



Puma Biotechnology Reports Second Quarter 2017 Financial Results

August 9, 2017

LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the second quarter ended June 30, 2017.

Unless otherwise stated, all comparisons are for the second quarter and six months ended June 30, 2017, compared to the second quarter and six months ended June 30, 2016.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$77.8 million, or \$2.10 per share, for the second quarter of 2017, compared to a net loss applicable to common stock of \$66.6 million, or \$2.05 per share, for the second quarter of 2016. Net loss applicable to common stock for the first six months of 2017 was \$150.7 million, or \$4.08 per share, compared to \$137.6 million, or \$4.23 per share, for the first six months of 2016.

Non-GAAP adjusted net loss was \$50.9 million, or \$1.38 per share, for the second quarter of 2017, compared to non-GAAP adjusted net loss of \$37.9 million, or \$1.17 per share, for the second quarter of 2016. Non-GAAP adjusted net loss for the first six months of 2017 was \$94.0 million, or \$2.54 per share, compared to non-GAAP adjusted net loss of \$79.3 million, or \$2.44 per share, for the first six months 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 second quarter of 2017 was \$45.9 million. Net cash used in operating activities for the first six months of 2017 was \$82.0 million. At June 30, 2017, Puma had cash and cash equivalents of \$80.8 million and marketable securities of \$70.8 million, compared to cash and cash equivalents of \$194.5 million and marketable securities of \$35.0 million at December 31, 2016.

“During the second quarter of 2017, we achieved a significant milestone for Puma with the U.S. Food and Drug Administration’s (FDA) Oncologic Drugs Advisory Committee meeting, which led to last month’s FDA approval of NERLYNX™ (neratinib) for the extended adjuvant treatment of HER2-positive early stage breast cancer. This marked a major milestone for breast cancer patients and for Puma,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “Despite advances in early stage HER2-positive breast cancer treatment, there continues to be a need to reduce the risk of disease recurrence. NERLYNX has been demonstrated to significantly reduce that risk and offers physicians and their patients another treatment option. NERLYNX is now commercially available by prescription in the United States. We are also working with the European Medicines Agency (EMA) on their review of our marketing authorization application (MAA) for this indication and we expect the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the EMA, to issue an opinion regarding the MAA for neratinib in the first quarter of 2018.”

Mr. Auerbach added, “Also, during the second quarter, we presented data at the 2017 American Society of Clinical Oncology Annual Meeting from a Phase II trial of neratinib, which highlighted positive results from the TBCRC 022 trial in patients with HER2-positive metastatic breast cancer with brain metastases. In addition, during the quarter, we also achieved the targeted patient enrollment in our Phase III NALA trial of neratinib in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments (third-line disease) in the setting of metastatic disease. We anticipate that primary analysis of data related to the NALA trial will be available during the first half of 2018.

“In the second half of this year, we anticipate the following clinical milestones: (i) presentation of the 5-year disease free survival (DFS) data from the ExteNET Phase III trial of NERLYNX as an extended adjuvant treatment in HER2-positive early stage breast cancer in the third quarter of 2017 and (ii) reporting additional data in the fourth quarter of 2017 from the Phase II trial of neratinib as an extended adjuvant treatment in HER2-positive early stage breast cancer using loperamide, budesonide and colestipol anti-diarrheal prophylaxis.”

Operating Expenses

Operating expenses were \$78.2 million for the second quarter of 2017, compared to \$66.5 million for the second quarter of 2016. Operating expenses for the first six months of 2017 were \$151.4 million, compared to \$137.7 million for the first six months of 2016.

Selling, General and Administrative Expenses:

Selling, general and administrative (SG&A) expenses were \$24.9 million for the second quarter of 2017, compared to \$12.3 million for the second quarter of 2016. SG&A expenses for the first six months of 2017 were \$43.3 million, compared to \$23.3 million for

the first six months of 2016. The approximately \$20.0 million increase during the first six months of 2017 compared to the first six months of 2016 resulted primarily from increases of approximately \$2.6 million for stock-based compensation, \$13.7 million for professional fees and expenses, and \$2.1 million for payroll and related costs. These increases reflect overall corporate growth.

Research and Development Expenses:

Research and development (R&D) expenses were \$53.3 million for the second quarter of 2017, compared to \$54.2 million for the second quarter of 2016. R&D expenses for the first six months of 2017 were \$108.1 million, compared to \$114.4 million for the first six months of 2016. The approximately \$6.3 million decrease during the first six months of 2017, compared to the first six months of 2016, resulted primarily from decreases of approximately \$4.1 million for stock-based compensation and \$3.6 million for clinical trial expenses, offset by increases of \$0.9 million for internal clinical development and \$0.7 million for consultants and contractors related 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. NERLYNX™ (neratinib) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. 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 commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX 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.

IMPORTANT SAFETY INFORMATION

NERLYNX™ (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.
- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common adverse reactions ($\geq 5\%$) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and www.NERLYNX.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H₂-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- **Lactation:** Advise women not to breastfeed.

Please see [Full Prescribing Information](#) for additional safety information.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the benefits of NERLYNX, the CHMP's opinion regarding the MAA for neratinib, 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 only recently commenced commercialization and shipment of its only FDA approved product; the Company's dependence upon the commercial success of NERLYNX™ (neratinib); the Company's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company's ability to achieve or sustain profitability; the Company's ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company's operations; the effectiveness of sales and marketing efforts; the Company's ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; 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; risks pertaining to securities class action, derivative and defamation lawsuits; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. 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 June 30, (Unaudited)		Six Months Ended June 30, (Unaudited)	
	2017	2016	2017	2016
Operating expenses:				
Selling, general and administrative	\$ 24.9	\$ 12.3	\$ 43.3	\$ 23.3
Research and development	53.3	54.2	108.1	114.4
Totals	<u>78.2</u>	<u>66.5</u>	<u>151.4</u>	<u>137.7</u>
Loss from operations	<u>(78.2)</u>	<u>(66.5)</u>	<u>(151.4)</u>	<u>(137.7)</u>
Other income (expenses):				
Interest income	0.4	0.3	0.7	0.5
Other income (expense)	-	(0.4)	-	(0.4)
Totals	<u>0.4</u>	<u>(0.1)</u>	<u>0.7</u>	<u>0.1</u>
Net loss	<u>\$ (77.8)</u>	<u>\$ (66.6)</u>	<u>\$ (150.7)</u>	<u>\$ (137.6)</u>
Net loss per common share—basic and diluted	<u>\$ (2.10)</u>	<u>\$ (2.05)</u>	<u>\$ (4.08)</u>	<u>\$ (4.23)</u>
Weighted-average common shares outstanding—basic and diluted	<u>36,992,017</u>	<u>32,493,092</u>	<u>36,961,760</u>	<u>32,485,750</u>

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

June 30,	December 31,
<u>2017</u>	<u>2016</u>

Cash and cash equivalents	\$ 80.8	\$ 194.5
Marketable securities	70.8	35.0
Working capital	113.6	199.0
Stockholders' equity	120.1	209.8

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Cash provided by (used in):		
Operating activities	\$ (82.0)	\$ (65.8)
Investing activities	(36.0)	91.9
Financing activities	4.3	0.2
Increase (decrease) in cash and cash equivalents	\$ (113.7)	\$ 26.3

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 six months ended June 30, 2017, stock-based compensation represented approximately 34.6% and 43.1% 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 June 30,	
	2017	2016
GAAP net loss	\$ (77.8)	\$ (66.6)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative	7.3	6.1 (1)
Research and development	19.6	22.6 (2)
Non-GAAP adjusted net loss	\$ (50.9)	\$ (37.9)
GAAP net loss per share - basic and diluted	\$ (2.10)	\$ (2.05)
Adjustment to net loss (as detailed above)	0.72	0.88
Non-GAAP adjusted net loss per share	\$ (1.38)	\$ (1.17) (3)

	Six Months Ended June 30,	
	2017	2016
GAAP net loss	\$ (150.7)	\$ (137.6)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative	14.6	12.1 (1)
Research and development	42.1	46.2 (2)
Non-GAAP adjusted net loss	\$ (94.0)	\$ (79.3)

GAAP net loss per share - basic and diluted	\$	(4.08)	\$	(4.23)
Adjustment to net loss (as detailed above)		1.54		1.79
Non-GAAP adjusted net loss per share	\$	<u>(2.54)</u>	\$	<u>(2.44)</u> (4)

- (1) To reflect a non-cash charge to operating expense for Selling, 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 36,992,017 and 32,493,092 weighted average common shares outstanding for the three months ended June 30, 2017 and 2016, respectively.
- (4) Non-GAAP adjusted net loss per share was calculated based on 36,961,760 and 32,485,750 weighted average common shares outstanding for the six months ended June 30, 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

David Schull or Amiad Finkelthal

+1-212-845-4200

david.schull@russopartnersllc.com

amiad.finkelthal@russopartnersllc.com