PUMA BIOTECHNOLOGY, INC.
Form 8-K
January 11, 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 11, 2018

PUMA BIOTECHNOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35703**	**77-0683487**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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))
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 it met today with the Committee for Medicinal Products for Human Use (CHMP) Scientific Advisory Group on Oncology (SAG). SAG was asked to provide an opinion on the clinical relevance of the 5-year absolute treatment difference in invasive disease free survival seen in the Phase III ExteNET trial and on the risk of gastrointestinal toxicity with neratinib and its acceptability in the proposed patient population in the Company s Marketing Authorization Application (MAA) for neratinib. Based on the feedback from SAG and the rapporteurs, the Company intends to modify the summary of product characteristics (SmPC), sometimes referred to as the European product label, in its MAA for neratinib to further refine the intended population to patients at a high risk of disease recurrence.

CHMP will be conducting an oral hearing to discuss the MAA for neratinib on January 23, 2018, and the Company has been invited to present the risk benefit profile of neratinib in the identified population at this meeting.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements regarding the Company s intent to modify the SmPC and the expected timing of CHMP s oral hearing on the MAA for neratinib. 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 11, 2018

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