PUMA BIOTECHNOLOGY, INC.
Form 8-K
August 02, 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): August 2, 2017 (July 31, 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 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On July 31, 2017, the Board of Directors of Puma Biotechnology, Inc. (the Company ) approved the promotion of Richard P. Bryce, MBChB, MRCGP and MFPM, from Senior Vice President, Clinical Research and Development to Chief Medical and Scientific Officer of the Company, effective August 1, 2017. In connection with his promotion, Dr. Bryce s annual base salary will increase from $413,255 to $454,580.

**Item 8.01 Other Events.**

On August 2, 2017, the Company announced that the Committee for Medicinal Products for Human Use (the CHMP ), the scientific committee of the European Medicines Agency, had issued its Day-180 List of Outstanding Issues in the process of their ongoing regulatory review of the Company s Marketing Authorisation Application ( MAA ) for neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in patients who have previously been treated with trastuzumab (Herceptin®)-based adjuvant therapy.

The CHMP has requested additional data analyses related to the safety and efficacy of neratinib and has instituted a clock stop in order to allow the Company time to respond to this List of Outstanding Issues. The CHMP has set a deadline of December 22, 2017 for the Company to respond to the list. The Company expects the CHMP to issue an opinion regarding the MAA for neratinib in the first quarter of 2018.

**Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the expected timing with respect to the CHMP s opinion regarding the MAA for neratinib. 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 currently has no product revenue, 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 for others 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 Annual Report on Form 10-K for the year ended December 31, 2016. 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: August 2, 2017

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