

PUMA BIOTECHNOLOGY, INC.

Form 8-K

June 29, 2018

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): June 29, 2018

PUMA BIOTECHNOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction

of incorporation)

001-35703
(Commission

File Number)
10880 Wilshire Boulevard, Suite 2150

77-0683487
(IRS Employer

Identification No.)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01 Other Events.

Puma Biotechnology, Inc. (the Company) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorization for the medicinal product NERLYNX® (neratinib) 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 the completion of prior adjuvant trastuzumab based therapy. The CHMP recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The decision is consistent with the CHMP's positive trend vote, which was communicated to the Company on June 26, 2018.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the EC's decision regarding the Company's Marketing Authorization Application, and steps the Company may take in the future to gain marketing approval in Europe. All statements other than historical facts are forward looking statements and are based on the Company's current expectations, forecasts and assumptions. 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 risk and uncertainties are identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and any subsequent documents the Company files with the Securities and Exchange Commission. 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.

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: June 29, 2018

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