PUMA BIOTECHNOLOGY, INC.
Form 8-K
January 15, 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): January 9, 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 January 9, 2019, Puma Biotechnology, Inc. (the Company) entered into a License Agreement (the Agreement) with Knight Therapeutics Inc. (Knight).

Pursuant to the Agreement, the Company granted to Knight, under certain of the Company s intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license (i) to commercialize any product containing neratinib and certain related compounds (the Licensed Product) in Canada (the Territory), (ii) to seek and maintain regulatory approvals for the Licensed Products in the Territory and (iii) to manufacture the Licensed Products anywhere in the world solely for the development and commercialization of the Licensed Products in the Territory for human use, subject to the terms of the Agreement and a supply agreement to be negotiated and executed by the parties.

Under the terms of the Agreement, the Company will be solely responsible for the manufacturing and supply of the Licensed Products to Knight, but under limited circumstances Knight may obtain the right to manufacture the Licensed Products under the supply agreement.

The Agreement sets forth the parties respective obligations with respect to the commercialization of the Licensed Products. Within the Territory, the Company will be solely responsible for obtaining the regulatory approval for the indication of extended adjuvant treatment of HER2-positive early stage breast cancer (Initial Indication) and Knight will use commercially reasonable efforts to prepare, file and manage regulatory filings for any other indications in the field of human use. Promptly after obtaining the regulatory approval for the Initial Indication in the Territory, the Company will transfer such regulatory approval to Knight, and Knight will own and hold any regulatory approvals for the Licensed Products in the Territory in its name.

Pursuant to the Agreement, the Company is entitled to upfront and development milestones of up to US$2.0 million, and sales milestone payments of up to CAN$7.0 million, payable upon achievement of the milestone events specified in the Agreement. Furthermore, 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 Licensed Product-by-Licensed Product basis, until the later of (i) the expiration or abandonment of the last valid claim of the licensed patents that covers such Licensed Product in the Territory, or (ii) the earlier of (x) the time when generic competitors to such Licensed Product have achieved seventy percent (70%) or more market share in the Territory based on unit volume, or (y) ten (10) years following the date of first commercial sale of such Licensed Product in the Territory. 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. Knight may terminate the agreement with ninety (90) days written notice in the event either party or both parties receive any written claim alleging that the manufacture or commercialization of the Licensed Products in the Territory infringes, misappropriates, or otherwise violates any intellectual property rights of a third party. 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: January 15, 2019

By: /s/ Alan H. Auerbach
Alan H. Auerbach

Chief Executive Officer and President