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Puma Biotechnology Reports Third Quarter 2012 Financial Results

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LOS ANGELES

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, 2012.

The Company reported a net loss applicable to common stock of \$25.9 million, or \$1.29 per share, for the quarter ended September 30, 2012. Net loss applicable to common stock for the nine months ended September 30, 2012, was \$52.4 million, or \$2.62 per share.

Net cash used in operating activities for the quarter ended September 30, 2012, was \$7.6 million. Net cash used in operating activities for the nine months ended September 30, 2012, was \$19.2 million.

As of September 30, 2012, Puma had cash and cash equivalents of \$33.3 million, compared to \$53.4 million at December 31, 2011. On October 24, 2012, the Company announced the closing of an underwritten public offering from which it received net proceeds of approximately \$129.1 million, after deducting the underwriting discount and estimated offering expenses payable by the Company.

Total operating expenses for the quarter ended September 30, 2012, were \$25.9 million. Total operating expenses for the nine months ended September 30, 2012, were \$52.5 million. Operating expenses in the quarter were primarily driven by clinical development expenses for the Company's lead product candidate, PB272 (neratinib), the transition of the PB272 clinical trial program to Puma from the drug's licensor, hiring staff and building out our corporate infrastructure.

General and administrative expenses for the third quarter of 2012 were \$8.0 million. Total general and administrative expenses for the nine months ended September 30, 2012, were \$11.0 million. General and administrative expenses for the quarter included approximately \$6.6 million in employee stock-based compensation expense, which primarily consisted of an increase in the estimated valuation of the outstanding anti-dilutive warrant held by the Company's Chief Executive Officer and President.

Research and development expenses for the third quarter of 2012 were \$17.8 million. Total research and development expenses for the nine months ended September 30, 2012, were \$41.4 million. Research and development expenses for the quarter included accruals for ongoing outside clinical development and CRO/licensor service expenses of \$15.6 million related to the PB272 clinical trials that were ongoing at the time Puma licensed the drug. Puma's license agreement for PB272 established a limit on the Company's expenses related to these trials, and the Company anticipates that it will reach this limit during the fourth quarter of 2012. Following such time, the company from which Puma licensed PB272 will be responsible for the expenses related to these clinical trials until such trials are completed.

"During the third quarter of 2012, Puma made significant progress with the clinical development of our drug candidate PB272 and continued to build our corporate infrastructure," said Alan H. Auerbach, Chief Executive Officer and President. "We will continue to move forward aggressively with the clinical development of PB272 during the remainder of 2012 and look forward to a strong clinical development program during 2013. Our clinical development plan includes (i) initiating our Phase III clinical trial of PB272 in combination with chemotherapy in HER2+ metastatic breast cancer patients who have failed previous HER2 directed therapy, which we anticipate will occur later this year or early next year; (ii) completing the ongoing Phase II trial of neratinib in combination with temsirolimus in fourth line HER2+ metastatic breast cancer, which we anticipate reporting additional data from later in 2012, and subsequently initiating the Phase III trial of the combination of neratinib plus temsirolimus, which we anticipate will begin in 2013; (iii) completing the ongoing Phase II trial of PB272 in patients with HER2+ metastatic breast cancer that has metastasized to the brain, which we also anticipate reporting data from in 2013; (iv) completing our ongoing Phase II trial of PB272 as a neoadjuvant treatment for patients with HER2+ breast cancer, which we expect to report data from in 2013; (v) initiating a Phase II trial of PB272 in patients with HER2 mutated non-small cell lung cancer, which we expect will occur later this year or early next year; and (vi) initiating a Phase II trial of PB272 in breast cancer patients with a newly identified genetic mutation, which we also expect will occur later this year."

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 non-small cell lung cancer.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements that 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. 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.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended		Nine Months Ended		Period from
	September 30,		September 30,		September 15, 2010 (date of inception) to September 30, 2012
	2012	2011	2012	2011	
Operating expenses:					
General and administrative	\$ 8,025,241	\$ 333,766	\$ 10,961,744	\$ 371,804	\$ 20,288,262
Research and development	17,779,419	-	41,353,708	-	42,180,080
Depreciation and amortization	68,824	168	187,060	336	197,762
Totals	<u>25,873,484</u>	<u>333,934</u>	<u>52,502,512</u>	<u>372,140</u>	<u>62,666,104</u>
Loss from operations	<u>(25,873,484)</u>	<u>(333,934)</u>	<u>(52,502,512)</u>	<u>(372,140)</u>	<u>(62,666,104)</u>
Other income (expenses):					
Interest income	14,444	-	62,596	-	66,379
Other income (expense)	-	(13,500)	-	(13,500)	(80,000)
Totals	<u>14,444</u>	<u>(13,500)</u>	<u>62,596</u>	<u>(13,500)</u>	<u>(13,621)</u>
Net loss	<u>\$(25,859,040)</u>	<u>\$ (347,434)</u>	<u>\$(52,439,916)</u>	<u>\$ (385,640)</u>	<u>\$(62,679,725)</u>
Net loss per common share—basic and diluted	<u>\$ (1.29)</u>	<u>\$ (0.09)</u>	<u>\$ (2.62)</u>	<u>\$ (0.10)</u>	
Weighted-average common shares outstanding—basic and diluted	<u>20,040,000</u>	<u>4,000,000</u>	<u>20,040,000</u>	<u>4,000,000</u>	

PUMA BIOTECHNOLOGY, INC.
(A DEVELOPMENT STAGE COMPANY)
LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2012	December 31, 2011
Cash and cash equivalents	\$ 33,346,638	\$ 53,381,734
Working capital	7,456,595	53,076,619
Stockholders' equity	9,002,536	54,372,535

	Nine months ended September 30, 2012	September 15, 2010 (date of inception) to September 30, 2012
Cash provided by (used in):		
Operating activities	\$(19,202,622)	\$(21,034,571)
Investing activities	(833,306)	(2,578,513)
Financing activities	-	56,959,722
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Increase (decrease) in cash	<u>\$(20,035,928)</u>	<u>\$ 33,346,638</u>

Language:

English

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