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Puma Biotechnology Reports Second Quarter 2012 Financial Results

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (OTCBB: PBYI), a development stage biopharmaceutical company, today announced financial results for the second quarter ended June 30, 2012.

For the quarter ended June 30, 2012, Puma reported a net loss applicable to common stock of \$14.8 million, or \$0.74 per share. Net loss applicable to common stock for the six months ended June 30, 2012, was \$26.6 million, or \$1.33 per share.

Net cash used in operating activities for the quarter ended June 30, 2012, was \$8.8 million. Net cash used in operating activities for the six months ended June 30, 2012, was \$11.6 million. As of June 30, 2012, Puma had cash and cash equivalents of \$41.0 million, compared to \$53.4 million at December 31, 2011.

Total operating expenses for the quarter ended June 30, 2012 were \$14.8 million. Total operating expenses for the six months ended June 30, 2012, were \$26.6 million. The operating expenses in the quarter were primarily driven by clinical development expenses for our 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 second quarter of 2012 were \$1.7 million. Total general and administrative expenses for the six months ended June 30, 2012, were \$2.9 million.

Research and development expenses for the second quarter of 2012 were \$13.0 million. Total research and development expenses for the six months ended June 30, 2012, were \$23.6 million. Included in the research and development expenses for the second quarter of 2012 are outside clinical development expenses of \$10.3 million related to the transition of the ongoing PB272 clinical trials to Puma from the licensor, approximately \$3 million of which represented duplicate costs incurred for the licensor's services in connection with these trials. The Company anticipates that as this transition has largely been completed, these costs will decrease significantly in future quarters.

"The second quarter of 2012 brought many significant achievements and advancements for Puma as we continued to make 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 2012. 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; (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; (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 2012, (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; 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.

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		Six Months Ended		Period from
	June 30,		June 30,		September 15,
	2012	2011	2012	2011	2010 (date of inception) to June 30, 2012
Operating expenses:					
General and administrative	\$ 1,701,877	\$ 34,097	\$ 2,936,503	\$ 38,038	\$ 12,263,021
Research and development	13,005,907	-	23,574,289	-	24,400,661
Depreciation and amortization	69,495	168	118,236	168	128,938
Totals	<u>14,777,279</u>	<u>34,265</u>	<u>26,629,028</u>	<u>38,206</u>	<u>36,792,620</u>
Loss from operations	<u>(14,777,279)</u>	<u>(34,265)</u>	<u>(26,629,028)</u>	<u>(38,206)</u>	<u>(36,792,620)</u>
Other income (expenses):					
Interest income	22,516	-	48,152	-	51,935
Other income (expense)	-	-	-	-	(80,000)
Totals	<u>22,516</u>	<u>-</u>	<u>48,152</u>	<u>-</u>	<u>(28,065)</u>
Net loss	<u><u>\$(14,754,763)</u></u>	<u><u>\$ (34,265)</u></u>	<u><u>\$(26,580,876)</u></u>	<u><u>\$ (38,206)</u></u>	<u><u>\$(36,820,685)</u></u>
Net loss per common share—basic and diluted	<u><u>\$ (0.74)</u></u>	<u><u>\$ (0.01)</u></u>	<u><u>\$ (1.33)</u></u>	<u><u>\$ (0.01)</u></u>	
Weighted-average common shares outstanding—basic and diluted	<u><u>20,040,000</u></u>	<u><u>4,000,000</u></u>	<u><u>20,040,000</u></u>	<u><u>4,000,000</u></u>	

PUMA BIOTECHNOLOGY, INC.
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LIQUIDITY AND CAPITAL RESOURCES

	June 30, 2012	December 31, 2011
Cash and cash equivalents	\$ 41,001,998	\$ 53,381,734
Working capital	26,286,237	53,076,619
Stockholders' equity	28,038,843	54,372,535

September 15,
2010 (date of
inception) to

Six months ended

