



Puma Biotechnology Reports Third Quarter 2016 Financial Results

November 9, 2016

LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2016.

Unless otherwise stated, all comparisons are for the third quarter and nine months ended September 30, 2016, compared to the third quarter and nine months ended September 30, 2015.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$65.8 million, or \$2.02 per share, for the third quarter of 2016, compared to a net loss of \$60.4 million, or \$1.87 per share, for the third quarter of 2015. Net loss applicable to common stock for the nine months ended September 30, 2016 was \$203.4 million, or \$6.26 per share, compared to \$177.6 million, or \$5.55 per share, for the nine months ended September 30, 2015.

Non-GAAP adjusted net loss was \$36.0 million, or \$1.11 per share, for the third quarter of 2016, compared to non-GAAP adjusted net loss of \$35.5 million, or \$1.10 per share, for the third quarter of 2015. Non-GAAP adjusted net loss for the nine months ended September 30, 2016 was \$115.4 million, or \$3.55 per share, compared to \$104.3 million, or \$3.26 per share, for the nine months ended September 30, 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.

Net cash used in operating activities for the third quarter of 2016 was \$34.9 million. Net cash used in operating activities for the nine months ended September 30, 2016 was \$100.7 million. At September 30, 2016, Puma had cash and cash equivalents of \$52.5 million and marketable securities of \$56.4 million, compared to cash and cash equivalents of \$31.6 million and marketable securities of \$184.3 million at December 31, 2015. The Company's balance of cash, cash equivalents and marketable securities at the end of the quarter does not include the net proceeds of approximately \$162 million received from the Company's public offering in October 2016.

"During the third quarter, we achieved several key milestones, including the European Medicines Agency's (EMA) validation of the Marketing Authorization Application (MAA) for neratinib as an extended adjuvant treatment of HER2-positive early stage breast cancer in Europe, and the U.S. Food and Drug Administration's (FDA) acceptance of the New Drug Application (NDA) for neratinib as an extended adjuvant treatment for patients with early stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab (Herceptin)-based therapy," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma.

"We anticipate a number of additional milestones through the end of 2016 and first half of 2017," Mr. Auerbach added. "These include: (i) reporting additional data in the fourth quarter of 2016 from the Phase II trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer using loperamide and budesonide prophylaxis; (ii) reporting additional Phase II data in the fourth quarter of 2016 from the FB-7 neoadjuvant HER2-positive breast cancer trial in the subgroup of patients who are MammaPrint High; (iii) reporting data in the fourth quarter of 2016 from the Phase II trial of neratinib plus fulvestrant in patients with HER2 non-amplified breast cancer that has a HER2 mutation; (iv) reporting data in the first half of 2017 from the Phase III trial of neratinib in third-line HER2-positive metastatic breast cancer patients; and (v) reporting data during the first half of 2017 from the Phase II trial of neratinib in HER2-positive metastatic breast cancer patients with brain metastases."

Operating Expenses

Operating expenses were \$66.0 million for the third quarter of 2016, compared to \$60.7 million for the third quarter of 2015. Operating expenses for the nine months ended September 30, 2016 were \$203.7 million, compared to \$178.2 million for the nine months ended September 30, 2015.

General and Administrative Expenses:

General and administrative expenses were \$14.0 million for the third quarter of 2016, compared to \$8.8 million for the third quarter of 2015. General and administrative expenses for the nine months ended September 30, 2016 were \$37.3 million, compared to \$22.2 million for the nine months ended September 30, 2015. The increase of approximately \$15.1 million during the nine months ended September 30, 2016 compared to the same period in 2015 resulted primarily from increases of approximately \$7.5 million in stock-based compensation, \$1.9 million in payroll and related costs, \$3.7 million in professional fees and expenses, and \$1.6 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 \$52.0 million for the third quarter of 2016, compared to \$51.9 million for the third quarter of 2015. Research and development expenses for the nine months ended September 30, 2016 were \$166.4 million, compared to \$156.0 million for the nine months ended September 30, 2015. The increase of approximately \$10.4 million during the nine months ended September 30, 2016 compared to the same period in 2015 resulted primarily from increases of approximately \$7.2 million in stock-based compensation, \$3.7 million for internal clinical development, regulatory affairs and quality assurance and internal chemical manufacturing expenses, and \$2.7 million in consultants and contractors related expenses, offset by a \$3.3 million decrease in clinical trial expenses.

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. 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.

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

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2016	2015	2016	2015
Operating expenses:				
General and administrative	\$ 14.0	\$ 8.8	\$ 37.3	\$ 22.2
Research and development	52.0	51.9	166.4	156.0
Totals	<u>66.0</u>	<u>60.7</u>	<u>203.7</u>	<u>178.2</u>
Loss from operations	<u>(66.0)</u>	<u>(60.7)</u>	<u>(203.7)</u>	<u>(178.2)</u>
Other income (expenses):				
Interest income	0.2	0.3	0.7	0.6
Other income (expense)	-	-	(0.4)	-
Totals	<u>0.2</u>	<u>0.3</u>	<u>0.3</u>	<u>0.6</u>
Net loss	<u>\$ (65.8)</u>	<u>\$ (60.4)</u>	<u>\$ (203.4)</u>	<u>\$ (177.6)</u>
Net loss per common share—basic and diluted	<u>\$ (2.02)</u>	<u>\$ (1.87)</u>	<u>\$ (6.26)</u>	<u>\$ (5.55)</u>

Weighted-average common shares outstanding—basic and diluted

32,497,168 32,303,203 32,489,584 32,018,869

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

	September 30, 2016	December 31, 2015
	<u> </u>	<u> </u>
Cash and cash equivalents	\$ 52.5	\$ 31.6
Marketable securities	56.4	184.3
Receivable	1.2	-
Working capital	79.8	191.1
Stockholders' equity	91.1	206.0
	Nine Months Ended	Nine Months Ended
	September 30, 2016	September 30, 2015
	<u> </u>	<u> </u>
Cash provided by (used in):		
Operating activities	\$ (100.7)	\$ (121.4)
Investing activities	121.4	(125.5)
Financing activities	0.3	232.0
	<u> </u>	<u> </u>
Increase in cash and cash equivalents	<u>\$ 21.0</u>	<u>\$ (14.9)</u>

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)

	<u>Three Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
GAAP net loss	<u>\$ (65.8)</u>	<u>\$ (60.4)</u>
Adjustments:		
Stock-based compensation -		
General and administrative	7.7	4.7 (1)
Research and development	22.1	20.2 (2)
Non-GAAP adjusted net loss	<u>\$ (36.0)</u>	<u>\$ (35.5)</u>
GAAP net loss per share - basic and diluted	\$ (2.02)	\$ (1.87)
Adjustment to net loss (as detailed above)	0.91	0.77
Non-GAAP adjusted net loss per share	<u>\$ (1.11)</u>	<u>\$ (1.10) (3)</u>

	Nine Months Ended September 30,	
	2016	2015
GAAP net loss	<u>\$ (203.4)</u>	<u>\$ (177.6)</u>
Adjustments:		
Stock-based compensation -		
General and administrative	19.7	12.2 (1)
Research and development	<u>68.3</u>	<u>61.1</u> (2)
Non-GAAP adjusted net loss	<u>\$ (115.4)</u>	<u>\$ (104.3)</u>
GAAP net loss per share - basic and diluted	\$ (6.26)	\$ (5.55)
Adjustment to net loss (as detailed above)	<u>2.71</u>	<u>2.29</u>
Non-GAAP adjusted net loss per share	<u>\$ (3.55)</u>	<u>\$ (3.26)</u> (4)

- (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 32,497,168 and 32,303,203 weighted average common shares outstanding for the three months ended September 30, 2016 and 2015, respectively.
- (4) Non-GAAP adjusted net loss per share was calculated based on 32,489,584 and 32,018,869 weighted average common shares outstanding for the nine months ended September 30, 2016 and 2015, respectively.



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