PUMA BIOTECHNOLOGY, INC.
Form 8-K
December 18, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): December 17, 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 Number)**

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(Address of principal executive offices, including 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 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 financing accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On December 17, 2018, Puma Biotechnology, Inc. (the Company) announced top line results from the Phase III NALA trial of the Company s lead drug candidate PB272 (neratinib) in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments in the setting of metastatic disease. The Phase III NALA trial is a randomized controlled trial of neratinib plus capecitabine versus Tykerb® (lapatinib) plus capecitabine in patients with third-line HER2-positive metastatic breast cancer. The trial enrolled 621 patients who were randomized (1:1) to receive either neratinib plus capecitabine or lapatinib plus capecitabine. The trial was conducted globally at sites in North America, Europe, Asia-Pacific and South America. The co-primary endpoints of the trial are centrally confirmed progression free survival (PFS) and overall survival (OS). An alpha level of 1% was allocated to the PFS and 4% allocated to OS. The study was to be considered positive if either of the co-primary endpoints was positive. The Company reached agreement with the U.S. Food and Drug Administration (the FDA) under a Special Protocol Assessment for the design of the Phase III clinical trial and the European Medicines Agency (the EMA) also provided follow-on scientific advice consistent with that of the FDA regarding the Company s Phase III trial design and endpoints used in the trial.

For the primary analysis of centrally confirmed PFS, treatment with neratinib plus capecitabine resulted in a statistically significant improvement in centrally confirmed PFS (p=0.0059) compared to treatment with lapatinib plus capecitabine. For the primary analyses of OS, neratinib plus capecitabine resulted in an improvement in OS that did not achieve statistical significance but trended positively in favor of the neratinib plus capecitabine arm of the study (p=0.21). For the secondary endpoint of time to intervention for symptomatic central nervous system disease, which is also referred to as brain metastases, the results of the trial showed that treatment with neratinib plus capecitabine led to an improvement over the combination of lapatinib plus capecitabine (p=0.043).

The safety profile of neratinib in the Phase III NALA study was consistent with previous clinical trials of neratinib.

The Company expects full results of the trial to be submitted to health authorities around the world, including the FDA and the EMA. The Company expects results of the trial to be submitted for presentation at a major medical conference in 2019.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements regarding the timing of full results of the NALA trial, as well as the submission of results of the trial to health authorities around the world. 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, including the risk factors disclosed in the 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, 2017. 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: December 17, 2018

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