
**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): July 18, 2014

PUMA BIOTECHNOLOGY, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35703
(Commission
File Number)

77-0683487
(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))
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Item 1.01 Entry Into a Material Definitive Agreement.

On July 18, 2014, Puma Biotechnology, Inc. (the "Company") entered into an amendment (the "Amendment") to that certain License Agreement, dated August 18, 2011 (the "License Agreement"), by and between the Company and Pfizer Inc. ("Pfizer") whereby Pfizer granted the Company a worldwide license for the development, manufacture and commercialization of neratinib (oral), neratinib (intravenous), PB357, and certain related compounds, as further described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

The Amendment amends the License Agreement to (i) reduce the royalty rate payable by the Company to Pfizer on sales of licensed products, (ii) release Pfizer from its obligation to pay for certain out-of-pocket costs incurred or accrued on or after January 1, 2014 to complete certain ongoing clinical studies, and (iii) provide that Pfizer and the Company will continue to cooperate to effect the transfer to the Company of certain records, regulatory filings, materials and inventory controlled by Pfizer as promptly as reasonably practicable.

The foregoing summary of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment. The Company expects to file a copy of the Amendment as an exhibit to its Quarterly Report on Form 10-Q for its quarter ending September 30, 2014.

Item 8.01 Other Events.

On July 22, 2014, the Company issued a press release announcing the Amendment. In addition, the Company issued a press release announcing top line results from the Phase III clinical trial of the Company's investigational drug PB272 (neratinib) for the extended adjuvant treatment of breast cancer (ExteNET Trial). A conference call has been scheduled to be held July 22, 2014 at 2:00 p.m. PDT (5:00 p.m. EDT) to discuss the Amendment and the trial results. Copies of the press releases are filed herewith as Exhibits 99.1 and 99.2 and are incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated July 22, 2014, entitled "Puma Biotechnology Announces Amendment to Neratinib Licensing Agreement with Pfizer"

99.2 Press Release dated July 22, 2014, entitled "Puma Biotechnology Announces Positive Top Line Results from Phase III PB272 Trial in Adjuvant Breast Cancer (ExteNET Trial)"

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: July 22, 2014

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated July 22, 2014, entitled "Puma Biotechnology Announces Amendment to Neratinib Licensing Agreement with Pfizer"
99.2	Press Release dated July 22, 2014, entitled "Puma Biotechnology Announces Positive Top Line Results from Phase III PB272 Trial in Adjuvant Breast Cancer (ExteNET Trial)"



News Release

Puma Biotechnology Announces Amendment to Neratinib Licensing Agreement with Pfizer

LOS ANGELES, Calif., July 22, 2014 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced an amendment to its licensing agreement with Pfizer for Puma’s investigational drug PB272 (neratinib). Puma is currently developing PB272 for the treatment of patients with HER2-positive breast cancer and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

At the time that Puma licensed PB272 from Pfizer, a number of ongoing clinical trials (legacy clinical trials) that had been previously initiated by Pfizer were transferred to Puma. The original license agreement set a limit on the amount of external expenses that Puma would incur in completing these legacy clinical trials. Puma reached this limit in the fourth quarter of 2012. The original license agreement also provided that Pfizer would be responsible for all expenses for these ongoing legacy trials above the pre-determined limit until the trials were completed.

The amendment to the license agreement provides that Puma will now be solely responsible for the expenses associated with the ongoing legacy clinical trials. Puma anticipates that this will result in an increase in research and development expenses, which will total approximately \$30 million. Puma further anticipates that a significant percentage of this approximately \$30 million will occur in 2014 and will decrease over time until the trials are completed.

In addition, according to the terms of the original license agreement, upon commercialization of neratinib, Puma is obligated to pay Pfizer incremental annual royalties ranging between 10 to 20 percent of net sales of neratinib. Under the terms of the amendment to the license agreement, upon commercialization of neratinib, Puma will be obligated to pay Pfizer annual royalties on net sales of neratinib at a fixed rate in the low- to mid- teens.

“We are pleased to enter into this amendment to the licensing agreement for neratinib. By assuming responsibility for the expenses associated with the ongoing legacy clinical trials, and by fixing the royalty rate for the drug at a reduced rate, we believe that we have significantly improved the potential value of the drug,” said Alan H. Auerbach, Chief Executive Officer and President.

Conference Call and Webcast

Puma Biotechnology will host a conference call to discuss the amendment to the license agreement for neratinib at 2:00 p.m. PDT (5:00 p.m. EDT) on Tuesday, July 22, 2014. The conference call may be accessed by dialing 1-877-709-8150 for domestic callers and 1-201-689-8354 for international callers. Please specify to the operator that you would like to join the “Puma Biotechnology Update Call.” The conference call will also be webcast live and accessible through the Investor Relations section of Puma’s website at http://www.pumabiotechnology.com/ir_events.html and will be archived there for 30 days following the call. Please visit Puma’s website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About Puma Biotechnology

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. The Company is initially focused on the development of PB272 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive breast cancer and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding the anticipated increases in, the timing of the increases in and the decrease over time in research and development expenses. All forward-looking statements included in this press release 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 has no product revenue and no products approved for marketing; the Company's dependence on PB272, which is still under development and may never receive regulatory approval; 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; the Company's dependence on licensed intellectual property; and the other risk factors disclosed in the periodic 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, 2013. 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.

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News Release

Puma Biotechnology Announces Positive Top Line Results from Phase III PB272 Trial in Adjuvant Breast Cancer (ExteNET Trial)

Neratinib Achieves Statistically Significant Improvement in Disease Free Survival

Company Plans to File for Regulatory Approval in First Half of 2015

LOS ANGELES, Calif., July 22, 2014 – Puma Biotechnology, Inc. (NYSE: PBYY), a development stage biopharmaceutical company, announced top line results from the Phase III clinical trial of Puma’s investigational drug PB272 (neratinib) for the extended adjuvant treatment of breast cancer (ExteNET Trial). The ExteNET trial is a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in women with early stage HER2-positive breast cancer.

More specifically, the ExteNET trial enrolled 2,821 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomized to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of two years after randomization in the trial.

The primary endpoint of the trial was disease free survival (DFS). The results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo. The hazard ratio was determined to be 0.67 which was statistically significant with a p-value of 0.0046. The secondary endpoint of the trial was disease free survival including ductal carcinoma in situ (DFS-DCIS). The results of the trial demonstrated that treatment with neratinib resulted in a 37% improvement in disease free survival including ductal carcinoma in situ versus placebo. The hazard ratio was determined to be 0.63 which was statistically significant with a p-value of 0.0009. Based on these results from the ExteNET study, Puma plans to file for regulatory approval of neratinib in the extended adjuvant setting in the first half of 2015.

Full results of the ExteNET trial for PB272 will be presented at a future scientific meeting

“We are very pleased with the results of the ExteNET trial with neratinib. This represents the first trial with a HER2 targeted agent that has shown a statistically significant benefit in the extended adjuvant setting, which we believe provides a meaningful point of differentiation for neratinib in the treatment of HER2 positive breast cancer,” said Alan H. Auerbach, Chief Executive Officer and President. “While the use of trastuzumab in the adjuvant setting has led to a reduction in disease recurrence in patients with early stage HER2-positive breast cancer, there remains an unmet clinical need for further improvement in outcome in order to attempt to further reduce this risk of recurrence. The results of the ExteNET study demonstrate that we may be able to provide this type of improvement with neratinib to further help the patients with this disease.”

Conference Call and Webcast

The Company will host a conference call to discuss the ExteNET trial results, as well as the amendment to the license agreement for neratinib, at 2:00 p.m. PDT (5:00 p.m. EDT) on Tuesday, July 22, 2014. The conference call may be accessed by dialing 1-877-709-8150 for domestic callers and 1-201-689-8354 for international callers. Please specify to the operator that you would like to join the “Puma Biotechnology Update Call.” The conference call will also be webcast live and accessible through the Investor Relations section of Puma’s website at http://www.pumabiotechnology.com/ir_events.html and will be archived there for 30 days following the call. Please visit Puma’s website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

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Forward-Looking Statements:

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