



Puma Biotechnology Reports First Quarter 2017 Financial Results

May 10, 2017

LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the first quarter ended March 31, 2017.

Unless otherwise stated, all comparisons are for the first quarter 2017 compared to the first quarter 2016.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$72.9 million, or \$1.97 per share, for the first quarter of 2017, compared to a net loss applicable to common stock of \$71.0 million, or \$2.19 per share, for the first quarter of 2016.

Non-GAAP adjusted net loss was \$43.1 million, or \$1.16 per share, for the first quarter of 2017, compared to non-GAAP adjusted net loss of \$41.5 million, or \$1.28 per share, for the first quarter of 2016. 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 first quarter of 2017 was \$36.0 million. At March 31, 2017, Puma had cash and cash equivalents of \$105.1 million and marketable securities of \$88.9 million, compared to cash and cash equivalents of \$194.5 million and marketable securities of \$35.0 million at December 31, 2016.

"We made significant progress with our lead investigational drug, neratinib, during the first quarter of 2017," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We look forward to continuing to work with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) as they review our New Drug Application (NDA) and Marketing Authorization Application (MAA) filings, respectively, and we look forward to presenting the data on neratinib at the upcoming FDA Oncologic Drugs Advisory Committee on May 24th.

"Data on neratinib was also presented at the 2017 American Association for Cancer Research Annual Meeting in April which included data on the use of anti-diarrheal prophylaxis to reduce the diarrhea with neratinib in the extended adjuvant treatment of patients with early stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab-based therapy (CONTROL trial). There was also clinical data presented on neratinib in the treatment of patients who have solid tumors with activating HER2 or HER3 mutations (SUMMIT trial). Additional data was also presented on the combination of T-DM1 and neratinib in patients with HER2 positive metastatic breast cancer (MBC) that has previously been treated with pertuzumab and trastuzumab. We look forward to continuing to achieve our objectives and believe that Puma is very well-positioned to build value for our shareholders."

Mr. Auerbach added, "During 2017, we anticipate the following key milestones with neratinib: (i) reporting data from the Phase III trial in third-line HER2-positive MBC patients in the second quarter of 2017; (ii) 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; (iii) reporting final 5-year disease free survival (DFS) data during the second quarter of 2017 from the ExteNET Phase III trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer; and (iv) 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 \$73.2 million for the first quarter of 2017, compared to \$71.2 million for the first quarter of 2016.

General and Administrative Expenses:

General and administrative expenses were \$18.4 million for the first quarter of 2017, compared to \$11.0 million for the first quarter of 2016. The approximately \$7.4 million increase resulted primarily from increases of approximately \$1.4 million for stock-based compensation, \$3.9 million for professional fees, \$1.3 million for payroll and related costs, and \$0.5 million for facility and equipment costs. These increases reflect overall corporate growth.

Research and Development Expenses:

Research and development (R&D) expenses were \$54.8 million for the first quarter of 2017, compared to \$60.2 million for the first quarter of 2016. The approximately \$5.4 million decrease resulted primarily from decreases of approximately \$1.1 million for stock-based compensation and \$5.0 million for clinical trial expenses, partially offset by an increase of \$0.6 million for consultants

and contractors. For our existing clinical trials, we expect R&D expenses to decrease in subsequent quarters as clinical trials wind down.

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 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, 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 March 31, (Unaudited)	
	2017	2016
Operating expenses:		
General and administrative	\$ 18.4	\$ 11.0
Research and development	54.8	60.2
Totals	<u>73.2</u>	<u>71.2</u>
Loss from operations	<u>(73.2)</u>	<u>(71.2)</u>
Other income (expenses):		
Interest income	0.3	0.3
Other income (expense)	-	-
Totals	<u>0.3</u>	<u>0.3</u>
Net loss	<u>\$ (72.9)</u>	<u>\$ (71.0)</u>
Net loss per common share—basic and diluted	<u>\$ (1.97)</u>	<u>\$ (2.19)</u>
Weighted-average common shares outstanding—basic and diluted	<u>36,931,167</u>	<u>32,478,408</u>

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

	March 31, 2017	December 31, 2016
Cash and cash equivalents	\$ 105.1	\$ 194.5
Marketable securities	88.9	35.0
Working capital	160.9	199.0
Stockholders' equity	167.4	209.8
	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Cash provided by (used in):		
Operating activities	\$ (36.0)	\$ (35.0)
Investing activities	(54.1)	81.5
Financing activities	0.7	0.2
Increase (decrease) in cash and cash equivalents	<u>\$ (89.4)</u>	<u>\$ 46.7</u>

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 months ended March 31, 2017, stock-based compensation represented approximately 40.9% of net loss. 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)

	<u>Three Months Ended March 31,</u>	
	<u>2017</u>	<u>2016</u>
GAAP net loss	<u>\$ (72.9)</u>	<u>\$ (71.0)</u>
Adjustments:		
Stock-based compensation -		
General and administrative	7.3	5.9 (1)
Research and development	22.5	23.6 (2)
Non-GAAP adjusted net loss	<u>\$ (43.1)</u>	<u>\$ (41.5)</u>
GAAP net loss per share - basic and diluted	\$ (1.97)	\$ (2.19)
Adjustment to net loss (as detailed above)	0.81	0.91
Non-GAAP adjusted net loss per share	<u>\$ (1.16)</u>	<u>\$ (1.28) (3)</u>

(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 36,931,167 and 32,478,408 weighted average common shares outstanding for the three months ended March 31, 2017 and 2016, respectively.



Contact:

Puma Biotechnology, Inc.

Alan H. Auerbach or Mariann Ohanesian, +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

or

Russo Partners

Amiad Finkelthal or David Schull, +1 212 845 4200

amiad.finkelthal@russopartnersllc.com

david.schull@russopartnersllc.com