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Puma Biotechnology Reports Third Quarter 2015 Financial Results

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LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced financial results for the third quarter ended September 30, 2015.

Unless otherwise stated, all comparisons are for the third quarter and nine months ended September 30, 2015, compared to the third quarter and nine months ended September 30, 2014.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of \$60.4 million, or \$1.87 per share, for the third quarter of 2015, compared to a net loss of \$35.9 million, or \$1.19 per share, for the third quarter of 2014. Net loss for the nine months ended September 30, 2015 was \$177.6 million, or \$5.55 per share, compared to \$94.5 million, or \$3.16 per share, for the nine months ended September 30, 2014.

Non-GAAP adjusted net loss was \$35.5 million, or \$1.10 per share, for the third quarter of 2015, compared to \$25.4 million, or \$0.84 per share, for the third quarter of 2014. Non-GAAP adjusted net loss for the nine months ended September 30, 2015 was \$104.3 million, or \$3.26 per share, compared to \$71.7 million, or \$2.40 per share, for the nine months ended September 30, 2014. 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 2015 was \$36.8 million. Net cash used in operating activities for the nine months ended September 30, 2015 was \$121.4 million. At September 30, 2015, Puma had cash and cash equivalents of \$23.6 million and marketable securities of \$224.2 million, compared to cash and cash equivalents of \$38.5 million and marketable securities of \$102.8 million at December 31, 2014. Puma's current level of cash and cash equivalents and marketable securities includes net proceeds of approximately \$205.1 million from a public offering of the Company's common stock, which was completed in January 2015.

"We continued to make significant progress with the neratinib clinical program in the third quarter," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "Puma achieved a number of milestones, including the presentation of additional data on patients with centrally confirmed HER2-positive disease from our Phase III ExteNET Trial at the American Society of Clinical Oncology (ASCO) 2015 Breast Cancer Symposium and the publication in the *Journal of the National Comprehensive Cancer Network* of a patient with HER2 non-amplified (HER2-negative) metastatic breast cancer who also had a HER2 activating mutation and was successfully treated with PB272. We continue to anticipate filing for regulatory approval of PB272 for the extended adjuvant treatment of HER2-positive breast cancer in the first quarter of 2016.

"We anticipate a number of additional milestones through the end of 2015 and beyond. These include (i) presentations of additional data from the Phase III ExteNET Trial in the extended adjuvant treatment of early stage HER2-positive breast cancer (anticipated in the fourth quarter of 2015); (ii) publication of Phase III ExteNET Trial results (anticipated in the fourth quarter of 2015); (iii) presentation of the Phase II FB-7 trial of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer (anticipated in the fourth quarter of 2015); (iv) presentation of data from our Phase II trial of PB272 in HER2 non-amplified breast cancer that has a HER2 mutation (anticipated in the fourth quarter of 2015); (v) reporting initial data from the Phase II trial of neratinib in extended adjuvant HER2-positive early stage breast cancer using loperamide prophylaxis (anticipated in the fourth quarter of 2015); (vi) publication of results to date on the use of prophylactic loperamide to reduce the neratinib-related diarrhea (anticipated in the fourth quarter of 2015); (vii) completing the ongoing Phase II trial of PB272 in patients with HER2-positive metastatic breast cancer that has metastasized to the brain (anticipated in the first half of 2016); and (viii) expanding additional cohorts in our Phase II basket trial of PB272 in patients with solid tumors with activating HER2 mutations (anticipated in the fourth quarter of 2015)."

Operating Expenses

Based on GAAP, operating expenses were \$60.7 million for the third quarter of 2015, compared to \$36.0 million for the third quarter of 2014. Operating expenses for the nine months ended September 30, 2015 were \$178.2 million, compared to \$94.7 million for the nine months ended September 30, 2014. The increase in operating expenses for the third quarter of 2015 compared to the third quarter of 2014 was primarily driven by an increase in stock-based compensation expense of \$14.4 million, an increase in clinical trial expense of \$5.1 million and an increase in internal research and development expense of \$3.0 million. The increase in operating expenses for the nine months ended September 30, 2015 compared to the same period in 2014 was primarily driven by an increase in stock-based compensation of \$50.5 million, an increase in clinical trial expense of \$19.4 million and an increase in internal research and development expense of \$8.2 million.

General and Administrative Expenses:

Based on GAAP, general and administrative expenses were \$8.8 million for the third quarter of 2015, compared to \$3.9 million for the third quarter of 2014. General and administrative expenses for the nine months ended September 30, 2015 were \$22.2 million compared to \$11.3 million for the nine months ended September 30, 2014.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$51.9 million for the third quarter of 2015, compared to \$32.1 million for the third quarter of 2014. Research and development expenses for the nine months ended September 30, 2015 were \$156.0 million, compared to \$83.4 million for the nine months ended September 30, 2014.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. The Company aims to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. The Company is initially focused on the development of PB272 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive breast cancer and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

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 anticipated timing for regulatory filings and for 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 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, 2014 and Quarterly Reports on Form 10-Q for the quarters ended June 30, 2015 and September 30, 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		Nine Months Ended	
	September 30,		September 30,	
	(Unaudited)		(Unaudited)	
	2015	2014	2015	2014
Operating expenses:				
General and administrative	\$ 8.8	\$ 3.9	\$ 22.2	\$ 11.3
Research and development	51.9	32.1	156.0	83.4
Totals	60.7	36.0	178.2	94.7
Loss from operations	(60.7)	(36.0)	(178.2)	(94.7)
Other income (expenses):				
Interest income	0.3	0.1	0.6	0.2
Other income (expense)	-	-	-	-
Totals	0.3	0.1	0.6	0.2
Net loss	\$ (60.4)	\$ (35.9)	\$ (177.6)	\$ (94.5)
Net loss per common share—basic and diluted	\$ (1.87)	\$ (1.19)	\$ (5.55)	\$ (3.16)
Weighted-average common shares outstanding—basic and diluted	32,303,203	30,117,819	32,018,869	29,936,254

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

	September 30, 2015	December 31, 2014
Cash and cash equivalents	\$ 23.6	\$ 38.5
Marketable securities	224.2	102.8
Licensor receivable	-	1.8
Working capital	229.3	105.0
Stockholders' equity	244.8	117.0
	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Cash provided by (used in):		
Operating activities	\$ (121.4)	\$ (58.7)
Investing activities	(125.5)	(85.5)
Financing activities	232.0	129.4
Decrease in cash and cash equivalents	<u>\$ (14.9)</u>	<u>\$ (14.8)</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)

	Three Months Ended September 30,	
	2015	2014
GAAP net loss	\$ (60.4)	\$ (35.9)
Adjustments:		
Stock-based compensation -		
General and administrative	4.7	1.4
Research and development	20.2	9.1
Non-GAAP adjusted net loss	<u>\$ (35.5)</u>	<u>\$ (25.4)</u>

(1)

(2)

GAAP net loss per share - basic and diluted	\$	(1.87)	\$	(1.19)	
Adjustment to net loss (as detailed above)		0.77		0.35	
Non-GAAP adjusted net loss per share	\$	(1.10)	\$	(0.84)	(3)

Nine Months Ended September 30,

	2015	2014	
GAAP net loss	\$ (177.6)	\$ (94.5)	
Adjustments:			
Stock-based compensation -			
General and administrative	12.2	4.1	(1)
Research and development	61.1	18.7	(2)
Non-GAAP adjusted net loss	\$ (104.3)	\$ (71.7)	
GAAP net loss per share - basic and diluted	\$ (5.55)	\$ (3.16)	
Adjustment to net loss (as detailed above)	2.29	0.76	
Non-GAAP adjusted net loss per share	\$ (3.26)	\$ (2.40)	(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 32,303,203 and 30,117,819 weighted average common

shares outstanding for the three months ended September 30, 2015 and 2014, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 32,018,869 and 29,936,254 weighted average common

shares outstanding for the nine months ended September 30, 2015 and 2014, respectively.

Language:

English

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