PUMA BIOTECHNOLOGY, INC. Form 8-K February 01, 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): February 1, 2018 (January 30, 2018)

PUMA BIOTECHNOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation) 001-35703 (Commission File Number) 10880 Wilshire Boulevard, Suite 2150 77-0683487 (IRS Employer Identification No.)

Los Angeles, California 90024

(Address of principal executive offices) (Zip Code)

(424) 248-6500

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(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 30, 2018, Puma Biotechnology, Inc. (the Company) entered into an exclusive license agreement (the Agreement) with CANbridgepharma Limited (CANbridge).

Pursuant to the Agreement, the Company granted to CANbridge, under certain of the Company s intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license to develop and commercialize any pharmaceutical product containing neratinib (the Licensed Product) for the treatment of human disease (the Field) in the People s Republic of China (the Territory), including mainland China, Hong Kong, Macao, and Taiwan (each, a Region).

The Agreement sets forth the parties respective obligations with respect to the development, commercialization and supply of the Licensed Product. CANbridge will, at its expense, develop the Licensed Product for the purpose of obtaining regulatory approval in the Field and in the Territory, subject to the Company s approval of certain aspects of clinical studies conducted by CANbridge. Within the Territory, CANbridge will be solely responsible, at its expense, for regulatory and commercialization activities. The Company will be solely responsible, subject to certain exceptions, 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 \$30 million and potentially receive regulatory milestone payments totaling up to \$40 million and sales-based milestone payments totaling up to \$185 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 Region-by-Region basis, until (i) the later of the expiration or abandonment of the last licensed patent covering the Licensed Product in such Region or (ii) the earlier of (x) the date upon which sales of generic versions of the Licensed Product reach a specified level in such Region, or (y) the tenth anniversary of the first commercial sale of the Licensed Product in such Region. 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; provided that if CANbridge materially breaches its development or commercialization obligations in a particular Region, the Company may terminate the Agreement solely with respect to such Region. CANbridge may terminate the agreement at its convenience.

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.

Date: February 1, 2018

PUMA BIOTECHNOLOGY, INC.

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

Chief Executive Officer and President