PUMA BIOTECHNOLOGY, INC.
Form 8-K
April 14, 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): April 14, 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 April 14, 2016, Puma Biotechnology, Inc. (the Company) announced that results from the NEfERT-T Phase II clinical trial of neratinib in ERBB2-positive metastatic breast cancer patients were published online in *JAMA Oncology*. The article, entitled Neratinib Plus Paclitaxel vs. Trastuzumab Plus Paclitaxel in Previously Untreated Metastatic ERBB2-Positive Breast Cancer: The NEfERT-T Randomized Clinical Trial, appears in the April 14, 2016 online issue and will be published in a future print issue of the journal.

The NEfERT-T trial is a randomized, two-arm Phase II trial of neratinib plus the anticancer drug paclitaxel versus trastuzumab (Herceptin) plus paclitaxel as a first-line treatment for ERBB2-positive (previously referred to as HER2-positive) locally recurrent or metastatic breast cancer. The trial enrolled 479 patients in 33 countries who had not received prior anticancer therapy for locally recurrent or metastatic disease. Patients were randomized to receive first-line treatment with either paclitaxel plus neratinib or paclitaxel plus trastuzumab. The primary endpoint of the trial was progression-free survival (PFS). The secondary endpoints of the study included objective response rate (ORR) and the incidence of central nervous system (CNS) metastases, including brain metastases.

The results of the trial demonstrated that the progression-free survival for the patients who received the combination of paclitaxel plus neratinib was 12.9 months and the progression-free survival for the patients who received the combination of paclitaxel plus trastuzumab was 12.9 months (hazard ratio 1.02, p=0.89). The objective response rate in the trial for the patients who received the combination of paclitaxel plus neratinib was 74.8% and the objective response rate for the patients who received the combination of paclitaxel plus trastuzumab was 77.6% (p=0.52).

With respect to the incidence of CNS metastases (e.g., brain metastases), treatment with the combination of paclitaxel plus neratinib resulted in a 52% reduction in the incidence of CNS metastases compared to the incidence of CNS metastases in patients who received the combination of paclitaxel plus trastuzumab. Symptomatic or progressive CNS recurrences occurred in 20 patients (8.3%) in the neratinib-paclitaxel group and 41 patients (17.3%) in the trastuzumab-paclitaxel group (relative risk 0.48, p=0.002). The estimated Kaplan-Meier 2-year incidence of CNS recurrences was 16.3% in the neratinib-paclitaxel group and 31.2% in the trastuzumab-paclitaxel group (hazard ratio 0.45, p=0.004). These results reflect a statistically significant difference between the two treatment arms.

Forward-Looking Statements:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the publication of clinical trial results. 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: April 14, 2016

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