



News Release

Puma Biotechnology Reports First Quarter 2014 Financial Results

LOS ANGELES, Calif., May 12, 2014 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced financial results for the first quarter ended March 31, 2014.

Unless otherwise stated, all comparisons are for the first quarter of 2014 compared to the first quarter of 2013.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$19.8 million, or \$0.67 per share, for the first quarter of 2014, compared to a net loss of \$11.8 million, or \$0.41 per share, for the first quarter of 2013.

Adjusted net loss applicable to common stock was \$14.6 million, or \$0.50 per share, for the first quarter of 2014, compared to an adjusted net loss applicable to common stock of \$10.3 million, or \$0.36 per share, for the first quarter of 2013. 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 the 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.

As of March 31, 2014, Puma reported cash and cash equivalents of \$163.4 million and marketable securities of \$32.7 million, compared to cash and cash equivalents of \$43.0 million and marketable securities of \$40.9 million at December 31, 2013. Puma's current level of cash and cash equivalents includes net proceeds of approximately \$129.4 million from a public offering of the Company's common stock, which was completed in February 2014. As previously noted, Puma's license agreement for PB272 established a limit on the Company's expenses related to the licensor 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 March 31, 2014, the Company reported a receivable of approximately \$13.3 million associated with outstanding invoices to the licensor.

"During the first quarter of 2014 we achieved several important milestones, including the continued advancement of our Phase II and Phase III clinical trials for PB272. We also strengthened the Company's intellectual property portfolio through the successful outcome of the European patent opposition proceedings, which resulted in our patent claims for treating cancers with T790M mutations being upheld, and strengthened the Company's financial position with a public offering that resulted in net proceeds of approximately \$129 million," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma.

"We look forward to continuing to advance the clinical development of PB272 during the remainder of 2014," noted Mr. Auerbach. "More specifically, we anticipate that we will (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 in the second half of 2014; (ii) initiate a Phase III trial of the combination of PB272 plus temsirolimus in the second 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, with the potential to report data in 2014; (iv) complete our ongoing Phase II trial of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer (NSABP FB-7), which we expect to report data from in the first

half of 2014; (v) report data from our Phase II trial of PB272 in patients with HER2-mutated non-small cell lung cancer in 2014; (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 in 2014; (vii) continue our Phase II basket trial of PB272 in patients with solid tumors with an activating HER2 mutation, which we also have the potential to report initial data from in 2014; (viii) 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 (ix) 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 \$19.8 million for the first quarter of 2014, compared to \$11.8 million for the first quarter of 2013.

Adjusted operating expenses were \$14.7 million for the first quarter of 2014, compared to \$10.4 million for the first quarter of 2013. Adjusted operating expenses exclude stock-based compensation expenses and licensor legacy clinical trial costs. 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 \$3.5 million for the first quarter of 2014, compared to \$2.3 million for the first quarter of 2013.

Adjusted general and administrative expenses were \$2.2 million for the first quarter of 2014, compared to \$1.8 million for the first quarter of 2013.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$16.3 million for the first quarter of 2014, compared to \$9.5 million for the first quarter of 2013.

Adjusted research and development expenses were \$12.5 million for the first quarter of 2014, compared to \$8.5 million for the first quarter of 2013. The increase in adjusted research and development expenses from the first quarter of 2013 was driven primarily by increases of \$1.7 million in internal clinical development expenses, \$1.2 million in outside other clinical development expenses, \$0.4 million in outside CRO/licensor services and \$0.3 million in internal regulatory affairs and quality assurance expenses.

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 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, 2013. 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. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in millions except share and per share data)

	Three Months Ended		Period from
	March 31,		September 15,
	2014	2013	2010 (date of inception) to March 31, 2014
Operating expenses:			
General and administrative	\$ 3.5	\$ 2.3	\$ 47.5
Research and development	16.3	9.5	111.8
Totals	<u>19.8</u>	<u>11.8</u>	<u>159.3</u>
Loss from operations	<u>(19.8)</u>	<u>(11.8)</u>	<u>(159.3)</u>
Other income (expenses):			
Interest income	0.0	0.0	0.3
Other income (expense)	<u>(0.0)</u>	<u>0.0</u>	<u>(0.1)</u>
Totals	<u>0.0</u>	<u>0.0</u>	<u>0.2</u>
Net loss	<u>\$ (19.8)</u>	<u>\$ (11.8)</u>	<u>\$ (159.0)</u>
Net loss applicable to common stock	<u>\$ (19.8)</u>	<u>\$ (11.8)</u>	<u>\$ (159.0)</u>
Net loss per common share—basic and diluted	<u>\$ (0.67)</u>	<u>\$ (0.41)</u>	
Weighted-average common shares outstanding—basic and diluted	<u>29,567,071</u>	<u>28,676,666</u>	

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

	March 31, 2014	December 31, 2013
Cash and cash equivalents	\$ 163.4	\$ 43.0
Marketable securities	32.7	40.9
Licensor receivable	13.3	9.8
Working capital	191.4	77.1
Stockholders' equity	198.8	84.0
	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013
Cash provided by (used in):		
Operating activities	\$ (17.0)	\$ (18.5)
Investing activities	7.9	(27.3)
Financing activities	<u>129.4</u>	<u>-</u>
Increase (decrease) in cash	<u>\$ 120.3</u>	<u>\$ (45.8)</u>

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

	GAAP Measure (Reported)	Expense Adjustments		Non-GAAP Measure (Adjusted)
	Three Months Ended March 31, 2014	Stock-based compensation	Licensor legacy clinical trials	Three Months Ended March 31, 2014
	<i>2014 Operating expense:</i>			
General and administrative	\$ 3.5	\$ (1.3)	\$ -	\$ 2.2
Research and development	16.3	(3.8)	-	12.5
Loss from operations	(19.8)	5.1	-	(14.7)
Other income (expense):				
Interest income	0.0	-	-	0.0
Other expense	(0.0)	-	-	(0.0)
Totals	0.0	-	-	0.0
Net loss	\$ (19.8)	\$ 5.1	\$ -	\$ (14.7)
Net loss applicable to common stock	\$ (19.8)	\$ 5.1	\$ -	\$ (14.7)
Net loss per common share - basic and diluted	\$ (0.67)	\$ 0.17	\$ -	\$ (0.50)
Weighted-average common shares outstanding - basic and diluted	29,567,071	29,567,071	29,567,071	29,567,071

	GAAP Measure (Reported)	Expense Adjustments		Non-GAAP Measure (Adjusted)
	Three Months Ended March 31, 2013	Stock-based compensation	Licensor legacy clinical trials	Three Months Ended March 31, 2013
	<i>2013 Operating expense:</i>			
General and administrative	\$ 2.3	\$ (0.4)	\$ -	\$ 1.9
Research and development	9.5	(0.7)	(0.3)	8.5
Loss from operations	(11.8)	1.1	0.3	(10.4)
Other income (expense):				
Interest income	-	-	-	-
Other expense	-	-	-	-
Totals	-	-	-	-
Net loss	\$ (11.8)	\$ 1.1	\$ 0.3	\$ (10.4)
Net loss applicable to common stock	\$ (11.8)	\$ 1.1	\$ 0.3	\$ (10.4)
Net loss per common share - basic and diluted	\$ (0.41)	\$ 0.04	\$ 0.01	\$ (0.36)
Weighted-average common shares outstanding - basic and diluted	28,676,666	28,676,666	28,676,666	28,676,666