PUMA BIOTECHNOLOGY, INC.
Form 8-K
December 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): December 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))
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 December 6, 2017, Puma Biotechnology, Inc. (the Company) announced that the Company will present updated interim results from a Phase II clinical trial of the Company s drug neratinib at the 2017 San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled, Effects of adding budesonide or colestipol to loperamide prophylaxis on neratinib-associated diarrhea in patients with HER2-positive early stage breast cancer: the CONTROL trial, will be presented as a poster presentation on December 7 at 5:00 p.m. CST.

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets.

The main adverse event seen to date in clinical trials of neratinib is diarrhea and, more specifically, grade 3 diarrhea. In the Phase III ExteNET trial of neratinib as extended adjuvant treatment of HER2-positive early stage breast cancer that has previously been treated with adjuvant Herceptin, 95.4% of the patients experienced all grade diarrhea and 39.8% of the patients experienced grade 3 or higher diarrhea (there was one event of grade 4 diarrhea). The CONTROL trial is an international, open-label, Phase II study investigating the use of loperamide prophylaxis with or without other agents in the reduction of neratinib-associated diarrhea that has a primary endpoint of the incidence of grade 3 diarrhea.

In the CONTROL trial, patients with HER2-positive early stage breast cancer who had completed trastuzumab-based adjuvant therapy received neratinib daily for a period of one year. The trial initially tested high dose loperamide prophylaxis given for the first 2 cycles (56 days) of treatment (12 mg on days 1-14, 8 mg on days 15-56 and as needed thereafter). The CONTROL trial was then expanded to include two additional cohorts. One cohort received the combination of loperamide and budesonide and the other cohort received the combination of loperamide plus colestipol. Budesonide is a locally acting corticosteroid that the Company believes targets the inflammation identified in a preclinical model of neratinib-induced diarrhea and colestipol is a bile acid sequestrant that the Company believes targets potential bile acid malabsorption that could result from such inflammation.

The interim analysis of the trial presented in the poster included a total of 137 patients who received neratinib plus loperamide prophylaxis, 64 patients who received neratinib plus loperamide prophylaxis for 2 cycles and budesonide for 1 cycle, and 120 patients who received neratinib plus loperamide prophylaxis for 1 cycle and colestipol for 1 cycle.

The results of the trial showed that the incidence of grade 3 diarrhea for the 137 patients who received the loperamide prophylaxis was 30.7%. For the 137 patients who received the loperamide prophylaxis, the median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 3 days. For the 137 patients who received loperamide prophylaxis, 20.4% discontinued neratinib due to diarrhea.

For the 64 patients who received the combination of loperamide plus budesonide, the results of the trial showed that the incidence of grade 3 diarrhea was 26.6%. The median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 2 days. For the 64 patients who received loperamide plus budesonide prophylaxis, 10.9% discontinued neratinib due to diarrhea.

For the 120 patients who received the combination of loperamide plus colestipol, the results of the trial showed that the incidence of grade 3 diarrhea was 10.8%. The median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 3 days. For the 120 patients who received loperamide plus colestipol prophylaxis, 1.7% discontinued neratinib due to diarrhea. Further information is provided in Table 1 below:

Table 1: Characteristics of Treatment-Emergent Diarrhea

Study	**CONTROL**			**ExteNET**
	Loperamide (n=137)	**Loperamide + budesonide (n=64)**	**Loperamide + colestipol (n=120)**	**Loperamide prn (n=1408)**
Diarrhea, %				
Any grade	79.6	86.0	66.7	95.4
Grade 1	24.8	25.0	30.0	22.9
Grade 2	24.1	34.4	25.8	32.5
Grade 3[a]	30.7	26.6	10.8	39.8
Grade 4	0	0	0	0.1
Median cumulative duration, days				
Any grade	14.0	24.0	16.0	59.0
Grade ³2	5.0	6.0	3.5	10.0
Grade ³3[a]	3.0	2.0	3.0	5.0
Median diarrhea episodes/patient				
Any grade	2.0	9.0	2.5	8.0
Grade ³2	2.0	3.0	1.0	3.0
Grade ³3[a]	1.0	1.0	1.0	2.0
Action taken, %				
Dose hold	15.3	18.8	9.2	33.9
Dose reduction	7.3	3.1	4.2	26.4
Discontinuation	20.4	10.9	1.7	16.8
Hospitalization	1.5	0	0	1.4
Duration of neratinib treatment, months				
Median	11.5	11.9	3.7	11.6

[a] No grade 4 events in the CONTROL study; one grade 4 event in the ExteNET study.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the benefits of NERLYNX® and neratinib, the Company s clinical trials and the announcement of data relative to those 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 only recently commenced commercialization and shipment of its only FDA approved product; the Company s dependence upon the commercial success of NERLYNX (neratinib); the Company s history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company s ability to achieve or sustain profitability; the Company s ability to

predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company s operations; the effectiveness of sales and marketing efforts; the Company s ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; 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; risks pertaining to securities class action, derivative and defamation lawsuits; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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: December 6, 2017

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