$ (6.26)	
Adjustment to net loss (as detailed above)	2.25	2.71	
Non-GAAP adjusted net loss per share	\$ (3.90)	\$ (3.55)	(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 37,214,002 and 32,497,168 weighted average common shares outstanding for the three months ended September 30, 2017 and 2016, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 37,046,765 and 32,489,584 weighted average common shares outstanding for the nine months ended September 30, 2017 and 2016, respectively.

Language:

English

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