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Puma Biotechnology Reports Third Quarter 2013 Financial Results

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2013.

Unless otherwise stated, all comparisons are for the third quarter and nine months ended September 30, 2013, compared to the third quarter and nine months ended September 30, 2012.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$14.3 million, or \$0.50 per share, for the third quarter of 2013, compared to a net loss of \$25.9 million, or \$1.29 per share, for the third quarter of 2012. Net loss applicable to common stock for the nine months ended September 30, 2013, was \$38.7 million, or \$1.35 per share, compared to \$52.4 million, or \$2.62 per share, for the nine months ended September 30, 2012.

Adjusted net loss applicable to common stock was \$12.3 million, or \$0.43 per share, for the third quarter of 2013, compared to adjusted net loss applicable to common stock of \$3.6 million, or \$0.18 per share, for the third quarter of 2012. Adjusted net loss applicable to common stock for the nine months ended September 30, 2013, was \$33.6 million, or \$1.17 per share, compared to \$11.5 million, or \$0.58 per share, for the nine months ended September 30, 2012. Adjusted net loss applicable to common stock excludes stock-based compensation expense and external costs associated with ongoing clinical trials of our lead product candidate, PB272 (neratinib (oral)), that Puma assumed from a licensor and which it refers to as licensor legacy clinical trials. For a reconciliation of adjusted net loss applicable to common stock to reported net loss applicable to common stock, please see the financial tables at the end of this news release.

Net cash used in operating activities for the third quarter of 2013 was \$12.0 million. Net cash used in operating activities for the nine months ended September 30, 2013, was \$41.4 million. At September 30, 2013, Puma had cash and cash equivalents of \$51.3 million and marketable securities of \$44.4 million, compared to \$137.4 million of cash and cash equivalents at December 31, 2012. As previously noted, Puma's license agreement for PB272 established a limit on the Company's expenses related to certain clinical trials Puma assumed from the licensor, or legacy clinical trials. Puma reached this limit, or cap, during the fourth quarter of 2012; therefore, the licensor is responsible for expenses related to the legacy clinical trials until such trials are completed. The license agreement requires the Company to bill the licensor quarterly for external "out-of-pocket" costs in excess of the cap cost. At September 30, 2013, the Company reported a receivable of approximately \$11.3 million associated with outstanding invoices to the licensor. The Company anticipates receiving payments for these outstanding invoices by the end of 2013.

"During the third quarter of 2013, we continued to execute on our ongoing Phase II and Phase III trials of PB272 (neratinib)," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "During the quarter, we also initiated a Phase II trial of PB272 for the treatment of patients with solid tumors that have a HER2 activating mutation (basket trial). We anticipate seeing the first results from our basket trial in the fourth quarter of 2013 or in the beginning of 2014.

"In addition," noted Mr. Auerbach, "we expect to (i) complete the ongoing Phase II clinical trial of PB272 in combination with temsirolimus in fourth-line HER2-positive metastatic breast cancer, which we anticipate reporting additional data from later in 2013 or in early 2014; (ii) initiate a Phase III trial of the combination of PB272 plus temsirolimus in the first half of 2014; (iii) complete the ongoing Phase II trial of PB272 in patients with HER2-positive metastatic breast cancer that has metastasized to the brain, which we anticipate reporting data from later in 2013 or in early 2014; (iv) complete our two ongoing Phase II trials of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer (I-SPY2 and NSABP FB-7), both of which we expect to report data from in the fourth quarter of 2013; (v) report data from our Phase II trial of PB272 in patients with HER2 mutated non-small cell lung cancer later in 2013; (vi) continue our Phase II trial of PB272 in HER2-negative breast cancer patients who have a HER2 mutation, which we also have the potential to report initial data from later in 2013; (vii) complete our ongoing Phase II randomized trial of PB272 as a first-line treatment for HER2-positive metastatic breast cancer, which we expect to report data from in the first half of 2014; and (viii) complete our Phase III trial of PB272 as an adjuvant treatment for HER2 positive breast cancer, which we expect to report data from in the first half of 2014."

Operating Expenses

Based on GAAP, operating expenses were \$14.3 million for the third quarter of 2013, compared to \$25.9 million for the third quarter of 2012. Operating expenses for the nine months ended September 30, 2013, were \$38.8 million, compared to \$52.5 million for the nine months ended September 30, 2012.

Adjusted operating expenses were \$12.3 million for the third quarter of 2013, compared to \$3.6 million in the third quarter of 2012. Adjusted operating expenses exclude stock-based compensation expenses and licensor legacy clinical trial costs. Adjusted operating expenses for the nine months ended September 30, 2013, were \$33.7 million, compared to \$11.6 million for the nine months ended September 30, 2012. For a reconciliation of adjusted operating expenses to reported operating expenses, please see the financial tables at the end of this news release.

General and Administrative Expenses:

Based on GAAP, general and administrative expenses were \$2.3 million in the third quarter of 2013, compared to \$8.1 million in the third quarter of 2012. General and administrative expenses for the nine months ended September 30, 2013, were \$6.8 million compared to \$11.1 million for the nine months ended September 30, 2012.

Adjusted general and administrative expenses were \$1.8 million for the third quarter of 2013, compared to \$1.5 million in the third quarter of 2012. Adjusted general and administrative expenses for the nine months ended September 30, 2013, were \$5.4 million, compared to \$4.6 million for the nine months ended September 30, 2012.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$12.0 million in the third quarter of 2013, compared to \$17.8 million in the third quarter of 2012. Research and development expenses for the nine months ended September 30, 2013, were \$32.0 million, compared to \$41.4 million for the nine months ended September 30, 2012.

Adjusted research and development expenses were \$10.5 million in the third quarter of 2013, compared to \$2.1 million in the third quarter of 2012. The increase in adjusted research and development expenses from the third quarter of 2012 was driven primarily by costs associated with the initiation of Puma-sponsored clinical trials and the testing and validation of the active pharmaceutical ingredient of our lead drug candidate. Adjusted research and development expenses for the nine months ended September 30, 2013, were \$28.3 million, compared to \$7.0 million for the nine months ended September 30, 2012.

About Puma Biotechnology

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. 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 metastatic 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 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, 2012. 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
(A DEVELOPMENT STAGE COMPANY)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in millions except per share data)

	Three Months Ended		Nine Months Ended		Period from
	September 30,		September 30,		September 15,
	2013	2012	2013	2012	2010 (date of inception) to September 30, 2013
Operating expenses:					
General and administrative	\$ 2.3	\$ 8.1	\$ 6.8	\$ 11.1	\$ 41.0
Research and development	12.0	17.8	32.0	41.4	82.5
Totals	<u>14.3</u>	<u>25.9</u>	<u>38.8</u>	<u>52.5</u>	<u>123.5</u>
Loss from operations	<u>(14.3)</u>	<u>(25.9)</u>	<u>(38.8)</u>	<u>(52.5)</u>	<u>(123.5)</u>
Other income (expenses):					
Interest income	-	-	0.1	0.1	0.2
Other income (expense)	-	-	-	-	-
Totals	<u>-</u>	<u>-</u>	<u>0.1</u>	<u>0.1</u>	<u>0.2</u>
Net loss	<u>\$ (14.3)</u>	<u>\$ (25.9)</u>	<u>\$ (38.7)</u>	<u>\$ (52.4)</u>	<u>\$ (123.3)</u>
Net loss per common share—basic and diluted	<u>\$ (0.50)</u>	<u>\$ (1.29)</u>	<u>\$ (1.35)</u>	<u>\$ (2.62)</u>	
Weighted-average common shares outstanding—basic and diluted	<u>28,682,055</u>	<u>20,040,000</u>	<u>28,678,439</u>	<u>20,040,000</u>	

PUMA BIOTECHNOLOGY, INC.
(A DEVELOPMENT STAGE COMPANY)
LIQUIDITY AND CAPITAL RESOURCES
(in millions except per share data)

	September 30,	December 31,
	2013	2012
Cash and cash equivalents	\$ 51.3	\$ 137.4
Marketable securities	44.4	-
Licensor receivable	11.3	10.6
Working capital	91.4	127.3
Stockholders' equity	94.8	128.9
	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Cash provided by (used in):		
Operating activities	\$ (41.4)	\$ (19.2)
Investing activities	(44.8)	(0.8)
Financing activities	0.1	-
Increase (decrease) in cash	<u>\$ (86.1)</u>	<u>\$ (20.0)</u>

Reconciliation of GAAP and Non-GAAP Financial Information
(in millions except share and per share data)

	GAAP Measure (Reported)			Non-GAAP Measure			GAAP Measure (Reported)			Non-GAAP Measure		
	Three Months Ended September 30, 2013	Expense Adjustments		Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013	Expense Adjustments		Nine Months Ended September 30, 2013				
		Stock-based compensation	Licensors			Stock-based compensation	Licensors					
			legacy clinical trials				legacy clinical trials					
Operating expense:												
General and administrative	2.3	(0.5)	-	1.8	6.8	(1.4)	-	5.4				
Research and development	12.0	(1.3)	(0.2)	10.5	32.0	(3.0)	(0.7)	28.3				
Loss from operations	(14.3)	1.8	0.2	(12.3)	(38.8)	4.4	0.7	(33.7)				
Other income (expense):												
Interest income	-	-	-	-	0.1	-	-	0.1				
Other expense	-	-	-	-	-	-	-	-				
Totals	-	-	-	-	0.1	-	-	0.1				
Net loss	(14.3)	1.8	0.2	(12.3)	(38.7)	4.4	0.7	(33.6)				
Net loss applicable to common stock	(14.3)	1.8	0.2	(12.3)	(38.7)	4.4	0.7	(33.6)				
Net loss per common share—basic and diluted	\$ (0.50)	\$ 0.06	\$ 0.01	\$ (0.43)	\$ (1.35)	\$ 0.15	\$ 0.02	\$ (1.17)				
Weighted-average common shares outstanding—basic and diluted	28,682,055	28,682,055	28,682,055	28,682,055	28,678,439	28,678,439	28,678,439	28,678,439				

	GAAP Measure (Reported)			Non-GAAP Measure			GAAP Measure (Reported)			Non-GAAP Measure		
	Three Months Ended September 30, 2012	Expense adjustments		Three Months Ended September 30, 2012	Nine Months Ended September 30, 2012	Expense Adjustments		Nine Months Ended September 30, 2012				
		Stock-based compensation	Licensors			Stock-based compensation	Licensors					
			legacy clinical trials				legacy clinical trials					
Operating expense:												
General and administrative	8.1	(6.6)	-	1.5	11.1	(6.5)	-	4.6				
Research and development	17.8	(0.2)	(15.5)	2.1	41.4	(0.5)	(33.9)	7.0				
Loss from operations	(25.9)	6.8	15.5	(3.6)	(52.5)	7.0	33.9	(11.6)				
Other income (expense):												
Interest income	-	-	-	-	0.1	-	-	0.1				

Other expense	-	-	-	-	-	-	-	-
Totals	-	-	-	-	0.1	-	-	0.1
Net loss	(25.9)	6.8	15.5	(3.6)	(52.4)	7.0	33.9	(11.5)
Net loss applicable to common stock	(25.9)	6.8	15.5	(3.6)	(52.4)	7.0	33.9	(11.5)
Net loss per common share—basic and diluted	\$ (1.29)	\$ 0.34	\$ 0.77	\$ (0.18)	\$ (2.62)	\$ 0.35	\$ 1.69	\$ (0.58)
Weighted-average common shares outstanding—basic and diluted	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000	20,040,000

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