

PUMA BIOTECHNOLOGY, INC.
Form 8-K
January 23, 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): January 23, 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.)

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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) has communicated a negative trend vote after meeting with the Company today to discuss the Marketing Authorization Application (MAA) for neratinib for the extended adjuvant treatment of early stage HER2-positive breast cancer. A negative trend vote means it is unlikely that CHMP will provide a positive opinion related to the Company's MAA at the formal CHMP decision vote scheduled in February 2018, and that additional steps would need to be taken to gain marketing approval in Europe. CHMP indicated that, in its opinion, the benefit risk assessment is negative as the study results are based on evidence from a single pivotal trial and the 2- and 5-year invasive disease free survival (iDFS) benefits observed to-date may lack sufficient clinical relevance.

CHMP's opinion was based on the results from both the Phase III ExteNET trial in extended adjuvant early stage HER2-positive breast cancer and the Phase II CONTROL trial in extended adjuvant early stage HER2-positive breast cancer.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements regarding the expected timing and substance of CHMP's opinion and formal decision regarding the Company's MAA, and steps to be taken to gain marketing approval in Europe. All forward-looking statements included in this Current Report on Form 8-K 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, including 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 Quarterly Report on Form 10-Q for the quarter ended September 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.

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: January 23, 2018

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