

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 6, 2021

PUMA BIOTECHNOLOGY, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35703
(Commission
File Number)

77-0683487
(IRS Employer
Identification No.)

**10880 Wilshire Boulevard, Suite 2150
Los Angeles, California 90024**
(Address of principal executive offices) (Zip Code)

(424) 248-6500
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	PBYI	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 6, 2021, Puma Biotechnology, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2021. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 2.02, including the accompanying exhibit, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section. The information in this Item 2.02 shall not be incorporated by reference into any filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press Release dated May 6, 2021](#)

104 Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: May 6, 2021

By: /s/ Alan H. Auerbach
Alan H. Auerbach
Chief Executive Officer and President



News Release

Puma Biotechnology Reports First Quarter 2021 Financial Results

LOS ANGELES, Calif., May 6, 2021 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the first quarter ended March 31, 2021. Unless otherwise stated, all comparisons are for the first quarter of 2021 compared to the first quarter of 2020.

Product revenue, net consists entirely of sales revenue from NERLYNX[®], Puma's first commercial product. Net NERLYNX revenue in the first quarter of 2021 was \$45.8 million, compared to \$48.6 million in the first quarter of 2020.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported net income of \$16.5 million, or \$0.41 per basic share and \$0.40 per diluted share, for the first quarter of 2021, compared to a net loss of \$16.9 million, or \$0.43 per share, for the first quarter of 2020.

Non-GAAP adjusted net income was \$22.4 million, or \$0.56 per basic share and \$0.55 per diluted share for the first quarter of 2021, compared to non-GAAP adjusted net loss of \$8.0 million, or \$0.20 per share, for the first quarter of 2020. Non-GAAP adjusted net income excludes stock-based compensation expense. For a reconciliation of GAAP net income (loss) to non-GAAP adjusted net income (loss) and GAAP net income (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 provided by operating activities for the first quarter of 2021 was \$15.7 million, compared to net cash used in operating activities of \$11.5 million in the first quarter of 2020. At March 31, 2021, Puma had cash, cash equivalents and marketable securities of \$109.1 million, compared to cash, cash equivalents and marketable securities of \$93.4 million at December 31, 2020.

“During the first quarter, we continued to face the challenges brought about by the COVID-19 pandemic and the reduction in commercial access caused by it,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “We are hopeful that with the progress made with vaccinations, commercial access will improve in 2021 which will greatly aid our commercial abilities. We continue to remain focused on and committed to providing support to patients battling cancer.”

“In terms of clinical development, we are pleased that during the first quarter we were able to achieve the completion of enrollment in the randomized cohorts of the Phase II SUMMIT trial of neratinib for patients with hormone receptor-positive breast cancer that has a HER2 mutation. Enrollment in the other cohorts in SUMMIT continued as well, including for patients with EGFR exon 18 mutated non-small cell lung cancer and HER2 mutated cervical cancer. Additionally, our global partners continued to launch NERLYNX in several new countries during the first quarter and we look forward to launches in additional countries throughout 2021.”

Mr. Auerbach added, “We anticipate the following key milestones over the next 12 months: (i) reporting top line data from the randomized cohort of the Phase II SUMMIT trial of neratinib in hormone receptor positive breast cancer that has a HER2 mutation (2021); (ii) reporting Phase II data from the SUMMIT trial of neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations (H2-2021); (iii) conducting a pre-NDA meeting with the FDA to discuss accelerated approval of neratinib in HER2-mutated

hormone receptor positive breast cancer and HER2-mutated cervical cancer (2021); (iv) reporting data from the Phase II TBCRC-022 trial of the combination of Kadcyła plus neratinib in patients with HER2-positive breast cancer with brain metastases who have previously been treated with Kadcyła (H2-2021); (v) conducting a meeting with the FDA to discuss the potential for an accelerated approval pathway for neratinib in non-small cell lung cancer patients with EGFR exon 18 mutations who have previously been treated with an EGFR tyrosine kinase inhibitor (2021); and (vi) receiving regulatory decisions for the extended adjuvant HER2-positive early stage breast cancer indication in additional countries (2021).”

Revenue

Total revenue consists of product revenue, net from sales of NERLYNX, Puma’s first commercial product, license revenue from Puma’s sub-licensees and royalty revenue. For the first quarter ended March 31, 2021, total revenue was \$98.2 million, of which \$45.8 million was net product revenue, \$50.0 million was license revenue and \$2.4 million was royalty revenue. The \$50.0 million of license revenue in the first quarter of 2021 represents an upfront payment for providing our existing partner Pierre Fabre with development, manufacturing, and commercial rights to NERLYNX in Greater China. Total revenue was \$51.2 million in the first quarter of 2020, of which \$48.6 million was net product revenue, \$2.0 million was license revenue, and \$0.6 million was royalty revenue.

Operating Costs and Expenses

Total operating costs and expenses were \$78.0 million for the first quarter of 2021, compared to \$65.5 million for the first quarter of 2020.

Cost of Sales

Cost of sales was \$29.6 million for the first quarter of 2021, of which \$20.0 million represents a termination fee paid to a former sub-licensee for the return of commercial rights to NERLYNX in Greater China. Cost of sales was \$9.1 million for the first quarter of 2020.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$28.2 million for the first quarter of 2021, compared to \$30.9 million for the first quarter of 2020. The \$2.7 million decrease resulted primarily from decreases in stock-based compensation expense of approximately \$1.1 million, travel and meetings of approximately \$1.4 million and other expenses of approximately \$0.4 million, partially offset by an increase in professional fees of approximately \$0.3 million.

Research and Development Expenses

Research and development expenses were \$20.2 million for the first quarter of 2021, compared to \$25.5 million for the first quarter of 2020. The \$5.3 million decrease resulted primarily from decreases in clinical trial costs of approximately \$2.7 million, stock-based compensation expense of approximately \$2.0 million and consultant and contractor costs of approximately \$0.6 million.

Total Other Expenses

Total other expenses were \$3.7 million for the first quarter of 2021, compared to \$2.6 million for the first quarter of 2020. The \$1.1 million increase resulted primarily from decreases in interest income and other income of approximately \$0.5 million, as well as an increase in interest expense of \$0.5 million.

Conference Call

Puma Biotechnology will host a conference call to discuss its first quarter 2021 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 6, 2021. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (international). Please dial in at least 10 minutes in advance and inform the operator that you would like to join 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 shortly after completion of the call and will be archived on Puma'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. Puma in-licenses the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in 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. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. NERLYNX was granted marketing authorization by the European Commission in 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 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:

- As a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
- In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer, who have received two or more prior anti-HER2 based regimens in the metastatic setting.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea. If diarrhea occurs despite recommended prophylaxis, treat 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 3 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 (reported in ³ 5% of patients) were as follows:

- NERLYNX as a single agent: Diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increased, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased, and urinary tract infection.
- NERLYNX in combination with capecitabine: Diarrhea, nausea, vomiting, decreased appetite, constipation, fatigue/asthenia, weight decreased, dizziness, back pain, arthralgia, urinary tract infection, upper respiratory tract infection, abdominal distention, renal impairment, and muscle spasms.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) 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. When patients require gastric acid reducing agents, use an H₂-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after H₂-receptor antagonists.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- Moderate CYP3A4 and P-glycoprotein (P-gp) dual 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.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at www.NERLYNX.com or 1-855-816-5421.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the worldwide expansion of NERLYNX and Puma's anticipated milestones. 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, any adverse impact on Puma's business or the global economy and financial markets, generally, from the global COVID-19 pandemic, and 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, 2020. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

Contacts

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

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull or Maggie Beller, Russo Partners, +1 212 845 4200

david.schull@russopartnersllc.com

maggie.beller@russopartnersllc.com

#####

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended March 31,	
	2021 (Unaudited)	2020 (Unaudited)
Revenues:		
Product revenue, net	\$ 45.8	\$ 48.6
License revenue	50.0	2.0
Royalty revenue	2.4	0.6
Total revenue	98.2	51.2
Operating costs and expenses:		
Cost of sales	29.6	9.1
Selling, general and administrative	28.2	30.9
Research and development	20.2	25.5
Total operating costs and expenses	78.0	65.5
Income (loss) from operations	20.2	(14.3)
Other income (expenses):		
Interest income	—	0.4
Interest expense	(3.5)	(3.0)
Legal verdict expense	(0.2)	(0.1)
Other income	—	0.1
Total other expenses	(3.7)	(2.6)
Net income (loss) before income taxes	16.5	(16.9)
Income tax expense	—	—
Net income (loss)	\$ 16.5	\$ (16.9)
Net income (loss) per share of common stock—basic	\$ 0.41	\$ (0.43)
Net income (loss) per share of common stock—diluted	\$ 0.40	\$ (0.43)
Weighted-average shares of common stock outstanding—basic	40,260,864	39,291,162
Weighted-average shares of common stock outstanding—diluted	40,894,868	39,291,162

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

	March 31, 2021 (Unaudited)	December 31, 2020
	Cash and cash equivalents	\$ 95.7
Marketable securities	13.4	8.1
Working capital	23.4	31.9
Stockholders' equity (deficit)	16.4	(6.0)
	Three Months Ended March 31, 2021 (Unaudited)	Three Months Ended March 31, 2020 (Unaudited)
Cash provided by (used in):		
Operating activities	\$ 15.7	\$ (11.5)
Investing activities	(5.3)	34.3
Financing activities	—	—
Increase (decrease) in cash and cash equivalents, and restricted cash	\$ 10.4	\$ 22.8

Use of Non-GAAP 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 income (loss) and net income (loss) per share calculated in accordance with GAAP and as adjusted to remove the impact of stock-based compensation. For the three months ended March 31, 2021 and 2020, stock-based compensation represented approximately 12.1% and 15.8% 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, 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 SUBSIDIARIES
Reconciliation of GAAP Net Income (Loss) to Non-GAAP Adjusted Net Income (Loss) and
GAAP Net Income (Loss) Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
GAAP net income (loss)	\$ 16.5	\$ (16.9)
Adjustments:		
Stock-based compensation -		
Selling, general and administrative	3.6	4.7(1)
Research and development	2.3	4.2(2)
Non-GAAP adjusted net income (loss)	\$ 22.4	\$ (8.0)
GAAP net income (loss) per share—basic	\$ 0.41	\$ (0.43)
Adjustment to net income (loss) (as detailed above)	0.15	0.23
Non-GAAP adjusted basic net income (loss) per share	\$ 0.56	\$ (0.20)(3)
GAAP net income (loss) per share—diluted	\$ 0.40	\$ (0.43)
Adjustment to net income (loss) (as detailed above)	0.15	0.23
Non-GAAP adjusted diluted net income (loss) per share	\$ 0.55(4)	\$ (0.20)(5)

- (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 (loss) per share was calculated based on 40,260,864 and 39,291,162 weighted-average shares of common stock outstanding for the three months ended March 31, 2021 and 2020, respectively.
- (4) Non-GAAP adjusted diluted net income per share was calculated based on 40,894,868 weighted-average shares of common stock outstanding for the three months ended March 31, 2021.
- (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, 2020, as these shares would be considered anti-dilutive.