PUMA BIOTECHNOLOGY, INC.
Form 8-K
March 30, 2016

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): March 28, 2016

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 March 28, 2016, Puma Biotechnology, Inc. (the Company) announced that based on its recent meetings with the U.S. Food and Drug Administration (FDA), the Company now plans to submit its New Drug Application (NDA) for the approval of neratinib for the treatment of extended adjuvant breast cancer that has previously been treated with a trastuzumab-containing regimen in mid-2016.

The Company recently conducted a series of meetings and communications with the FDA. The purpose of these communications was to provide the FDA with the data from neratinib s non-clinical and clinical development programs that will form the basis of the Company s NDA for neratinib for the treatment of extended adjuvant breast cancer that has previously been treated with a trastuzumab-containing regimen. The data discussed with the FDA included preclinical data (pharmacology, toxicology, reproductive toxicity, 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) and the Phase II trial of neratinib monotherapy in the extended adjuvant treatment of HER2-positive early stage breast cancer where patients received loperamide prophylaxis in order to prevent the neratinib-related diarrhea. Following its review of this material, the FDA requested that the Company amend the current statistical analysis plan for the ExteNET trial to incorporate the FDA s recommendations with regard to rules for censoring the data for recurrent disease events or death.

For the primary endpoint of the ExteNET trial (Invasive Disease Free Survival), the analysis was based on all recurrent disease events and deaths occurring within 2 years and 28 days post randomization. The FDA has requested that events (disease recurrence or deaths) observed after missing 2 or more scheduled disease assessments be censored at the last available disease assessment time prior to the event occurrence. The FDA s requested approach was a sensitivity analysis used in the ExteNET trial s original statistical analysis plan but will now be the primary analysis approach used in the trial s updated statistical analysis plan. In order to accommodate this change, the Company expects to delay filing its NDA for neratinib for the treatment of extended adjuvant breast cancer that has previously been treated with a trastuzumab-containing regimen until mid-2016.

The primary analysis results of the trial do not appear to be altered materially by the updated analysis approach. Provided below are the results of the original and updated analyses of the primary endpoint of invasive disease-free survival (iDFS) for the intent to treat (ITT) population:

(1) ITT population applying the original event and censoring rule:

179 iDFS events

33% reduction in risk of iDFS vs. placebo (hazard ratio=0.67 (0.50, 0.91), 1-sided P=0.005)

iDFS rates 93.9% (neratinib arm) vs. 91.6% (placebo arm)

(2) ITT population applying the revised event and censoring rule per FDA:

173 iDFS events

34% reduction in risk of iDFS vs. placebo (hazard ratio=0.66 (0.49, 0.90), 1-sided P=0.004)

iDFS rates 94.2% (neratinib arm) vs. 91.9% (placebo arm)

On March 28, 2016, the Company hosted a conference call and webcast to discuss the updated results from the ExteNET trial using the event and censoring rule requested by the FDA. A copy of the slide presentation from the webcast is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Forward-Looking Statements:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the anticipated timing for the filing of a new drug application. 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, 2015 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Slide Presentation

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: March 29, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Slide Presentation