PUMA BIOTECHNOLOGY, INC.
Form 8-K
June 06, 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): June 5, 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 June 5, 2016, Puma Biotechnology, Inc. (the Company) announced that positive results from an investigator sponsored Phase II trial of neratinib with HER2-mutated, non-amplified breast cancer were presented in a poster discussion session at the American Society of Clinical Oncology (ASCO) 2016 Annual Meeting in Chicago, Illinois.

In the trial, patients with HER2 mutated breast cancer (either in their primary or metastatic tumor) received 240 mg of neratinib daily. Patients received loperamide (16 mg per day initially) prophylactically for the first cycle of treatment in order to reduce the neratinib-related diarrhea. For the 16 patients enrolled in the trial, 16 patients (100%) had HER2-negative disease, 15 patients (94%) were hormone receptor positive (estrogen receptor or progesterone receptor positive), and for the patients with metastatic disease, patients had received a median of 3 prior regimens (range 2-10 prior regimens) before entering the trial. Among these 16 patients, 14 had activating HER2 mutations and 2 patients had HER2 mutations of unknown significance.

The primary endpoint of the Phase II trial was clinical benefit rate (CBR), defined as complete response (CR), partial response (PR) or stable disease (SD) greater than or equal to 6 months. The trial was designed to detect a CBR of 20%. In the 14 patients with activating HER2 mutations, 5/14 (36%) achieved clinical benefit, including 1 patient (7%) with a CR, 1 patient (7%) with a PR, and 3 patients (21%) with SD for greater than or equal to 6 months. The median duration of response in these 5 patients was 6 (range 6-14+) months. The median progression-free survival for all 14 patients with activating HER2 mutations in the trial was 5.0 months. In the 2 patients with HER2 mutations of unknown significance, there was no clinical benefit seen with neratinib.

The Company also noted that based on the preclinical data that has demonstrated that the combination of an anti-estrogen with a HER2 inhibitor results in enhanced anti-tumor activity in preclinical models of estrogen receptor positive/HER2-mutated breast tumors, the study has been amended to administer the combination of neratinib plus fulvestrant in eligible hormone receptor positive breast cancer patients who have an activating HER2 mutation in the tumor. Enrollment in this cohort is currently ongoing and results from this cohort receiving the combination of fulvestrant plus neratinib will be presented at a future medical meeting.

The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 16 patients enrolled in the study, 4 patients (25%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for the patients in the study was 1.5 days.

Forward-Looking Statements:

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the anticipated timing relating to clinical trials and the announcement of data relative to these trials. 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. 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: June 6, 2016

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