PUMA BIOTECHNOLOGY, INC.
Form 8-K
November 30, 2015

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): November 30, 2015

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))

Item 8.01 Other Events.

On November 30, 2015, Puma Biotechnology, Inc. (the Company) announced that based on its recent meeting with the European Medicines Agency (EMA), the Company plans to submit a Marketing Authorisation Application (MAA) for the approval of neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in patients who have previously been treated with a trastuzumab-containing regimen in the first half of 2016.

The Company recently conducted an MAA pre-submission meeting with the EMA. The purpose of this meeting was to provide the EMA with data from neratinib s non-clinical and clinical development programs that will form the basis of MAA sections for EMA review and approval. The data discussed with the EMA included non-clinical data (pharmacology, toxicology and carcinogenicity) and clinical trial data including the data from the Phase III trial of neratinib in the extended adjuvant treatment of HER2-positive early stage breast cancer (ExteNET trial). Upon review of this material, the EMA assessed that there were no critical concerns that would prevent the Company from submitting a complete MAA for European centralized review in support of neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in patients who have previously been treated with a trastuzumab-containing regimen.

Forward-Looking Statements:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the development of the Company s drug candidates and the timing of regulatory filings. 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 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, 2014 and any subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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.

SIGNATURES

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: November 30, 2015

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