Puma Biotechnology Reports Third Quarter 2018 Financial Results

November 1, 2018

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2018. Unless otherwise stated, all comparisons are for the third quarter 2018 compared to the third quarter 2017.

Net product revenue in the third quarter of 2018 was $52.6 million, compared to net product revenue of $6.1 million in the third quarter of 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 on July 17, 2017, and the Company began shipment to wholesalers at the end of July 2017.

Based on generally accepted accounting principles in the United States (GAAP), Puma reported a net loss applicable to common stock of $14.2 million, or $0.37 per share, for the third quarter of 2018, compared to a net loss applicable to common stock of $77.2 million, or $2.07 per share, for the third quarter of 2017. Net loss applicable to common stock for the first nine months of 2018 was $82.9 million, or $2.19 per share, compared to $227.9 million, or $6.15 per share, for the first nine months of 2017.

Non-GAAP adjusted net income was $6.6 million, or $0.17 per basic share and $0.16 per diluted share, for the third quarter of 2018, compared to non-GAAP adjusted net loss of $50.7 million, or $1.36 per share, for the third quarter of 2017. Non-GAAP adjusted net loss for the first nine months of 2018 was $14.5 million, or $0.38 per basic and diluted share, compared to non-GAAP adjusted net loss of $144.7 million, or $3.90 per share, for the first nine months of 2017. Non-GAAP adjusted net income (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 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 used in operating activities for the third quarter of 2018 was $7.3 million. Net cash used in operating activities for the first nine months of 2018 was $31.2 million. At September 30, 2018, Puma had cash and cash equivalents of $68.3 million and marketable securities of $59.7 million, compared to cash and cash equivalents of $81.7 million at December 31, 2017.

“The third quarter of 2018 marked the achievement of another important milestone for Puma with the European Commission granting marketing authorization for NERLYNX for the extended adjuvant treatment of hormone receptor positive HER2-positive early stage breast cancer,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “We expect this new medicine to be commercially available to patients in Europe in 2019, beginning with the expected launch in Germany during the first half of 2019 and followed by additional countries throughout Europe in the second half of 2019.”

“We also continue to drive toward expanding availability of NERLYNX throughout the world,” Mr. Auerbach added. “In the third quarter, our New Drug Submission was accepted in Canada, and our licensing partner in China, CANbridge Pharmaceutical Inc., received confirmation that the country’s National Medical Products Administration accepted its New Drug Application for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, following adjuvant trastuzumab based-therapy.”

Mr. Auerbach added, “We anticipate the following key milestones over the next 12 months: (i) reporting data from the Phase III NALA trial in third-line metastatic breast cancer patients in the fourth quarter of 2018 or first half of 2019; (ii) submitting for regulatory approval of NERLYNX for the extended adjuvant HER2-positive early stage breast cancer indication in additional countries in the fourth quarter of 2018 and first half of 2019; (iii) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2018; (iv) reporting additional data from the Phase II SUMMIT trial in the fourth quarter of 2018 or first half of 2019; and (v) meeting with the FDA in the first quarter of 2019 to discuss the clinical development and regulatory strategy for neratinib in HER2 mutated cancers based on the results of the ongoing SUMMIT Phase II trial.”

Revenue

Total revenue consists of net product revenue from sales of NERLYNX, Puma’s first and only commercial product to date, and license revenue. For the third quarter of 2018, total revenue was $62.6 million, of which $52.6 million was net product revenue and $10.0 million was license revenue received from one of Puma’s sub-licensees. For the first nine months of 2018, total revenue was $179.9 million, of which $139.4 million was net product revenue and $40.5 million was license revenue. The FDA approved NERLYNX for commercial sale in the United States in July 2017 and Puma commenced shipment to wholesalers in late July.

Operating Costs and Expenses

Operating costs and expenses were $73.9 million for the third quarter of 2018, compared to $83.5 million for the third quarter of 2017. Operating costs and expenses for the first nine months of 2018 were $256.0 million, compared to $234.9 million for the first

nine months of 2017.

Cost of Sales:

Cost of sales was $9.0 million for the third quarter of 2018 and $24.3 million for the first nine months of 2018, compared to $1.5 million for the third quarter and first nine months of 2017. The Company had no product sales prior to the third quarter of 2017.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were $28.5 million for the third quarter of 2018, compared to $32.5 million for the third quarter of 2017. SG&A expenses for the first nine months of 2018 were $105.2 million, compared to $75.8 million for the first nine months of 2017. The $29.4 million year-to-date increase was attributable to increases of approximately $26.9 million in internal expenses, such as payroll and payroll-related expenses attributable to the addition of a salesforce since the third quarter of 2017. External expenses declined approximately $1.5 million during the same time period and employee stock-based compensation increased approximately $4.0 million, primarily related to the addition of sales staff to support the commercial launch of NERLYNX in the United States. Puma expects SG&A expenses in 2018 and into 2019 to remain higher than in 2017 as it markets NERLYNX commercially in the United States and launches the product in other territories.

Research and Development Expenses:

Research and development (R&D) expenses were $36.4 million for the third quarter of 2018, compared to $49.5 million for the third quarter of 2017. R&D expenses for the first nine months of 2018 were $126.5 million, compared to $157.5 million for the first nine months of 2017. The $31.0 million year-to-date decrease resulted primarily from decreases of approximately $18.9 million in stock-based compensation and of approximately $15.4 million for external expenses related to clinical trials, manufacturing and logistics associated with clinical supply. Puma expects R&D expenses in 2018 to continue to decline slightly when compared with R&D expenses in 2017 based on a decline in clinical trial activities as existing trials continue to wind down.

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 U.S. Food and Drug Administration 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≥ 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 inpatients 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 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 the benefits of NERLYNX and neratinib, the progress and expected timing of the Company's clinical trials, the announcement of data relative to those trials, and the worldwide commercialization of NERLYNX. 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, 2017. 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 September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2018	2017	2018	2017
Product revenue, net	$ 52.6	$ 6.1	$ 139.4	$ 6.1
License revenue	10.0	—	40.5	—
Total revenue	62.6	6.1	179.9	6.1
Operating costs and expenses:				
Cost of sales	9.0	1.5	24.3	1.5
Selling, general and administrative	28.5	32.5	105.2	75.8
Research and development	36.4	49.5	126.5	157.6
Totals	73.9	83.5	256.0	234.9
Loss from operations	(11.3)	(77.4)	(76.1)	(228.8)
Other income (expenses):				
Interest income	0.6	0.3	1.1	1.0
Interest expense	(3.5)	—	(7.2)	—
Other expense	-	(0.1)	(0.7)	(0.1)
Totals	(2.9)	0.2	(6.8)	0.9

Net loss	$ (14.2)	$ (77.2)	$ (82.9)	$ (227.9)
Net loss per common share—basic and diluted	$ (0.37)	$ (2.07)	$ (2.19)	$ (6.15)
Weighted-average common shares outstanding—basic and diluted	38,043,174	37,214,002	37,855,249	37,046,765

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 68.3	$ 81.7
Marketable securities	59.7	—
Working capital	116.5	48.1
Stockholders' equity	45.9	53.3

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Cash provided by (used in):		
Operating activities	$ (31.2)	$ (136.9)
Investing activities	(60.2)	8.1
Financing activities	78.0	14.0
Decrease in cash and cash equivalents, and restricted cash	$ (13.4)	$ (114.8)

Non-GAAP Financial Measures

In addition to operating results as calculated in accordance with 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, 2018, stock-based compensation represented approximately 32.0% and 29.5% of operating expense (which does not include cost of sales), 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 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 September 30,		
	2018	**2017**	
GAAP net loss	$ (14.2)	$ (77.2)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	9.4	8.3	(1)
Research and development	11.4	18.2	(2)
Non-GAAP adjusted net income (loss)	$ 6.6	$ (50.7)	

GAAP net loss per share - basic	$ (0.37)		$ (2.07)	
Adjustment to net income (loss) (as detailed above)	0.54		0.71	
Non-GAAP adjusted net income (loss) per share	$ 0.17		$ (1.36)	(3)
GAAP net loss per share—diluted	$ (0.36)		$ (2.07)	
Adjustment to net loss (as detailed above)	0.52		0.71	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.16	(4)	$ (1.36)	(5)

	Nine Months Ended September 30,		
	2018	2017	
GAAP net loss	$ (82.9)	$ (227.9)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	27.0	23.0	(1)
Research and development	41.4	60.2	(2)
Non-GAAP adjusted net loss	$ (14.5)	$ (144.7)	
GAAP net loss per share - basic and diluted	$ (2.19)	$ (6.15)	
Adjustment to net loss (as detailed above)	1.81	2.25	
Non-GAAP adjusted net loss per share	$ (0.38)	$ (3.90)	(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 net income (loss) per share was calculated based on 38,043,174 and 37,214,002 weighted average common shares outstanding for the three months ended September 30, 2018 and 2017, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 39,677,446 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended September 30, 2018.

(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 September 30, 2017 as these shares would be considered anti-dilutive.

(6) Non-GAAP adjusted net loss per share was calculated based on 37,855,249 and 37,046,765 weighted average common shares outstanding for the nine months ended September 30, 2018 and 2017, respectively.

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