PUMA BIOTECHNOLOGY, INC.
Form 8-K
January 06, 2017

**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): January 6, 2017**

**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 January 6, 2017, Puma Biotechnology, Inc. (the Company ) announced that it expanded the fourth cohort from its Phase II SUMMIT clinical trial of its lead drug candidate PB272 (neratinib) as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial). The cohort that has been expanded is the cohort that includes patients with metastatic cervical cancer and whose tumors have a HER2 mutation.

The Phase II SUMMIT basket trial is an open-label, multicenter, multi-histology, international study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating ERBB mutations including EGFR, HER2 and HER3. The cohorts included in the basket study receiving neratinib monotherapy are hormone receptor-negative breast cancer; biliary tract cancers; endometrial cancer; gastric/esophageal cancer; ovarian cancer; and all other solid tumors with a HER2 mutation. The cohorts receiving combination treatment are hormone receptor-positive breast cancer (neratinib plus fulvestrant) and bladder cancer (neratinib plus paclitaxel). The cervical cancer patients initially entered the study in the other solid tumors with a HER2 mutation cohort, and due to the preliminary activity seen in the trial, the Company has expanded a separate cervical cancer cohort pursuant to the protocol for the trial. The expanded HER2-mutant cervical cancer cohort will now enroll a total of 18 patients. The Company expects to present the full results from the SUMMIT study in 2017.

**Forward-Looking Statements:**

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the Company s 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 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: January 6, 2017

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