PUMA BIOTECHNOLOGY, INC.
Form 8-K
April 03, 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): April 3, 2018 (March 30, 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 1.01 Entry into a Material Definitive Agreement.

On March 30, 2018 (the Effective Date), Puma Biotechnology, Inc. (the Company) entered into a License Agreement (the Agreement) with Pint Pharma International SA (Pint).

Pursuant to the Agreement, the Company granted to Pint, under certain of the Company s intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license to develop and commercialize any product containing neratinib and certain related compounds (the Licensed Product) in Latin America, including Argentina, Brazil, Chile, Colombia and Mexico (the Territory).

The Agreement sets forth the parties respective obligations with respect to the development, commercialization and supply of the Licensed Product. Pint will, at its expense, develop the Licensed Product for the purpose of obtaining regulatory approval in the Territory, subject to the Company s consent to conduct such development activities and approval of certain aspects of clinical studies conducted by Pint. Within the Territory, Pint will also be responsible for regulatory and commercialization activities. The Company will be solely responsible for the manufacturing and supply of the Licensed Product under a supply agreement that will be entered into between the parties, subject to certain exceptions therein.

Pursuant to the Agreement, the Company will receive an upfront payment of $10 million and is eligible to receive regulatory milestone payments totaling up to $9.5 million and sales-based milestone payments totaling up to $15 million. In addition, the Company is entitled to receive significant double-digit royalties calculated as a percentage of net sales of the Licensed Products in the Territory.

The term of the Agreement continues, on a country-by-country basis, until the later of (i) the expiration or abandonment of the last licensed patent covering the Licensed Product in such country, or (ii) the earlier of (x) the date upon which sales of generic versions of Licensed Product reach a specified level in such country, or (y) the tenth anniversary of the first commercial sale of the Licensed Product in such country. The Agreement may be terminated by either party if the other party commits a material breach, subject to a customary cure period, or if the other party is insolvent. Pint may also terminate the agreement at will, for certain safety concerns, or if Puma does not deliver certain specified documents to Pint within a certain period of time after the Effective Date.

The foregoing description of the Agreement is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

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: April 3, 2018

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