PUMA BIOTECHNOLOGY, INC.
Form 8-K
September 20, 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): September 20, 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 September 20, 2016, Puma Biotechnology, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) 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.

The submission is supported by the results of the ExteNET Phase III study, in which 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 disease free survival (DFS) rate for the neratinib arm was 93.9% and the 2-year invasive DFS rate for the placebo arm was 91.6%. For the pre-defined subgroup of patients with hormone receptor positive disease, the results of the trial demonstrated that treatment with neratinib resulted in a 49% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.51, p = 0.001). For the patients with hormone receptor positive disease, the 2-year invasive DFS rate for the neratinib arm was 95.4% and the 2-year invasive DFS rate for the placebo arm was 91.2%.

Results of the study were published online in *The Lancet Oncology* on February 10, 2016.

The most frequently observed adverse event for the neratinib-treated patients was diarrhea, with approximately 39.9% of the neratinib-treated patients experiencing grade 3 or higher diarrhea (1 patient (0.1%) had grade 4 diarrhea). Patients who received neratinib in the ExteNET trial did not receive any prophylaxis with antidiarrheal agents to prevent the neratinib-related diarrhea. In patients with HER2-positive early stage breast cancer who have previously been treated with adjuvant trastuzumab and received anti-diarrheal prophylaxis with loperamide, interim results of a Phase II study of neratinib monotherapy demonstrated that treatment with prophylactic loperamide reduced the rate of grade 3 or higher diarrhea to between 13.0% and 18.5%.

About ExteNET

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 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 DFS.

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: September 20, 2016

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