

CTI BIOPHARMA CORP
Form 8-K
June 09, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): June 9, 2015 (June 5, 2015)

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction)

001-12465 91-1533912
(Commission (I.R.S. Employer

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(State or other jurisdiction of incorporation or organization) (File Number) (Identification Number)

3101 Western Avenue, Suite 600

Seattle, Washington 98121

(Address of principal executive offices)

Registrant's telephone number, including area code: (206) 282-7100

Not applicable

(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 (see General Instruction A.2. below):

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))

Item 1.01. Entry into a Material Definitive Agreement.

On June 5, 2015, CTI BioPharma Corp. (the “Corporation”) entered into the First Amendment to the License Agreement (the “Amendment”), which became effective on June 8, 2015 (the “Effective Date”) amending the Development, Commercialization and License Agreement (the “License Agreement”), dated as of November 14, 2013, by and among the Corporation, Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, “Baxter”). Pursuant to the License Agreement, among other things, the Corporation granted to Baxter a license with respect to pacritinib, Baxter and the Corporation agreed to collaborate as to the development and commercialization of pacritinib, and the Corporation obtained the contingent right to receive certain milestone and royalty payments. Baxalta Incorporated, a wholly-owned subsidiary of Baxter International Inc., and certain of its affiliates (collectively, “Baxalta,” and, together with the Corporation, the “Parties”) have been assigned Baxter’s rights and obligations under the License Agreement.

Pursuant to the Amendment, two milestone payments from Baxalta to the Corporation were accelerated from the schedule contemplated by the License Agreement. The Corporation will, within three days of the Effective Date, receive a total advance of \$32 million from Baxalta relating to the following two milestone payments under the License Agreement: (i) the \$12 million development milestone payment payable in connection with the regulatory submission to the European Medicines Agency with respect to pacritinib (the “EMA Milestone”) and (ii) a \$20 million development milestone payment payable for the first treatment dosing of the last patient enrolled in PERSIST-2 (the “PERSIST-2 Milestone”), the ongoing randomized Phase 3 trial evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter.

Under the Amendment, each of the two milestone advances will bear interest at an annual rate of 9% percent until the earlier of (i) the date of first occurrence of the respective milestone and (ii) the date that the respective advance plus accrued interest is repaid in full. In the event that pacritinib development is terminated either because of a regulatory determination that the benefit/risk profile of the drug candidate is unacceptable or due to safety concerns or certain other reasons, including the failure of pacritinib to meet certain criteria or certain endpoints (each, a “Milestone Failure”), the Corporation would be required to repay the respective advance to Baxalta in eight quarterly installments beginning thirty days after the end of the calendar quarter of the first occurrence of a Milestone Failure and a final payment equal to the remainder of the unpaid balance (the “Repayment Terms”). Further, if (i) the EMA Milestone is not achieved prior to March 31, 2017 or (ii) the PERSIST-2 Milestone is not achieved prior to December 31, 2016, then the Corporation would also be required to repay the respective advance pursuant to the Repayment Terms. Repayment of the advances will be accelerated in the event of the commencement of insolvency proceedings, and certain other events of default. If a milestone is achieved, however, then the Corporation would remain entitled to the respective advance. In the event that the Corporation does not spend a specified amount on the development of pacritinib from the Effective Date through February 29, 2016, payments to Baxalta in an amount equal to such deficiency may be required or credited against amounts owed to the Corporation in certain circumstances.

In the Amendment, in lieu of entering into a manufacturing and supply agreement as contemplated by the License Agreement, the Parties have also agreed to changes in the provisions of the License Agreement regarding manufacturing and supply, including that the Parties will each be allocated up to 50% of the manufacturing (subject to certain conditions), with certain pricing adjustments based on comparative costs of supply.

Baxalta beneficially owns approximately 8.7% of the Corporation’s common stock as of April 30, 2015, and Baxalta Incorporated or its affiliates are parties to a registration rights agreement and other agreements with the Corporation.

The foregoing description is a summary of the actual text of the Amendment. The Corporation plans to file the Amendment as an exhibit to a subsequent Quarterly Report on Form 10-Q or as an amendment to this Report on Form 8-K.

Item 2.03. Creation of Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

On June 5, 2015, the Corporation entered into the Amendment. The information provided in the second and third paragraphs of Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

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.

CTI BIOPHARMA CORP.

Date: June 9, 2015 By: /s/ Louis A. Bianco
Louis A. Bianco
Executive Vice President, Finance and Administration