PUMA BIOTECHNOLOGY, INC.
Form 8-K
April 01, 2019

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): March 29, 2019

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 29, 2019, Puma Biotechnology, Inc. (the Company) entered into an exclusive license agreement (the Agreement) with Pierre Fabre Medicament SAS (Pierre Fabre).

Pursuant to the Agreement, the Company granted to Pierre Fabre, under certain of the Company s intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license to develop, manufacture and commercialize any pharmaceutical product containing neratinib (the Licensed Product) for therapeutic and prophylactic indications for human or veterinary use (the Field) for Europe, excluding Russia and Ukraine, and North Africa and francophone countries of West Africa (the Territory), subject to the terms of the Agreement.

The Agreement sets forth the parties respective obligations with respect to the development, commercialization, manufacture and supply of the Licensed Product. In September 2018 the European Commission granted marketing authorization for NERLYNX® (neratinib) for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy. Within the Territory, Pierre Fabre will be solely responsible, at its expense, for conducting additional clinical studies, leading regulatory activities in connection with the European Medicines Agency (EMA) and commercializing the Licensed Product. The Company will remain responsible for the funding of certain post-marketing approval studies required by the EMA and for the manufacturing and supply of the Licensed Product under a supply agreement that will be entered into between the parties.

Pursuant to the Agreement, the Company will receive an upfront payment of $60 million and potentially receive regulatory and commercial milestone payments totaling up to $345 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 until, on a country-by-country basis, the later of (i) the expiration or abandonment of the last licensed patent covering the Licensed Product in such country and (ii) the earlier of (x) the date upon which sales of generic versions of the 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 cure period, or if the other party is insolvent. Pierre Fabre may terminate the agreement at its convenience or if there is an evidence of safety issues with the Licensed Product.

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, 2019.

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 1, 2019

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