PUMA BIOTECHNOLOGY, INC.
Form 8-K
April 19, 2017

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): April 17, 2017

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 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.

On April 17, 2017, Puma Biotechnology, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) has scheduled the New Drug Application (NDA) for neratinib for discussion by the Oncologic Drugs Advisory Committee (ODAC) on May 24, 2017. Neratinib is an investigational therapy for the extended adjuvant treatment of early stage HER2-positive breast cancer that has previously been treated with a trastuzumab containing regimen.

ODAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cancer and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

The Company announced on September 20, 2016 that the FDA had accepted for filing the NDA for neratinib. The NDA for neratinib is based on 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, including statements regarding the ODAC s scheduled review of the NDA 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, which include, but are not limited to, the fact that the Company has no product revenue and no products approved for marketing, the Company s dependence on PB272, which is still under development and may never receive regulatory approval, the challenges associated with conducting and enrolling clinical trials, the risk that the results of clinical trials may not support the Company s drug candidate claims, even if approved, the risk that physicians and patients may not accept or use the Company s products, the Company s reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates, the Company s dependence on licensed intellectual property, and the other 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 Annual Report on Form 10-K for the year ended December 31, 2016. 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: April 18, 2017

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