



## Puma Biotechnology Reports First Quarter 2018 Financial Results

May 9, 2018

LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (NASDAQ: PBUI), a biopharmaceutical company, announced financial results for the first quarter ended March 31, 2018.

Unless otherwise stated, all comparisons are for the first quarter 2018 compared to the first quarter 2017.

On July 17, 2017, Puma Biotechnology received approval from the U.S. Food and Drug Administration (FDA) for NERLYNX® (neratinib) for the treatment of early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and the Company began shipment to wholesalers at the end of July 2017. Prior to the launch of NERLYNX the Company had no product revenue. Net product revenue from sales of NERLYNX in the first quarter of 2018 amounted to \$36.0 million, compared to net product revenue of \$6.1 million and \$20.1 million in the third and fourth quarters of 2017, respectively.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of \$24.3 million, or \$0.65 per share, for the first quarter of 2018, compared to a net loss applicable to common stock of \$72.9 million, or \$1.97 per share, for the first quarter of 2017.

Non-GAAP adjusted net income was \$1.1 million, or \$0.03 per basic share and \$0.02 per diluted share, for the first quarter of 2018, compared to non-GAAP adjusted net loss of \$43.1 million, or \$1.16 per basic and diluted share, for the first quarter of 2017. Non-GAAP adjusted net income (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 income (loss) and GAAP net loss per share to non-GAAP adjusted net income (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 2018 was \$6.3 million. At March 31, 2018, Puma had cash and cash equivalents of \$78.6 million, compared to cash and cash equivalents of \$81.7 million at December 31, 2017.

"We made substantial progress in the commercialization of our lead product, NERLYNX® (neratinib), during the first quarter of 2018," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "We quickly built momentum in the U.S. market, with net sales steadily rising since our launch. Our exclusive licensing agreements to date, with Pint Pharma in Latin America, CANbridge in mainland China and Taiwan, Medison Pharma in Israel, and Specialised Therapeutics Asia in South East Asia, demonstrate our commitment to also make NERLYNX accessible to patients globally while we continue to grow the U.S. market.

"We are also pleased with the updated National Comprehensive Cancer Network (NCCN) guidelines, which designate NERLYNX as a recommended combination treatment option for breast cancer patients with brain metastases. In addition, data on neratinib were published in the journal *Nature*, which included initial results from Puma's ongoing SUMMIT Phase II 'basket' clinical trial in patients with tumors harboring HER2 or HER3 mutations. SUMMIT is designed to evaluate the contributions of both genetic mutation and cancer type on individual patient response to neratinib. Information generated from the trial will help guide neratinib-based targeted therapy across a broad spectrum of tumor types with HER2 or HER3 mutations, including patients with rare tumors who may not otherwise have access to investigational therapies. We believe the publication of the initial SUMMIT data in this prestigious journal reflects the novelty and quality of this precision-medicine trial design, as well as the growing understanding that both tumor type and gene mutations play an important role in individual patients' response to cancer therapies such as neratinib."

Mr. Auerbach added, "During 2018, we anticipate the following key milestones: (i) reporting updated Phase I/II data from neratinib plus Kadcyla (T-DM1) in the HER2-positive metastatic breast cancer trial in the second quarter of 2018; (ii) re-assessment of the Marketing Authorisation Application for neratinib by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in mid-2018; (iii) reporting data from the Phase III trial in third-line metastatic breast cancer patients in the second half of 2018; (iv) submitting for regulatory approval for the extended adjuvant HER2-positive early stage breast cancer indication in select countries in the second half of 2018; and (v) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2018."

### Revenue

Total revenue consists of net product revenue from sales of NERLYNX, Puma's first and only commercial product to date, and license revenue. The FDA approved NERLYNX for commercial sale in the United States in July 2017 and the Company commenced shipment to wholesalers in late July. For the first quarter of 2018, total revenue was \$66.5 million, of which \$36.0 million was net product revenue and \$30.5 million was license revenue received from Puma's sub-licensees.

## Operating Expenses

Operating expenses were \$89.9 million for the first quarter of 2018, compared to \$73.2 million for the first quarter of 2017.

### *Cost of Sales:*

Cost of sales was \$6.4 million for the first quarter of 2018. The Company had no product sales prior to the third quarter of 2017.

### *Selling, General and Administrative Expenses:*

Selling, general and administrative expenses were \$36.6 million for the first quarter of 2018, compared to \$18.4 million for the first quarter of 2017. The \$18.2 million increase resulted primarily from increases of approximately \$7.8 million in payroll and related costs, \$6.6 million in marketing, market access, and legal expenses, \$1.7 million in travel and related costs, and \$1.7 million in stock-based compensation. These increases reflect the commercial launch of NERLYNX and overall corporate growth.

### *Research and Development Expenses:*

Research and development (R&D) expenses were \$46.9 million for the first quarter of 2018, compared to \$54.8 million for the first quarter of 2017. The \$7.9 million decrease resulted primarily from decreases of approximately \$6.1 million for stock-based compensation and \$4.0 million for clinical trial expenses, partially offset by an increase of \$2.2 million for payroll and related costs in medical affairs and commercial quality assurance. For our existing clinical trials, we expect R&D expenses to decrease in subsequent quarters as clinical trials continue to wind down.

## Conference Call

Puma Biotechnology will host a conference call to report its first quarter 2018 financial results and provide an update on the company's business and outlook at 1:30 p.m. PDT/4:30 p.m. EDT on Wednesday, May 9, 2018. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (international) at least 10 minutes prior to the start of the call and referencing the "Puma Biotechnology Conference Call." A live webcast of the conference call and presentation slides may be accessed on the Investors section of the Puma Biotechnology website at <http://www.pumabiotechnology.com/>. A replay of the call will be available approximately one hour after completion of the call and will be archived on the company's website for 90 days.

## 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, oral was approved by the U.S. Food and Drug Administration in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

Further information about Puma Biotechnology may be found at [www.pumabiotechnology.com](http://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  $\geq 2$  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](http://www.NERLYNX.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://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 and neratinib, the progress and expected timing of the Company's clinical trials, the announcement of data relative to those trials and the timing for anticipated regulatory approvals. All forward-looking statements 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 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, 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 March 31, (Unaudited)	
	2018	2017
Product revenue, net	\$ 36.0	\$ —
License revenue	30.5	—
Total revenue	66.5	—
Operating costs and expenses:		
Cost of sales	6.4	—
Selling, general and administrative	36.6	18.4
Research and development	46.9	54.8
Totals	89.9	73.2
Loss from operations	(23.4)	(73.2)
Other income (expenses):		
Interest income	0.2	0.3
Interest expense	(1.1)	—
Totals	(0.9)	0.3
Net loss	\$ (24.3)	\$ (72.9)
Net loss per common share—basic and diluted	\$ (0.65)	\$ (1.97)
Weighted-average common shares outstanding—basic and diluted	37,699,024	36,931,167

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

	March 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 78.6	\$ 81.7
Marketable securities	—	—
Working capital	53.1	48.1
Stockholders' equity	57.5	53.3
	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Cash provided by (used in):		
Operating activities	\$ (6.3)	\$ (36.0)
Investing activities	-	(54.1)
Financing activities	3.2	0.7
Decrease in cash and cash equivalents	<u>\$ (3.1)</u>	<u>\$ (89.4)</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, 2018 and 2017, stock-based compensation represented approximately 28.3% and 40.7% of operating expense, 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 Income (Loss) and GAAP Net Loss Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share (in millions except share and per share data) (Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
GAAP net loss	<u>\$ (24.3)</u>	<u>\$ (72.9)</u>
Adjustments:		
Stock-based compensation -		
Selling, general and administrative	9.0	7.3 (1)
Research and development	16.4	22.5 (2)
Non-GAAP adjusted net income (loss)	<u>\$ 1.1</u>	<u>\$ (43.1)</u>
GAAP net loss per share - basic	\$ (0.65)	\$ (1.97)
Adjustment to net loss (as detailed above)	0.68	0.81
Non-GAAP adjusted basic net income (loss) per share	<u>\$ 0.03</u>	<u>\$ (1.16) (3)</u>
GAAP net loss per share—diluted	\$ (0.60)	\$ (1.97)
Adjustment to net loss (as detailed above)	0.62	0.81
Non-GAAP adjusted diluted net income (loss) per share	<u>\$ 0.02 (4)</u>	<u>\$ (1.16) (5)</u>

(1) To reflect a non-cash charge to operating (1) 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 income (loss) per share was calculated based on 37,699,024 and 36,931,167 weighted average common shares outstanding for the three months ended March 31, 2018 and 2017, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 40,642,311 weighted average common shares outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended March 31, 2018.

(5) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in this non-GAAP adjusted diluted net loss per share for the three months ended March 31, 2017 as these shares would be considered anti-dilutive.

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