



News Release

Puma Biotechnology Reports Fourth Quarter and Full Year 2012 Financial Results

LOS ANGELES, Calif., April 1, 2013 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company (“Puma” or the “Company”), today announced financial results for the fourth quarter and year ended December 31, 2012.

Unless otherwise stated, all comparisons are for the fourth quarter and full year 2012, compared to the fourth quarter and full year 2011, respectively. The adjusted net loss applicable to common stock and adjusted operating expenses discussed below exclude stock-based compensation expense and costs associated with ongoing clinical trials that we assumed from the licensor and which we refer to as licensor legacy clinical trials.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$21.9 million, or \$0.83 per share, for the quarter ended December 31, 2012. Net loss applicable to common stock for the full year was \$74.3 million, or \$3.42 per share.

The Company reported adjusted net loss applicable to common stock of \$6.6 million, or \$0.25 per share, for the quarter ended December 31, 2012. Adjusted net loss applicable to common stock for the full year was \$16.8 million, or \$0.77 per share.

Net cash used in operating activities for the quarter ended December 31, 2012, was \$24.8 million. Net cash used in operating activities for the full year was \$44.0 million.

As of December 31, 2012, Puma had cash and cash equivalents of \$137.4 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 \$129.2 million, after deducting the underwriting discount and offering expenses payable by the Company.

Based on GAAP, operating expenses for the quarter ended December 31, 2012, were \$22.0 million. Operating expenses for the full year were \$74.4 million. Operating expenses in the quarter and for the full year were primarily driven by clinical development expenses associated with the licensor legacy clinical trials and stock-based compensation.

Total adjusted operating expenses for the quarter ended December 31, 2012, were \$6.7 million. Total adjusted operating expenses for the full year, were \$16.9 million. Operating expenses in the quarter were primarily driven by clinical development expenses for the Company’s lead product candidate, PB272 (neratinib), transition of the PB272 clinical trial program to Puma from the drug’s licensor, hiring of staff and building of the Company’s corporate infrastructure.

“During 2012, Puma made significant progress with the clinical development of our drug candidate PB272 in HER2-positive metastatic breast cancer, HER2-positive neoadjuvant breast cancer, HER2-mutated non-small cell lung cancer, and in HER2-negative breast cancer that has a HER2 mutation,” said Alan H. Auerbach, Chief Executive Officer and President. “We plan to continue to move forward aggressively with the clinical development of PB272 during 2013. Our clinical development plan includes (i) initiating our Phase III clinical trial of PB272 in combination with chemotherapy in HER2-positive metastatic breast cancer patients who have failed previous HER2 directed therapy (third-line disease), which we anticipate will occur in the second quarter; (ii) completing the on-going Phase II trial of neratinib in combination with temsirolimus in fourth line HER2-

positive metastatic breast cancer, which we anticipate reporting additional data from later this year, and subsequently initiating the Phase III trial of the combination of neratinib plus temsirolimus, which we anticipate will begin later in 2013; (iii) completing the on-going Phase II trial of PB272 in patients with HER2-positive metastatic breast cancer that has metastasized to the brain, which we also anticipate reporting data from later in 2013; (iv) completing our two ongoing Phase II trials of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer, which we expect to report data from in mid-2013 and late 2013, respectively; (v) continuing our Phase II trial of PB272 in patients with HER2 mutated non-small cell lung cancer, which we have the potential to report initial data from later this year; and (vi) continuing 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 this year.”

Fourth Quarter and Full Year 2012 Financial Highlights

General and Administrative (G&A) Expenses:

On a GAAP basis, G&A expenses for the fourth quarter of 2012 were \$13.8 million, compared to \$9.0 million for the fourth quarter of 2011. The increase was largely due to a \$4.6 million increase in stock-based compensation expense, which was primarily attributable to the recognition of additional expense associated with the anti-dilutive warrant previously issued to the Company’s CEO. In connection with the consummation of the Company’s public offering in October 2012, the final fair value of the anti-dilutive warrant was determined and an additional charge of \$12.0 million associated with the warrant was recognized in the fourth quarter. The Company will not recognize additional stock-based compensation expense associated with this warrant going forward.

Adjusted G&A expenses exclude the impact of stock-based compensation expense and were \$1.6 million for the fourth quarter of 2012, compared to \$1.4 million for the fourth quarter of 2011. The increase was primarily due to charges associated with Puma only occupying its current office suites for one month during the fourth quarter of 2011, compared to the full three months in the fourth quarter of 2012, and payment of business taxes.

On a GAAP basis, G&A expenses for the full year 2012 were \$24.8 million, compared to \$9.3 million for the full year 2011. The primary driver of the increase was additional stock-based compensation of \$18.2 million, which was primarily attributable to the recognition of additional expense associated with the anti-dilutive warrant previously issued to the Company’s CEO and described above. The remaining increase was primarily due to the Company being operational for a full 12 months in 2012, compared to three months in 2011.

For the full year 2012, adjusted G&A expenses were \$6.1 million, compared to \$1.7 million for the full year 2011. The increase was primarily due to the Company being operational for a full 12 months in 2012, compared to only three months in 2011.

Research and Development (R&D) Expenses:

On a GAAP basis, R&D expenses for the fourth quarter of 2012 were \$8.2 million, compared to \$0.8 million for the fourth quarter of 2011. The increase was primarily due to being fully staffed for the fourth quarter of 2012 and assuming operational control of the various clinical trials that were ongoing at the time that Puma licensed PB272 from the licensor. The increase also included \$2.7 million in costs associated with the licensor legacy clinical trials.

Adjusted R&D expenses, which exclude the impact of stock-based compensation expense and costs associated with the licensor legacy clinical trials, were \$5.1 million for the fourth quarter ended December 31, 2012, compared to \$0.8 million for the fourth quarter of 2011. The quarter to quarter increase represents a full three months of operations for the fourth quarter of 2012, compared to only two months during the fourth quarter of 2011. The fourth quarter also reflects the hiring of staff, primarily in the early part of 2012, along with preliminary work on the Company’s initiated Phase III and Phase II clinical trials.

On a GAAP basis, R&D expenses for the full year 2012 were \$49.6 million, compared to \$0.8 million for full year 2011. The increase was primarily attributable to a \$41.0 million increase in outside CRO/licensor services

and outside other clinical development costs, which primarily resulted from costs associated with certain licensor legacy clinical trials. Puma's license agreement for PB272 established a limit on the Company's expenses related to the licensor legacy clinical trials. The Company reached this limit during the fourth quarter of 2012; therefore, the licensor will be responsible for the future expenses related to these trials until such trials are completed. Excluding the impact of the costs associated with the licensor legacy clinical trials, the primary factors contributing to the remaining increase were staff additions and being fully functional for 12 months in 2012.

Adjusted R&D expenses for the full year 2012 were \$10.8 million, compared to \$0.8 million for the full year 2011. The increase resulted from the R&D operation being fully staffed and functional for 12 months in 2012, compared to staff additions during the two months of operations in 2011.

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, 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. 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.

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(Financial Tables Follow)

PUMA BIOTECHNOLOGY, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(in millions except per share data)

	Three Months Ended		Twelve Months Ended		Period from
	December 31,		December 31,		September 15,
	2012	2011	2012	2011	2010 (date
					of inception) to
					December 31, 2012
Operating expenses:					
General and administrative	\$ 13.8	\$ 9.0	\$ 24.8	\$ 9.3	\$ 34.1
Research and development	8.2	0.8	49.6	0.8	50.5
Totals	<u>22.0</u>	<u>9.8</u>	<u>74.4</u>	<u>10.1</u>	<u>84.6</u>
Loss from operations	<u>(22.0)</u>	<u>(9.8)</u>	<u>(74.4)</u>	<u>(10.1)</u>	<u>(84.6)</u>
Other income (expenses):					
Interest income	0.1	-	0.1	-	0.1
Other income (expense)	-	(0.1)	-	(0.1)	(0.1)
Totals	<u>0.1</u>	<u>(0.1)</u>	<u>0.1</u>	<u>(0.1)</u>	<u>0.0</u>
Net loss	<u>\$ (21.9)</u>	<u>\$ (9.9)</u>	<u>\$ (74.3)</u>	<u>\$ (10.2)</u>	<u>\$ (84.6)</u>
Net loss per common share—basic and diluted	<u>\$ (0.83)</u>	<u>\$ (0.52)</u>	<u>\$ (3.42)</u>	<u>\$ (1.32)</u>	
Weighted-average common shares outstanding—basic and diluted	<u>26,511,141</u>	<u>18,863,945</u>	<u>21,725,986</u>	<u>7,746,529</u>	

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

	December 31,	December 31,
	2012	2011
Cash and cash equivalents	\$ 137.4	\$ 53.4
Working capital	127.3	53.1
Stockholders' equity	128.9	54.4
	The Year	September 15,
	Ended	2010 (date of
	December 31,	inception) to
	2012	December 31, 2012
Cash provided by (used in):		
Operating activities	\$ (44.0)	\$ (45.8)
Investing activities	(1.2)	(3.0)
Financing activities	<u>129.3</u>	<u>186.2</u>
Increase (decrease) in cash	<u>\$ 84.1</u>	<u>\$ 137.4</u>

Reconciliation of GAAP and Non-GAAP Financial Information

(in millions except share and per share data)

	GAAP			Non-GAAP
	Measure	Expense adjustments		Measure
	(Reported)	Stock-based	Licensor legacy	(Adjusted)
Year Ended				Year Ended
December 31, 2012		compensation	clinical trials	December 31, 2012
<i>2012 Operating expense:</i>				
General and administrative	\$ 24.8	\$ (18.7)	\$ -	\$ 6.1
Research and development	49.6	(0.9)	(37.9)	10.8
Loss from operations	(74.4)	19.6	37.9	(16.9)
Other income (expense):				
Interest income	0.1	-	-	0.1
Other expense	-	-	-	-
Totals	0.1	-	-	0.1
Net loss	\$ (74.3)	\$ 19.6	\$ 37.9	\$ (16.8)
Net loss applicable to common stock	\$ (74.3)	\$ 19.6	\$ 37.9	\$ (16.8)
Net loss per common share - basic and diluted	\$ (3.42)	\$ 0.90	\$ 1.74	\$ (0.77)
Weighted-average common shares outstanding - basic and diluted	21,725,986	21,725,986	21,725,986	21,725,986
<i>4th Quarter 2012 Operating expense:</i>				
General and administrative	\$ 13.8	\$ (12.2)	\$ -	\$ 1.6
Research and development	8.2	(0.4)	(2.7)	5.1
Loss from operations	(22.0)	12.6	2.7	(6.7)
Other income (expense):				
Interest income	0.1	-	-	0.1
Other expense	-	-	-	-
Totals	0.1	-	-	0.1
Net loss	\$ (21.9)	\$ 12.6	\$ 2.7	\$ (6.6)
Net loss applicable to common stock	\$ (21.9)	\$ 12.6	\$ 2.7	\$ (6.6)
Net loss per common share - basic and diluted	\$ (0.83)	\$ 0.48	\$ 0.10	\$ (0.25)
Weighted-average common shares outstanding - basic and diluted	26,511,141	26,511,141	26,511,141	26,511,141
<i>2011 Operating expense:</i>				
General and administrative	\$ 9.3	\$ (7.6)	\$ -	\$ 1.7
Research and development	0.8	(0.1)	-	0.7
Loss from operations	(10.1)	7.7	-	(2.4)
Other income (expense):				
Interest income	-	-	-	-
Other expense	(0.1)	-	-	(0.1)
Totals	(0.1)	-	-	(0.1)
Net loss	\$ (10.2)	\$ 7.7	\$ -	\$ (2.5)
Net loss applicable to common stock	\$ (10.2)	\$ 7.7	\$ -	\$ (2.5)
Net loss per common share - basic and diluted	\$ (1.32)	\$ 0.99	\$ -	\$ (0.33)
Weighted-average common shares outstanding - basic and diluted	7,746,259	7,746,259	7,746,259	7,746,259