



News Release

Puma Biotechnology Reports Third Quarter 2014 Financial Results

LOS ANGELES, Calif., Nov. 10, 2014 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced financial results for the third quarter ended September 30, 2014.

Unless otherwise stated, all comparisons are for the third quarter and nine months ended September 30, 2014 compared to the third quarter and nine months ended September 30, 2013.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$35.8 million, or \$1.19 per share, for the third quarter of 2014, compared to a net loss of \$14.3 million, or \$0.50 per share, for the third quarter of 2013. Net loss applicable to common stock for the nine months ended September 30, 2014 was \$94.5 million, or \$3.17 per share, compared to \$38.7 million, or \$1.35 per share, for the nine months ended September 30, 2013.

Adjusted net loss applicable to common stock was \$25.4 million, or \$0.84 per share, for the third quarter of 2014, compared to adjusted net loss applicable to common stock of \$12.5 million, or \$0.44 per share, for the third quarter of 2013. Adjusted net loss applicable to common stock for the nine months ended September 30, 2014 was \$71.7 million, or \$2.41 per share, compared to \$34.3 million, or \$1.20 per share, for the nine months ended September 30, 2013. Adjusted net loss applicable to common stock excludes stock-based compensation expense, which represents a significant portion of overall expense and has no impact on the cash position of the Company. 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 2014 was \$24.3 million. Net cash used in operating activities for the nine months ended September 30, 2014 was \$58.7 million. At September 30, 2014, Puma had cash and cash equivalents of \$28.3 million and marketable securities of \$125.6 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 and marketable securities includes net proceeds of approximately \$129.4 million from a public offering of the Company's common stock, which was completed in February 2014.

“We are very proud of the milestones that were achieved by Puma during the third quarter of 2014,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “This includes the positive top-line results that were reported during the quarter from the Phase III trial of PB272 (neratinib) in extended adjuvant HER2 positive breast cancer (ExteNET trial), which demonstrated that neratinib achieved a statistically significant improvement in disease-free survival and disease-free survival that includes ductal carcinoma in situ. We look forward to proceeding with the regulatory filings for neratinib in extended adjuvant HER2 positive breast cancer currently anticipated for the first half of 2015. During the quarter we also announced Phase II data from a study of neratinib in patients with non-small cell lung cancer that has a HER2 mutation. In addition to the results showing that the combination of neratinib plus temsirolimus had good antitumor activity, for the first time we demonstrated that the prophylactic use of the antidiarrheal drug loperamide was able to greatly reduce the grade 3 or higher diarrhea that is typically seen with neratinib, which resulted in a greatly improved tolerability profile for the drug.

“In addition,” noted Mr. Auerbach, “we expect to (i) complete and report data from our ongoing Phase II randomized trial of PB272 as a first-line treatment for HER2-positive metastatic breast cancer during the fourth quarter of 2014; (ii) 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 fourth quarter of 2014; (iii) 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 in the fourth quarter of 2014; (iv) initiate a Phase III trial of the combination of PB272 plus temsirolimus during 2015; (v) 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 2015; (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 additional data from in 2015; and (vii) continue our Phase II basket trial of PB272 in patients with solid tumors with an activating HER2 mutation.”

Operating Expenses

Based on GAAP, operating expenses were \$36.0 million for the third quarter of 2014, compared to \$14.3 million for the third quarter of 2013. Operating expenses for the nine months ended September 30, 2014 were \$94.7 million compared to \$38.8 million for the nine months ended September 30, 2013.

Adjusted operating expenses were \$25.5 million for the third quarter of 2014, compared to \$12.5 million for the third quarter of 2013. Adjusted operating expenses for the nine months ended September 30, 2014 were \$71.9 million, compared to \$34.4 million for the nine months ended September 30, 2013. Adjusted operating expenses exclude stock-based compensation expenses. 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 \$3.9 million for the third quarter of 2014, compared to \$2.3 million for the third quarter of 2013. General and administrative expenses for the nine months ended September 30, 2014 were \$11.3 million compared to \$6.8 million for the nine months ended September 30, 2013.

Adjusted general and administrative expenses were \$2.5 million for the third quarter of 2014, compared to \$1.8 million for the third quarter of 2013. Adjusted general and administrative expenses for the nine months ended September 30, 2014 were \$7.2 million, compared to \$5.4 million for the nine months ended September 30, 2013.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$32.1 million for the third quarter of 2014, compared to \$12.0 million for the third quarter of 2013. Research and development expenses for the nine months ended September 30, 2014 were \$83.4 million, compared to \$32.0 million for the nine months ended September 30, 2013.

Adjusted research and development expenses were \$23.0 million for the third quarter of 2014, compared to \$10.7 million for the third quarter of 2013. Adjusted research and development expenses for the nine months ended September 30, 2014 were \$64.7 million, compared to \$29.0 million for the nine months ended September 30, 2013.

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.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

(in millions except share and per share data)

	Three Months Ended		Nine Months Ended		Period from
	September 30,		September 30,		September 15,
	2014	2013	2014	2013	2010 (date
					of inception) to
					September 30, 2014
Operating expenses:					
General and administrative	\$ 3.9	\$ 2.3	\$ 11.3	\$ 6.8	\$ 55.2
Research and development	32.1	12.1	83.4	32.0	178.9
Totals	<u>36.0</u>	<u>14.3</u>	<u>94.7</u>	<u>38.8</u>	<u>234.1</u>
Loss from operations	<u>(36.0)</u>	<u>(14.3)</u>	<u>(94.7)</u>	<u>(38.8)</u>	<u>(234.1)</u>
Other income (expenses):					
Interest income	0.1	0.0	0.2	0.1	0.5
Other income (expense)	0.0	0.0	(0.0)	0.0	(0.1)
Totals	<u>0.1</u>	<u>0.0</u>	<u>0.2</u>	<u>0.1</u>	<u>0.4</u>
Net loss	<u>\$ (35.8)</u>	<u>\$ (14.3)</u>	<u>\$ (94.5)</u>	<u>\$ (38.7)</u>	<u>\$ (233.7)</u>
Net loss per common share—basic and diluted	<u>\$ (1.19)</u>	<u>\$ (0.50)</u>	<u>\$ (3.16)</u>	<u>\$ (1.35)</u>	
Weighted-average common shares outstanding—basic and diluted	<u>30,117,819</u>	<u>28,682,055</u>	<u>29,936,254</u>	<u>28,678,439</u>	

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

	September 30,	December 31,
	2014	2013
Cash and cash equivalents	\$ 28.3	\$ 43.0
Marketable securities	125.6	40.9
Licensor receivable	1.8	9.8
Working capital	130.7	77.1
Stockholders' equity	141.6	84.0
	Nine Months Ended	Nine Months Ended
	September 30,	September 30,
	2014	2013
Cash provided by (used in):		
Operating activities	\$ (58.7)	\$ (41.5)
Investing activities	(85.5)	(44.8)
Financing activities	<u>129.4</u>	<u>0.1</u>
Increase (decrease) in cash	<u>\$ (14.8)</u>	<u>\$ (86.1)</u>

Reconciliation of GAAP and Non-GAAP Financial Information

(in millions except share and per share data)

	GAAP			GAAP		
	Measure (Reported)	Expense Adjustments	Non-GAAP Measure	Measure (Reported)	Expense Adjustments	Non-GAAP Measure
	Three Months Ended	Three Months Ended	Three Months Ended	Nine Months Ended	Nine Months Ended	Nine Months Ended
	September 30, 2014	Stock-based compensation	September 30, 2014	September 30, 2014	Stock-based compensation	September 30, 2014
Operating expense:						
General and administrative	\$ 3.87	\$ (1.38)	\$ 2.49	\$ 11.30	\$ (4.08)	\$ 7.22
Research and development	32.1	(9.1)	23.0	83.4	(18.7)	64.7
Loss from operations	(36.0)	10.4	(25.5)	(94.7)	22.8	(71.9)
Other income (expense):						
Interest income	0.1	-	0.1	0.2	-	0.2
Other expense	0.0	-	0.0	(0.0)	-	(0.0)
Totals	0.1	-	0.1	0.2	-	0.2
Net loss	\$ (36)	\$ 10	\$ (25)	\$ (94)	\$ 23	\$ (72)
Net loss applicable to common stock	\$ (35.8)	\$ 10.4	\$ (25.4)	\$ (94.5)	\$ 22.8	\$ (71.7)
Net loss per common share— basic and diluted	\$ (1.19)	\$ 0.35	\$ (0.84)	\$ (3.16)	\$ 0.76	\$ (2.40)
Weighted-average common shares outstanding—basic and diluted	30,117,819	30,117,819	30,117,819	29,936,254	29,936,254	29,936,254
	GAAP	Expense	Non-GAAP	GAAP	Expense	Non-GAAP
	Measure (Reported)	Adjustments	Measure	Measure (Reported)	Adjustments	Measure
	Three Months Ended	Three Months Ended	Three Months Ended	Nine Months Ended	Nine Months Ended	Nine Months Ended
	September 30, 2013	Stock-based compensation	September 30, 2013	September 30, 2013	Stock-based compensation	September 30, 2013
Operating expense:						
General and administrative	\$ 2.26	\$ (0.47)	\$ 1.79	\$ 6.80	\$ (1.35)	\$ 5.45
Research and development	12.1	(1.3)	10.7	32.0	(3.1)	29.0
Loss from operations	(14.3)	1.8	(12.5)	(38.8)	4.4	(34.4)
Other income (expense):						
Interest income	0.0	-	0.0	0.1	-	0.1
Other expense	0.0	-	0.0	0.0	-	0.0
Totals	0.0	-	0.0	0.1	-	0.1
Net loss	\$ (14.3)	\$ 1.8	\$ (12.5)	\$ (38.7)	\$ 4.4	\$ (34.3)
Net loss applicable to common stock	\$ (14.3)	\$ 1.8	\$ (12.5)	\$ (38.7)	\$ 4.4	\$ (34.3)
Net loss per common share— basic and diluted	\$ (0.50)	\$ 0.06	\$ (0.44)	\$ (1.35)	\$ 0.15	\$ (1.20)
Weighted-average common shares outstanding—basic and diluted	28,682,055	28,682,055	28,682,055	28,678,439	28,678,439	28,678,439