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Puma Biotechnology Reports Second Quarter 2016 Financial Results

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LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, today announced financial results for the second quarter ended June 30, 2016.

Unless otherwise stated, all comparisons are for the second quarter and six months ended June 30, 2016, compared to the second quarter and six months ended June 30, 2015.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$66.6 million, or \$2.05 per share, for the second quarter of 2016, compared to a net loss applicable to common stock of \$64.7 million, or \$2.01 per share, for the second quarter of 2015. Net loss applicable to common stock for the first half of 2016 was \$137.6 million, or \$4.23 per share, compared to \$117.1 million, or \$3.68 per share, for the first half of 2015.

Non-GAAP adjusted net loss was \$37.9 million, or \$1.17 per share, for the second quarter of 2016, compared to non-GAAP adjusted net loss of \$36.5 million, or \$1.13 per share, for the second quarter of 2015. Non-GAAP adjusted net loss for the first half of 2016 was \$79.3 million, or \$2.44 per share, compared to \$68.8 million, or \$2.16 per share, for the first half of 2015. 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. The Company anticipates that non-GAAP net loss will continue to decrease in subsequent quarters due to a continued reduction in clinical trial expenses and due to a reduction in expenses associated with the completion of the regulatory filings for neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in Europe and the United States, which were submitted in June and July, respectively.

Net cash used in operating activities for the second quarter of 2016 was \$30.8 million. Net cash used in operating activities for the first half of 2016 was \$65.8 million. At June 30, 2016, Puma had cash and cash equivalents of \$57.8 million and marketable securities of \$85.9 million, compared to cash and cash equivalents of \$31.6 million and marketable securities of \$184.3 million at December 31, 2015. The Company anticipates that net cash used in operating activities will continue to decrease in subsequent quarters due to a reduction in the expenses described above.

"We are very pleased with the accomplishments of the Company," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "These milestones include the submission of the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in June and the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in July for neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer based on the positive ExteNET Phase III trial. We also reported positive Phase II data from an investigator sponsored trial of neratinib in patients with HER2 mutated, non-amplified breast cancer in June. In addition, our Phase II trial of neratinib in the front-line treatment of HER2-positive metastatic breast cancer (NEFERT-T trial) was published in *JAMA Oncology* in April, and positive results from the I-SPY 2 Phase II clinical trial of neratinib for the neoadjuvant treatment of breast cancer was published in the July 7 issue of *The New England Journal of Medicine*.

"In the second half of 2016, we look forward to several regulatory and clinical milestones with neratinib. From the regulatory perspective, we look forward to working with the EMA and FDA as they review our MAA and NDA submission, respectively. We also look forward to continuing our development of neratinib in the second half of 2016 and beyond. We anticipate (i) reporting additional data from the Phase II trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer using loperamide prophylaxis in the fourth quarter of 2016; (ii) reporting additional Phase II data from the FB-7 neoadjuvant HER2-positive breast cancer trial in the subgroup of patients who are MammaPrint High in the fourth quarter of 2016; (iii) reporting data from the Phase II trial of neratinib plus fulvestrant in patients with HER2 non-amplified breast cancer that has a HER2 mutation during the fourth quarter of 2016; (iv) reporting data from the Phase III trial of neratinib in third-line HER2-positive metastatic breast cancer patients in either the fourth quarter of 2016 or the first quarter of 2017; and (v) reporting data from the Phase II trial of neratinib in metastatic breast cancer patients with brain metastases during the fourth quarter of 2016."

Operating Expenses

Operating expenses were \$66.5 million for the second quarter of 2016, compared to \$64.9 million for the second quarter of 2015. Operating expenses for the first half of 2016 were \$137.7 million compared to \$117.5 million for the first half of 2015.

General and Administrative Expenses:

General and administrative expenses were \$12.3 million for the second quarter of 2016, compared to \$5.5 million for the second quarter of 2015. General and administrative expenses for the first half of 2016 were \$23.3 million compared to \$13.4 million for the first half of 2015. The increase of approximately \$9.9 million resulted primarily from increases of approximately \$4.6 million in stock-based compensation, \$2.9 million in professional fees and expenses, \$1.3 million in payroll and related costs, and \$1.0 million in facility and equipment costs. These increases reflect higher legal and compliance expenses, as well as overall corporate growth.

Research and Development Expenses:

Research and development expenses were \$54.2 million for the second quarter of 2016, compared to \$59.4 million for the second quarter of 2015. Research and development expenses for the first half of 2016 were \$114.4 million, compared to \$104.1 million for the first half of 2015. The increase of approximately \$10.3 million resulted primarily from increases of approximately \$5.3 million in stock-based compensation and \$4.3 million for internal clinical development, regulatory and quality assurance expenses. We expect research and development expenses to decrease in subsequent quarters as we complete clinical trials and as our regulatory filings for neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer have been submitted in the United States and European Union.

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. 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 development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2.

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 commencement and completion of various clinical trials and the announcement of data relative to these trials and the expected decrease in non-GAAP net loss, certain expenses and net cash used in operating activities in subsequent quarters. All forward-looking statements included in this press release 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 fact that the Company has no product revenue and no products approved for marketing, the Company's dependence on PB272, which is still under development and may never receive regulatory approval, the challenges associated with conducting and enrolling clinical trials, the risk that the results of clinical trials may not support the Company's drug candidate claims, even if approved, the risk that physicians and patients may not accept or use the Company's products, the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates, the Company's dependence on licensed intellectual property, and the other 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 Annual Report on Form 10-K for the year ended December 31, 2015. 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.

(Financial Tables Follow)

**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)**

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	(Unaudited)		(Unaudited)	
	2016	2015	2016	2015
Operating expenses:				
General and administrative	\$ 12.3	\$ 5.5	\$ 23.3	\$ 13.4
Research and development	54.2	59.4	114.4	104.1
Totals	66.5	64.9	137.7	117.5
Loss from operations	(66.5)	(64.9)	(137.7)	(117.5)
Other income (expenses):				
Interest income	0.3	0.2	0.5	0.3

Other income (expense)	(0.4)	—	(0.4)	0.1
Totals	(0.1)	0.2	0.1	0.4
Net loss	\$ (66.6)	\$ (64.7)	\$ (137.6)	\$ (117.1)
Net loss per common share—basic and diluted	\$ (2.05)	\$ (2.01)	\$ (4.23)	\$ (3.68)
Weighted-average common shares outstanding—basic and diluted	32,493,092	32,158,108	32,485,750	31,874,346

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

	June 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 57.8	\$ 31.6
Marketable securities	85.9	184.3
Receivable	1.2	—
Working capital	114.8	191.1
Stockholders' equity	127.1	206.0
	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Cash provided by (used in):		
Operating activities	\$ (65.8)	\$ (84.6)
Investing activities	91.9	(120.8)
Financing activities	0.2	226.7
Increase in cash and cash equivalents	\$ 26.3	\$ 21.3

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of employee stock-based compensation. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods.

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 June 30,	
	2016	2015
GAAP net loss	\$ (66.6)	\$ (64.7)
Adjustments:		

Stock-based compensation -			
General and administrative	6.1	2.7	(1)
Research and development	22.6	25.5	(2)
Non-GAAP adjusted net loss	<u>\$ (37.9)</u>	<u>\$ (36.5)</u>	
GAAP net loss per share - basic and diluted	\$ (2.05)	\$ (2.01)	
Adjustment to net loss (as detailed above)	0.88	0.88	
Non-GAAP adjusted net loss per share	<u>\$ (1.17)</u>	<u>\$ (1.13)</u>	(3)

Six Months Ended June 30,

	<u>2016</u>	<u>2015</u>	
GAAP net loss	<u>\$ (137.6)</u>	<u>\$ (117.1)</u>	
Adjustments:			
Stock-based compensation -			
General and administrative	12.1	7.4	(1)
Research and development	46.2	40.9	(2)
Non-GAAP adjusted net loss	<u>\$ (79.3)</u>	<u>\$ (68.8)</u>	
GAAP net loss per share - basic and diluted	\$ (4.23)	\$ (3.68)	
Adjustment to net loss (as detailed above)	1.79	1.52	
Non-GAAP adjusted net loss per share	<u>\$ (2.44)</u>	<u>\$ (2.16)</u>	(4)

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- (1) To reflect a non-cash charge to operating expense for 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 32,493,092 and 32,158,108 weighted average common shares outstanding for the three months ended June 30, 2016 and 2015, respectively.
- (4) Non-GAAP adjusted net loss per share was calculated based on 32,485,750 and 31,874,346 weighted average common shares outstanding for the six months ended June 30, 2016 and 2015, respectively.

Language:

English

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