PUMA BIOTECHNOLOGY, INC.
Form 8-K
June 04, 2018

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 4, 2018 (June 2, 2018)

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))
Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On June 2, 2018, Puma Biotechnology, Inc. (the Company) announced that interim results from the Phase Ib/II FB-10 clinical trial of the Company s investigational drug PB272 (neratinib) given in combination with the antibody drug conjugate T-DM1 (Kadcyla, ado-trastuzumab emtansine) were presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting that is currently taking place in Chicago. The presentation entitled, NSABP FB-10: Phase IB Dose-Escalation Study Evaluating the Combination of Trastuzumab Emtansine (T-DM1) with Neratinib in Women with Metastatic HER2-Positive Breast Cancer was selected for a poster presentation.

The FB-10 study is an open-label, single arm study with a dose escalation phase and an expanded cohort phase to evaluate patients with HER2-positive metastatic breast cancer who had previously been treated with chemotherapy and the combination of trastuzumab (Herceptin) and pertuzumab (Perjeta). The primary aim of the Phase Ib portion of the study is to determine the safety and tolerability of the two-drug combination. The primary aim of the Phase II portion of the study is to demonstrate efficacy at the recommended Phase II dose of T-DM1 and neratinib. Study treatment during the Phase Ib portion consisted of the standard dose of T-DM1 at 3.6 mg/kg administered intravenously every 3 weeks and neratinib administered orally at escalating doses of 120, 160, 200 and 240 mg per day continuously. Primary diarrhea prophylaxis with high dose loperamide was administered to all patients. As of the date of the presentation, the study had enrolled 27 patients. Total study enrollment will be a maximum of 63 patients.

For the 20 patients who were evaluable for efficacy, the interim objective response (CR/PR, each as defined herein) rate was 60%. More specifically, the efficacy results from the trial demonstrated that 3 patients had a complete response (CR); 9 patients had a partial response (PR); 2 patients had stable disease (SD); and 6 patients had progressive disease (PD).

The interim safety results of the 27 patients with available safety assessments showed that the most frequently observed grade 3 adverse events were diarrhea, nausea, thrombocytopenia and hypertension. More specifically, grade 3 diarrhea was reported in 6 patients (22%), grade 3 nausea was reported in 3 patients (11%), grade 3 thrombocytopenia was reported in 4 patients (15%), and grade 3 hypertension was reported in 3 patients (11%). There was 1 dose limiting toxicity (DLT) at the 120 mg dose (1 of 6 patients), 3 DLTs at the 200 mg dose (3 of 8 patients) and 2 DLTs at the 240 mg dose (2 of 3 patients). There was no DLT for the 10 patients enrolled at the 160 mg dose. The Phase II portion of the trial is being conducted at the recommended Phase II dose of 160 mg of neratinib per day.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the enrollment in the Phase II portion of the Company s trial of PB272 in combination with T-DM1 in HER2-positive metastatic breast cancer, efficacy and safety of the combination of neratinib and T-DM1, benefits of neratinib the potential indications of the Company s drug candidates and the development of the Company s drug candidates, including, but not limited to, the anticipated timing for the commencement and completion of the Company s various clinical trials and announcement of data relative to these trials. All statements other than historical facts are forward looking statements and are based on the Company s current expectations, forecasts and assumptions. Forward looking statements 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 risk and uncertainties are identified in the Company s Annual Report on Form 10-K for the year ended December 31, 2017, the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and any subsequent documents the Company files with the Securities and Exchange Commission. 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.

SIGNATURE

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 4, 2018

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