Puma Biotechnology Reports Fourth Quarter and Full Year 2016 Financial Results

March 1, 2017

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2016.

Unless otherwise stated, all comparisons are for the fourth quarter and full year 2016 compared to the fourth quarter and full year 2015.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of $72.7 million, or $2.04 per share, for the fourth quarter of 2016, compared to a net loss of $61.7 million, or $1.90 per share, for the fourth quarter of 2015. Net loss applicable to common stock for the full year 2016 was $276.0 million, or $8.29 per share, compared to $239.3 million, or $7.45 per share, for the full year 2015.

Non-GAAP adjusted net loss was $43.4 million, or $1.22 per share, for the fourth quarter of 2016, compared to non-GAAP adjusted net loss of $40.0 million, or $1.23 per share, for the fourth quarter of 2015. Non-GAAP adjusted net loss for the full year 2016 was $158.8 million, or $4.77 per share, compared to $144.3 million, or $4.49 per share, for the full year 2015. Non-GAAP adjusted net loss 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 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 2016 was $41.0 million. Net cash used in operating activities for the full year 2016 was $141.7 million. At December 31, 2016, Puma had cash and cash equivalents of $194.5 million and marketable securities of $35.0 million, compared to cash and cash equivalents of $31.6 million and marketable securities of $184.3 million at December 31, 2015. The Company's balance of cash, cash equivalents and marketable securities at year-end 2016 includes the net proceeds of approximately $162 million received from the Company's public offering in October 2016.

"We made significant progress with the neratinib clinical program during the fourth quarter," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We presented additional results of several ongoing studies at the 2016 San Antonio Breast Cancer Symposium, including our Phase II CONTROL trial of PB272 in the extended adjuvant treatment of HER2-positive early stage breast cancer; a biomarker analysis of the NSABP FB-7 Phase II trial for the neoadjuvant treatment of HER2-positive locally advanced breast cancer; and the Phase II SUMMIT trial of PB272 for ERBB2 (HER2) mutant, HER2 non-amplified metastatic breast cancer. We also initiated a Managed Access Program for PB272 (neratinib) outside the United States, providing physicians and patients access to PB272 when there are limited or no other therapeutic options available."

Mr. Auerbach added, "During 2017, we anticipate the following key milestones with neratinib: (i) reporting additional data in the second quarter of 2017 from the Phase II CONTROL trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer using antidiarrheal prophylaxis with loperamide and other agents (budesonide, colestipol); (ii) reporting interim Phase I/II data in the second quarter of 2017 from the NSABP FB-10 trial of neratinib plus Kadcyla (T-DM1) in HER2-positive metastatic breast cancer (MBC); (iii) reporting data in the second quarter of 2017 from the Phase II SUMMIT basket trial of neratinib in patients with HER2 non-amplified solid tumors that have a HER2 mutation; (iv) reporting data from the Phase III trial in third-line HER2-positive MBC patients in the first half of 2017; (v) reporting data in the second quarter of 2017 from the TBCRC-022 Phase II trial of neratinib plus capecitabine in HER2-positive MBC patients with brain metastases; (vi) reporting Phase II data in the second quarter of 2017 from the SUMMIT basket trial of neratinib in HER2-negative breast cancer patients with HER2 mutations; (vii) reporting final 5-year disease free survival (DFS) data during the second half of 2017 from the ExteNET Phase III trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer; and (viii) announcing regulatory decisions in the United States and European Union on neratinib for the extended adjuvant treatment of patients with HER2-positive early stage breast cancer in the third quarter of 2017."

Operating Expenses

Operating expenses were $72.9 million for the fourth quarter of 2016, compared to $62.1 million for the fourth quarter of 2015. Operating expenses for the full year 2016 were $276.6 million compared to $240.3 million for the full year 2015.

General and Administrative Expenses:

General and administrative expenses were $16.5 million for the fourth quarter of 2016, compared to $9.6 million for the fourth quarter of 2015. General and administrative expenses for the full year 2016 were $53.8 million compared to $31.8 million for the full year 2015. The increase of approximately $22.0 million during the full year 2016 compared to the same period in 2015 resulted

primarily from increases of approximately $9.4 million in stock-based compensation, $2.8 million in payroll and related costs, $7.1 million in professional fees and expenses and $2.2 million in facility and equipment costs. These increases reflect higher legal and compliance expenses, as well as overall corporate growth.

Research and Development Expenses:

Research and development expenses were $56.4 million for the fourth quarter of 2016, compared to $52.5 million for the fourth quarter of 2015. Research and development expenses for the full year 2016 were $222.8 million, compared to $208.5 million for the full year 2015. The increase of approximately $14.3 million during the full year 2016 compared to the same period in 2015 resulted primarily from increases of approximately $12.8 million in stock-based compensation, $6.2 million for internal clinical development, regulatory affairs and quality assurance and internal chemical manufacturing expenses and $2.0 million in consultants and contractors related expenses, offset by a $6.8 million decrease in clinical trial expenses.

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 the potential announcement of regulatory decisions in the United States and European Union on neratinib for the extended adjuvant treatment of patients with HER2-positive early stage breast cancer and the Company's 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, 2016. 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. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended December 31, (Unaudited)		Twelve Months Ended December 31, (Audited)	
	2016	2015	2016	2015
Operating expenses:				
General and administrative	$ 16.5	$ 9.6	$ 53.8	$ 31.8
Research and development	56.4	52.5	222.8	208.5
Totals	72.9	62.1	276.6	240.3
Loss from operations	(72.9)	(62.1)	(276.6)	(240.3)
Other income (expenses):				
Interest income	0.3	0.4	1.0	1.0
Other income (expense)	(0.1)	-	(0.4)	-
Totals	0.2	0.4	0.6	1.0
Net loss	$ (72.7)	$ (61.7)	$ (276.0)	$ (239.3)

Net loss per common share—basic and diluted	$ (2.04)	$ (1.90)	$ (8.29)	$ (7.45)
Weighted-average common shares outstanding—basic and diluted	35,694,193	32,444,270	33,295,114	32,126,094

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

	December 31, 2016	December 31, 2015
Cash and cash equivalents	$ 194.5	$ 31.6
Marketable securities	35.0	184.3
Working capital	199.0	191.1
Stockholders' equity	209.8	206.0

	Twelve Months Ended December 31, 2016	Twelve Months Ended December 31, 2015
Cash provided by (used in):		
Operating activities	$ (141.7)	$ (154.5)
Investing activities	142.2	(85.9)
Financing activities	162.4	233.4
Increase (decrease) in cash and cash equivalents	$ 162.9	$ (7.0)

Non-GAAP Financial Measures

In addition to operating results as calculated in accordance with generally accepted accounting principles, or GAAP, the Company uses certain non-GAAP financial measures when planning, monitoring, and evaluating operational performance. The following table presents the Company's net loss and net loss per share calculated in accordance with GAAP and as adjusted to remove the impact of employee stock-based compensation. For the three and twelve months ended December 31, 2016, stock-based compensation represented approximately 40.4% and 42.5% of net loss, respectively. Although net loss is important to measure financial performance, the Company currently places an emphasis on cash burn and, more specifically, cash used in operations. Stock-based compensation appears in GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows. Due to its noncash nature, the Company believes these non-GAAP measures enhance understanding of financial performance, are more indicative of operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
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,		
	2016	**2015**	
GAAP net loss	$ (72.7)	$ (61.7)	
Adjustments:			
Stock-based compensation -			
General and administrative	6.9	5.0	(1)
Research and development	22.4	16.7	(2)
Non-GAAP adjusted net loss	$ (43.4)	$ (40.0)	
GAAP net loss per share - basic and diluted	$ (2.04)	$ (1.90)	
Adjustment to net loss (as detailed above)	0.82	0.67	
Non-GAAP adjusted net loss per share	$ (1.22)	$ (1.23)	(3)

	Twelve Months Ended December 31,				
	2016		2015		
GAAP net loss	$	(276.0)	$	(239.3)	
Adjustments:					
Stock-based compensation -					
General and administrative		26.6		17.2	(1)
Research and development		90.6		77.8	(2)
Non-GAAP adjusted net loss	$	(158.8)	$	(144.3)	
GAAP net loss per share - basic and diluted	$	(8.29)	$	(7.45)	
Adjustment to net loss (as detailed above)		3.52		2.96	
Non-GAAP adjusted net loss per share	$	(4.77)	$	(4.49)	(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 35,694,193 and 32,444,270 weighted average common shares outstanding for the three months ended December 31, 2016 and 2015, respectively.
(4) Non-GAAP adjusted net loss per share was calculated based on 33,295,114 and 32,126,094 weighted average common shares outstanding for the twelve months ended December 31, 2016 and 2015, respectively.

Contact:

Puma Biotechnology, Inc.
Alan H. Auerbach or Mariann Ohanesian, +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com
or
Russo Partners
David Schull or Darren Chia, +1 212 845 4226
david.schull@russopartnersllc.com
darren.chia@russopartnersllc.com