



Published on *Puma Biotechnology Investor Center* (<https://investor.pumabiotechnology.com>) on 5/9/19 1:10 pm PDT

Puma Biotechnology Reports First Quarter 2019 Financial Results

Release Date:

Thursday, May 9, 2019 1:10 pm PDT

Terms:

Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the first quarter ended March 31, 2019. Unless otherwise stated, all comparisons are for the first quarter 2019 compared to the first quarter of 2018.

Product revenue, net consists entirely of sales revenue from NERLYNX®, Puma's first commercial product. Net NERLYNX revenue in the first quarter of 2019 was \$45.6 million, compared to net NERLYNX revenue of \$36.0 million in the first quarter of 2018.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss of \$10.1 million, or \$0.26 per share, for the first quarter of 2019, compared to a net loss of \$24.3 million, or \$0.65 per share, for the first quarter of 2018.

Non-GAAP adjusted net income was \$8.1 million, or \$0.21 per basic share and \$0.20 per diluted share, for the first quarter of 2019, compared to non-GAAP adjusted net income of \$1.1 million, or \$0.03 per basic share and \$0.02 per diluted share, for the first quarter of 2018. Non-GAAP adjusted net income excludes stock-based compensation expense, which represents a significant portion of overall expense. For a reconciliation of GAAP net loss to non-GAAP adjusted net income and GAAP net loss per share to non-GAAP adjusted net income 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 2019 was \$16.1 million, compared to \$6.3 million in the first quarter of 2018. At March 31, 2019, Puma had cash and cash equivalents of \$48.8 million and marketable securities of \$101.6 million, compared to cash and cash equivalents of \$108.4 million and marketable securities of \$57.0 million at December 31, 2018. Puma's cash and cash equivalents at March 31, 2019 did not include a \$60.0 million upfront license payment that was received in April 2019. At March 31, 2019, the \$60.0 million upfront license payment was recorded in accounts receivable.

"Puma experienced lower than expected net product revenue in the first quarter of 2019," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "This reduction in net revenues was the result of an increase in expenses charged against gross revenue for the quarter. Additionally, net product revenue declined in the quarter as a result of an increase in patients discontinuing treatment with NERLYNX."

Mr. Auerbach added, "During 2019, we anticipate the following key milestones for Puma: (i) presenting data from the Phase III trial of neratinib in third-line metastatic breast cancer patients in the second quarter of 2019; (ii) filing a new drug application for neratinib based on the results of the Phase III trial in third-line metastatic breast cancer in the summer of 2019; (iii) meeting with the FDA to discuss the clinical development and regulatory strategy for the SUMMIT trial in the summer of 2019; (iv) receiving regulatory decisions for the extended adjuvant HER2-positive early stage breast cancer indication in other countries in the second half of 2019; (v) reporting additional data from the Phase II CONTROL trial in the second quarter of 2019; and (vi) reporting Phase II data from the SUMMIT basket trial in patients with HER2 mutations in the second half of 2019."

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma's first commercial product, and license revenue. For the first quarter ended March 31, 2019, total revenue was \$99.1 million, of which \$45.6 million was net NERLYNX revenue and \$53.5 million was license revenue received from Puma's sub-licensees. This compares to total revenue of \$66.5 million in the first quarter of 2018, of which \$36.0 million was net NERLYNX revenue and \$30.5 million was license revenue.

Operating Costs and Expenses

Total operating costs and expenses were \$89.2 million for the first quarter of 2019, compared to \$89.9 million for the first quarter of 2018.

Cost of Sales:

Cost of sales was \$8.0 million for the first quarter of 2019, compared to \$6.4 million for the first quarter of 2018.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were \$45.5 million for the first quarter of 2019, compared to \$36.6 million for the first quarter of 2018. The \$8.9 million increase resulted primarily from increases of approximately \$6.8 million for

professional fees such as legal fees and marketing and commercial support, approximately \$0.9 million related to employee stock-based compensation expense, approximately \$0.7 million in payroll and payroll related expenses, and approximately \$0.4 million in travel and meeting-related expenses.

Research and Development Expenses:

Research and development (R&D) expenses were \$35.7 million for the first quarter of 2019, compared to \$46.9 million for the first quarter of 2018. The \$11.2 million decrease resulted primarily from decreases of approximately \$8.1 million of stock-based compensation, \$2.1 million in internal R&D primarily related to payroll and payroll related expenses, \$1.5 million in clinical trial expenses primarily due to external clinical service, external manufacturing, testing and logistics, partially offset by increases in CRO-related expenses, grant expenditures and comparator drug expenses.

Total Other Income (Expenses)

Total other expenses were \$20.0 million for the first quarter of 2019, compared to total other expenses of \$0.9 million for the first quarter of 2018. Other expense recorded in the first quarter of 2019 includes \$16.4 million related to a March 2019 jury verdict against Puma in a defamation lawsuit, *Eshelman v. Puma Biotechnology, Inc., et al.*, and represents \$22.4 million in damages awarded to the plaintiff, net of a \$6.0 million anticipated insurance receivable. Puma intends to appeal the verdict and has filed a motion for a new trial or, in the alternative, a reduced damages award. The plaintiff has also filed motions seeking attorneys' fees and pre-judgment interest. The total amount of damages to be paid by Puma remains subject to the exhaustion of post-trial motions and appeals.

Conference Call

Puma Biotechnology will host a conference call to report its first quarter 2019 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 Thursday, May 9, 2019. 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 FDA 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 was granted marketing authorization by the European Commission in September 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

Further information about Puma Biotechnology may 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 at least 2 hours before or 10 hours after H2-receptor antagonists.

- 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 Puma's anticipated milestones for 2019. All forward-looking statements involve risks and uncertainties that could cause Puma'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 Puma with the Securities and Exchange Commission from time to time, including Puma's Annual Report on Form 10-K for the year ended December 31, 2018. 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)	
	2019	2018
Revenues:		
Product revenue, net	\$ 45.6	\$ 36.0
License revenue	53.5	30.5
Total revenue	99.1	66.5
Operating costs and expenses:		
Cost of sales	8.0	6.4
Selling, general and administrative	45.5	36.6
Research and development	35.7	46.9
Total operating costs and expenses	89.2	89.9
Profit from operations	9.9	(23.4)
Other income (expenses):		
Interest income	0.9	0.2
Interest expense	(4.5)	(1.1)
Legal verdict expenses	(16.4)	—
Other expense	-	—
Total other expenses	(20.0)	(0.9)
Net loss	\$ (10.1)	\$ (24.3)
Net loss per common share—basic and diluted	\$ (0.26)	\$ (0.65)
Weighted-average common shares outstanding—basic and diluted	38,481,824	37,699,024

LIQUIDITY AND CAPITAL RESOURCES
(in millions)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 48.8	\$ 108.4
Marketable securities	101.6	57.0
Working capital	154.8	135.9
Stockholders' equity	43.5	34.3
	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Cash provided by (used in):		
Operating activities	\$ (16.1)	\$ (6.3)
Investing activities	(44.6)	—
Financing activities	1.1	3.2
Decrease in cash and cash equivalents, and restricted cash	<u>\$ (59.6)</u>	<u>\$ (3.1)</u>

Non-GAAP Financial Measures

In addition to operating results as calculated in accordance with GAAP, Puma 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, 2019 and 2018, stock-based compensation represented approximately 22.4% and 30.4% of operating expenses, respectively, in each case excluding cost of sales. Puma's management believes that these non-GAAP financial measures are useful to enhance understanding of Puma's financial performance, and are more indicative of its 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 and

GAAP Net Loss Per Share to Non-GAAP Adjusted Income Per Share

(in millions except share and per share data)

(Unaudited)

	Three Months Ended March 31,		
	2019	2018	
GAAP net loss	\$ (10.1)	\$ (24.3)	
Adjustments:			
Stock-based compensation -			
Selling, general and administrative	9.9	9.0	(1)
Research and development	8.3	16.4	(2)
Non-GAAP adjusted net income	<u>\$ 8.1</u>	<u>\$ 1.1</u>	
GAAP net loss per share - basic	\$ (0.26)	\$ (0.65)	
Adjustment to net loss (as detailed above)	<u>0.47</u>	<u>0.68</u>	

Non-GAAP adjusted net income per share	\$ 0.21	\$ 0.03	(3)
GAAP net loss per share—diluted	\$ (0.26)	\$ (0.60)	
Adjustment to net loss (as detailed above)	0.46	0.62	
Non-GAAP adjusted diluted net income per share	\$ 0.20	\$ 0.02	(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 basic net income per share was calculated based on 38,481,824 and 37,699,024 weighted-average shares of common stock outstanding for the three months ended March 31, 2019 and 2018, respectively.

(4) Non-GAAP adjusted diluted net income per share was calculated based on 39,281,714 and 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, 2019 and 2018, respectively.

Language:

English

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Ticker: PBYI

Exchange: NASDAQ

ISIN:

US74587V1070

Source URL: <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-reports-first-quarter-2019-financial-results>