PUMA BIOTECHNOLOGY, INC.
Form 8-K
July 22, 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): July 21, 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 July 21, 2016, Puma Biotechnology, Inc. (the Company) announced that it had submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its lead product candidate PB272 (neratinib) for the extended adjuvant treatment of patients with early stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab (Herceptin®)-based therapy.

In addition, on July 21, 2016, the Company announced and hosted a conference call and slide presentation to discuss updated results from the Phase III clinical trial of neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer (ExteNET trial). The ExteNET trial is a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in women with early stage HER2-positive breast cancer.

The ExteNET trial randomized 2,840 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomized to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ, or death for a period of two years after randomization in the trial. The primary endpoint of the trial was invasive disease free survival (DFS). The results of the trial demonstrated that treatment with neratinib resulted in a 33% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.67, p = 0.009). The 2-year invasive DFS rate for the neratinib arm was 93.9% and the 2-year invasive DFS rate for the placebo arm was 91.6%. These results were previously reported at the 2015 American Society of Clinical Oncology meeting and updated results, including interim 3-year invasive DFS data, were presented at the 2015 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS).

As part of the data analysis for the NDA filing in the United States and the Marketing Authorisation Application (MAA) submission in Europe, an updated analysis that included an interim 5-year invasive DFS analysis was performed. This data analysis was performed in order to examine the durability of treatment effect beyond the 2-year data included in the primary analysis. This interim analysis was not a pre-planned analysis in the statistical analysis plan for the trial. For the primary endpoint of the trial, invasive DFS, the 5-year interim results of the trial demonstrated that treatment with neratinib resulted in a 26% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.74, p = 0.017). The 5-year interim invasive DFS rate for the neratinib arm was 90.4% and the 5-year interim invasive DFS rate for the placebo arm was 87.9%. Additional updated results for the 3-year invasive DFS rate and 4-year invasive DFS rate are shown in the table below:

DFS for Intent to Treat (ITT) Population

	3-Year DFS	4-Year DFS	5-Year Interim DFS
Neratinib	92.5%	91.4%	90.4%
Placebo	90.3%	89.2%	87.9%
Absolute invasive DFS Difference	2.2%	2.2%	2.5%

As an inclusion criteria for the ExteNET trial, patients needed to have tumors that were HER2 positive using local assessment. In addition, as a pre-defined subgroup in the trial, patients had centralized HER2 testing performed on their tumor as well. To date, centralized HER2 testing has been performed on 2,140 (75%) of the patients in the ExteNET trial, and further central testing on available samples is currently ongoing. For the 1,777 patients whose tumors were HER2 positive by central confirmation, the interim results of the trial demonstrated that treatment with neratinib resulted in a 30% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.70, p = 0.026). The 5-year interim invasive DFS rate for the centrally confirmed patients in the neratinib arm was 90.8% and the 5-year interim invasive DFS rate for the centrally confirmed patients in the placebo arm was 88.1%.

For the pre-defined subgroup of 1,631 patients with hormone receptor positive disease, the interim results of the trial demonstrated that treatment with neratinib resulted in a 41% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.59, p = 0.002). The 5-year interim invasive DFS rate for the neratinib arm was 91.7% and the 5-year interim invasive DFS rate for the placebo arm was 86.9%. Additional updated results for the 3-year invasive DFS rate and 4-year invasive DFS rate are shown in the table below:

DFS for Hormone Receptor Positive (HR-positive) Population

	3-Year DFS	4-Year DFS	5-Year Interim DFS
Neratinib	93.8%	92.9%	91.7%
Placebo	89.9%	88.6%	86.9%
Absolute invasive DFS Difference	3.9%	4.3%	4.8%

The Company anticipates that the full 5-year DFS data will be available in 2017.

A copy of the slide presentation is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Forward-Looking Statements:

This Current Report on Form 8-K and the slide presentation contain forward-looking statements, including statements regarding the potential indications of our drug candidates and the development of our drug candidates, including, but not limited to, the anticipated timing for the announcement of data from our clinical trials. All forward-looking statements included in this Current Report on Form 8-K and the slide presentation 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. 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: July 21, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Slide Presentation