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Puma Biotechnology Reports Fourth Quarter and Full Year 2014 Financial Results

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2014.

Unless otherwise stated, all comparisons are for the fourth quarter and full year 2014 compared to the fourth quarter and full year 2013, respectively.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$47.5 million, or \$1.57 per share, for the fourth quarter of 2014, compared to a net loss of \$15.9 million, or \$0.55 per share, for the fourth quarter of 2013. Net loss applicable to common stock for the full year 2014 was \$142.0 million, or \$4.73 per share, compared to \$54.6 million, or \$1.90 per share, for the full year 2013.

Adjusted net loss applicable to common stock was \$31.1 million, or \$1.03 per share, for the fourth quarter of 2014, compared to adjusted net loss applicable to common stock of \$12.8 million, or \$0.45 per share, for the fourth quarter of 2013. Adjusted net loss applicable to common stock for the full year 2014 was \$102.8 million, or \$3.43 per share, compared to \$47.1 million, or \$1.64 per share, for the full year 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 fourth quarter of 2014 was \$18.5 million. Net cash used in operating activities for the full year 2014 was \$77.2 million. At December 31, 2014, Puma had cash and cash equivalents of \$38.5 million and marketable securities of \$102.8 million, compared to cash and cash equivalents of \$43.0 million and marketable securities of \$40.9 million at December 31, 2013.

"2014 was another year of significant clinical advancement of PB272 as we achieved several clinical milestones," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "These clinical milestones relate to a number of different potential indications for neratinib, including extended adjuvant early stage HER2-positive breast cancer (based on the positive top line results from the ExteNET trial); neoadjuvant HER2-positive early stage breast cancer (based on the positive results from the I-SPY2 Phase II trial); HER2-positive locally recurrent or metastatic breast cancer (based on the NEFERTT Phase II trial); and HER2-mutated solid tumors (based on data on HER2-mutated breast cancer and the expansion of the basket trial). In addition, we were pleased during 2014 to report data from several trials that demonstrated that the use of high dose loperamide prophylaxis reduced the neratinib-related diarrhea and greatly improve the tolerability profile of the drug.

"We expect our research productivity to continue in 2015. In 2015, we expect to (i) present and publish the Phase III ExteNET trial results of PB272 in the extended adjuvant treatment of early stage HER2-positive breast cancer (anticipated in mid-2015); (ii) present and publish the Phase II NEFERTT trial results of PB272 as a first-line treatment for HER2-positive locally recurrent or metastatic breast cancer (anticipated in mid-2015); (iii) complete our ongoing Phase II FB-7 trial of PB272 as a neoadjuvant treatment for patients with HER2-positive breast cancer (anticipated in the first half of 2015); (iv) initiate our Phase II trial of neratinib monotherapy with high dose loperamide prophylaxis in the extended adjuvant treatment of early stage HER2-positive breast cancer (anticipated in the first quarter of 2015); (v) expand additional cohorts in our Phase II basket trial of PB272 in patients with solid tumors with an activating HER2-mutation (anticipated in the first half of 2015); (vi) 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 the second half of 2015; (vii) report data from our Phase II trial of PB272 in HER2-negative breast cancer patients who have a HER2 mutation (anticipated in the second half of 2015); and (viii) initiate a Phase III trial of the combination of PB272 plus tamsirolimus in fourth line HER2-positive metastatic breast cancer (anticipated in the second half of 2015)."

Operating Expenses

Based on GAAP, operating expenses were \$47.6 million for the fourth quarter of 2014, compared to \$16.0 million for the fourth quarter of 2013. Operating expenses for the full year 2014 were \$142.3 million, compared to \$54.8 million for the full year 2013.

General and Administrative Expenses:

Based on GAAP, general and administrative expenses were \$8.1 million for the fourth quarter of 2014, compared to \$3.0 million for the fourth quarter of 2013. General and administrative expenses for the full year 2014 were \$19.4 million,

compared to \$9.8 million for the full year 2013.

Research and Development Expenses:

Based on GAAP, research and development expenses were \$39.5 million for the fourth quarter of 2014, compared to \$13.0 million for the fourth quarter of 2013. Research and development expenses for the full year 2014 were \$122.9 million, compared to \$45.0 million for the full year 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, 2014. 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.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended		Years Ended	
	December 31, (Unaudited)		December 31, (Audited)	
	2014	2013	2014	2013
Operating expenses:				
General and administrative	\$ 8.1	\$ 3.0	\$ 19.4	\$ 9.8
Research and development	39.5	13.0	122.9	45.0
Totals	<u>47.6</u>	<u>16.0</u>	<u>142.3</u>	<u>54.8</u>
Loss from operations	<u>(47.6)</u>	<u>(16.0)</u>	<u>(142.3)</u>	<u>(54.8)</u>
Other income (expenses):				
Interest income	0.1	0.1	0.3	0.2
Other income (expense)	—	—	—	—
Totals	<u>0.1</u>	<u>0.1</u>	<u>0.3</u>	<u>0.2</u>
Net loss	<u>\$ (47.5)</u>	<u>\$ (15.9)</u>	<u>\$ (142.0)</u>	<u>\$ (54.6)</u>
Net loss per common share—basic and diluted	<u>\$ (1.57)</u>	<u>\$ (0.55)</u>	<u>\$ (4.73)</u>	<u>\$ (1.90)</u>
Weighted-average common shares outstanding—basic and diluted	<u>30,232,718</u>	<u>28,750,382</u>	<u>30,010,979</u>	<u>28,696,573</u>

PUMA BIOTECHNOLOGY, INC.
LIQUIDITY AND CAPITAL RESOURCES
(in millions)

	December 31, 2014	December 31, 2013
	<u>2014</u>	<u>2013</u>
Cash and cash equivalents	\$ 38.5	\$ 43.0
Marketable securities	102.8	40.9
Licensor receivable	1.8	9.8
Working capital	104.9	77.1
Stockholders' equity	117.0	84.0
	Year Ended	Year Ended
	December 31,	December 31,
	<u>2014</u>	<u>2013</u>
Cash provided by (used in):		
Operating activities	\$ (77.2)	\$ (55.0)
Investing activities	(63.3)	(41.5)
Financing activities	136.0	2.2
	<u>2014</u>	<u>2013</u>
Increase (decrease) in cash	<u>\$ (4.5)</u>	<u>\$ (94.4)</u>

Non-GAAP Financial Measures:

In addition to the Company's operating results, as calculated in accordance with GAAP, the Company uses certain non-GAAP financial measures when planning, monitoring, and evaluating its operational performance. The following table presents the Company's net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of employee stock-based compensation. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. The Company believes these non-GAAP financial measures enhance understanding of its financial performance, are more indicative of its operational performance and facilitate a better comparison among fiscal periods.

**Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and
GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share**
(in millions except share and per share data)
(Unaudited)

	Three Months Ended December 31,	
	2014	2013
	<u>2014</u>	<u>2013</u>
GAAP net loss	\$ (47.5)	\$ (15.9)
Adjustments:		
Stock-based compensation -		
General and administrative	5.1	1.0 (1)
Research and development	11.3	2.1 (2)
Non-GAAP adjusted net loss	<u>\$ (31.1)</u>	<u>\$ (12.8)</u>
GAAP net loss per share - basic and diluted	\$ (1.57)	\$ (0.55)
Adjustment to net loss (as detailed above)	<u>0.54</u>	<u>0.10</u>

	\$ (1.03)	\$ (0.45)	(3)
	Years Ended December 31,		
	2014	2013	
Non-GAAP adjusted net loss per share	\$ (1.03)	\$ (0.45)	(3)
GAAP net loss	\$ (142.0)	\$ (54.6)	
Adjustments:			
Stock-based compensation -			
General and administrative	9.2	2.3	(1)
Research and development	30.0	5.2	(2)
Non-GAAP adjusted net loss	\$ (102.8)	\$ (47.1)	
GAAP net loss per share - basic and diluted	\$ (4.73)	\$ (1.90)	
Adjustment to net loss (as detailed above)	1.30	0.26	
Non-GAAP adjusted net loss per share	\$ (3.43)	\$ (1.64)	(4)

(1) To reflect a non-cash charge to operating expense for General and Administrative Stock-based compensation.

(2) To reflect a non-cash charge to operating expense for Research and Development Stock-based compensation.

(3) Non-GAAP adjusted net loss per share was calculated based on 30,232,718 and 28,750,382 weighted average common shares outstanding for the three months ended December 31, 2014 and 2013, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 30,010,979 and 28,696,573 weighted average common shares outstanding for the years ended December 31, 2014 and 2013, respectively.

Language:

English

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