News Release

Puma Biotechnology Reports Fourth Quarter and Full Year 2015 Financial Results

LOS ANGELES, Calif., Feb. 29, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2015.

Unless otherwise stated, all comparisons are for the fourth quarter and full year 2015 compared to the fourth quarter and full year 2014, respectively.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of $61.7 million, or $1.90 per share, for the fourth quarter of 2015, compared to a net loss of $47.5 million, or $1.57 per share, for the fourth quarter of 2014. Net loss applicable to common stock for the full year 2015 was $239.3 million, or $7.45 per share, compared to $142.0 million, or $4.73 per share, for the full year 2014.

Non-GAAP adjusted net loss was $40.0 million, or $1.23 per share, for the fourth quarter of 2015, compared to non-GAAP adjusted net loss of $31.1 million, or $1.03 per share, for the fourth quarter of 2014. Non-GAAP adjusted net loss for the full year 2015 was $144.3 million, or $4.49 per share, compared to $102.8 million, or $3.43 per share, for the full year 2014. Non-GAAP adjusted net loss excludes stock-based compensation expense, which represents a significant portion of overall expense and has no impact on the Company's cash position. For a 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, please see the financial tables at the end of this news release.

Net cash used in operating activities for the fourth quarter of 2015 was $33.3 million. Net cash used in operating activities for the full year 2015 was $154.5 million. At December 31, 2015, Puma had cash and cash equivalents of $31.6 million and marketable securities of $184.3 million, compared to cash and cash equivalents of $38.5 million and marketable securities of $102.8 million at December 31, 2014. Puma's current level of cash and cash equivalents and marketable securities includes net proceeds of approximately $205.1 million from a public offering of the Company's common stock, which was completed in January 2015.

"During the fourth quarter of 2015, Puma accomplished several clinical and regulatory milestones that contributed significant value to the shareholders of the Company," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "From the clinical perspective, in December we reported additional data from our Phase III ExteNET trial at the San Antonio Breast Cancer Symposium (SABCS), which continued to demonstrate that after 3 years of follow up, treatment with neratinib resulted in a statistically significant benefit in disease-free survival in patients with early stage HER2 positive breast cancer who had completed one year of adjuvant trastuzumab therapy. In addition, at SABCS we presented interim data from the Phase II trial of neratinib in patients with HER2-negative breast cancer who have a HER2 mutation that showed compelling benefit with neratinib, both as a monotherapy and in combination with fulvestrant. We also announced the interim data from our Phase II trial of neratinib monotherapy in patients with early stage HER2-positive breast cancer who had completed treatment with adjuvant trastuzumab, which demonstrated that using the loperamide prophylaxis with neratinib monotherapy treatment resulted in a lower rate of overall diarrhea, specifically grade 3 diarrhea, and resulted in diarrhea that was short term in duration and self-limiting. From the regulatory perspective, in November we announced that based on our Marketing Authorization Application (MAA) pre-submission meeting with the European Medicines Agency (EMA), at which the EMA assessed that there were no critical concerns that would prevent us from submitting a complete MAA for European centralized review in support of neratinib for the extended adjuvant treatment of HER2-positive early stage

breast cancer in patients who have previously been treated with a trastuzumab-containing regimen, that we anticipate submitting an MAA for neratinib in this indication in the first half of 2016.

"We look forward to continuing to contribute value to shareholders with neratinib during 2016. We anticipate (i) submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) during the first quarter of 2016 and submitting the MAA to the EMA during the first half of 2016 for neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer based on the positive ExteNET Phase III trial; (ii) reporting additional data from the Phase II trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer using loperamide prophylaxis during the first half of 2016; (iii) reporting additional Phase II data from the FB-7 neoadjuvant HER2-positive breast cancer trial in the subgroup of patients who are MammaPrint High, during the first half of 2016; (iv) reporting Phase II data from an investigator sponsored trial of neratinib in patients with HER2-negative breast cancer who have a HER2 mutation in mid-2016; (v) reporting data from the Phase III trial of neratinib in third-line HER2-positive metastatic breast cancer patients in either the fourth quarter of 2016 or the first quarter of 2017; (vi) reporting data from the Phase II trial of neratinib in metastatic breast cancer patients with brain metastases during the fourth quarter of 2016; and (vii) reporting data from the Phase II trial of neratinib plus fulvestrant in patients with HER2 non-amplified breast cancer that has a HER2 mutation during the fourth quarter of 2016."

Operating Expenses

Operating expenses were $62.1 million for the fourth quarter of 2015, compared to $47.6 million for the fourth quarter of 2014. Operating expenses for the full year 2015 were $239.3 million compared to $142.3 million for the full year 2014.

General and Administrative Expenses:

General and administrative expenses were $9.6 million for the fourth quarter of 2015, compared to $8.1 million for the fourth quarter of 2014. General and administrative expenses for the full year 2015 were $31.8 million compared to $19.4 million for the full year 2014. Approximately $8.0 million of the year-over-year increase resulted from an increase in stock-based compensation expense, with the majority of the remaining increase made up of approximately $2.2 million in professional fees, $0.9 million in payroll and related expenses and $0.6 million in facility and equipment costs. These increases reflect our corporate growth.

Research and Development Expenses:

Research and development expenses were $52.5 million for the fourth quarter of 2015, compared to $39.5 million for the fourth quarter of 2014. Research and development expenses for the full year 2015 were $208.5 million, compared to $122.9 million for the full year 2014. Approximately $47.8 million of the year-over-year increase resulted from an increase in stock-based compensation expense, with the majority of the remaining increase made up of approximately $22.9 million in clinical trial expense, $9.0 million in internal costs such as payroll and related expenses, and $5.9 million in expenses related to consultants and contractors. These increases reflect our increased clinical trial activity.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2.

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 regulatory filings and 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 and current 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, 2015. 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
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended December 31, (Unaudited)		Years Ended December 31, (Audited)	
	2015	2014	2015	2014
Operating expenses:				
General and administrative	$ 9.6	$ 8.1	$ 31.8	$ 19.4
Research and development	52.5	39.5	208.5	122.9
Totals	62.1	47.6	240.3	142.3
Loss from operations	(62.1)	(47.6)	(240.3)	(142.3)
Other income (expenses):				
Interest income	0.4	0.1	1.0	0.3
Other income (expense)	—	—	—	—
Totals	0.4	0.1	1.0	0.3
Net loss	$ (61.7)	$ (47.5)	$ (239.3)	$ (142.0)
Net loss per common share—basic and diluted	$ (1.90)	$ (1.57)	$ (7.45)	$ (4.73)
Weighted-average common shares outstanding—basic and diluted	32,444,270	30,232,718	32,126,094	30,010,979

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

	December 31, 2015	December 31, 2014
Cash and cash equivalents	$ 31.6	$ 38.5
Marketable securities	184.3	102.8
Licensor receivable	-	1.8
Working capital	191.1	104.9
Stockholders' equity	206.0	117.0

	Year Ended December 31, 2015	Year Ended December 31, 2014
Cash provided by (used in):		
Operating activities	$ (154.5)	$ (77.2)
Investing activities	(85.9)	(63.3)
Financing activities	233.4	136.0
Increase (decrease) in cash	$ (7.0)	$ (4.5)

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our 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. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our 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,		
	2015	2014	
GAAP net loss	$ (61.7)	$ (47.5)	
Adjustments:			
Stock-based compensation -			
General and administrative	5.0	5.1	(1)
Research and development	16.7	11.3	(2)
Non-GAAP adjusted net loss	$ (40.0)	$ (31.1)	
GAAP net loss per share - basic and diluted	$ (1.90)	$ (1.57)	
Adjustment to net loss (as detailed above)	0.67	0.54	
Non-GAAP adjusted net loss per share	$ (1.23)	$ (1.03)	(3)

	Years Ended December 31,		
	2015	2014	
GAAP net loss	$ (239.3)	$ (142.0)	
Adjustments:			
Stock-based compensation -			
General and administrative	17.2	9.2	(1)
Research and development	77.8	30.0	(2)
Non-GAAP adjusted net loss	$ (144.3)	$ (102.8)	
GAAP net loss per share - basic and diluted	$ (7.45)	$ (4.73)	
Adjustment to net loss (as detailed above)	2.96	1.30	
Non-GAAP adjusted net loss per share	$ (4.49)	$ (3.43)	(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 32,444,270 and 30,232,718 weighted average common shares outstanding for the three months ended December 31, 2015 and 2014, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 32,126,094 and 30,010,979 weighted average common shares outstanding for the years ended December 31, 2015 and 2014, respectively.