Puma Biotechnology Announces Amendment to Neratinib Licensing Agreement with Pfizer

Release Date:
Tuesday, July 22, 2014 1:05 pm PDT

Terms:

Dateline City:
LOS ANGELES

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/investor_relations/events 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.

**Language:**
English

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**Ticker Slug:**
*Ticker: PBYI*
*Exchange: NYSE*
*ISIN:*
*US74587V1070*

**Source URL:** https://investor.pumabiotechnology.com/press-release/puma-biotechnology-announces-amendment-neratinib-licensing-agreement-pfizer