CTI BIOPHARMA CORP
Form 8-K
April 25, 2017

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): April 21, 2017

CTI BIOPHARMA CORP.
(Exact name of registrant as specified in its charter)

Washington	001-12465	91-1533912
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer 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:
¨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 April 21, 2017 (the “Restatement Date”), CTI BioPharma Corp. and its wholly-owned subsidiary, CTI Life Sciences Limited (collectively, the “Company”), entered into an Amended and Restated Exclusive License and Collaboration Agreement (the “Restated Agreement”) with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, “Servier”, and together with the Company, the “Parties”) pursuant to which the Parties amended and restated the Exclusive License and Collaboration Agreement entered into by the Parties on September 16, 2014 (the “Original Agreement”) regarding the development and commercialization of pixantrone dimaleate (PIXUVRI®) (the “Compound”, and to the extent incorporated in a pharmaceutical product, the “Licensed Product(s)”). The Restated Agreement replaces the Original Agreement in its entirety.

The Company has obtained conditional marketing authorization in the European Union to market PIXUVRI® for the treatment of adult patients with relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. Under the Restated Agreement, the Company will transfer its European marketing authorization to Servier upon positive, statistically significant results in an ongoing post-authorization Phase III clinical trial, PIX306, unless Servier elects to terminate the Restatement Agreement within thirty (30) days after the positive results.

Under the Restated Agreement, the Company has granted to Servier an exclusive, sublicensable (subject to certain exceptions) license to manufacture the Licensed Products worldwide, and an exclusive, sublicenseable (subject to certain exceptions) license to develop and commercialize the Licensed Products worldwide, excluding the United States (the “Company Territory”). The Parties have agreed to enter into a commercialization transition plan by July 31, 2017 whereby the Company will transfer to Servier medical affairs and commercialization activities relating to the Licensed Products in Israel, Turkey, Germany, Austria, the United Kingdom, Denmark, Finland, Norway and Sweden (collectively, the "Transition Territory"). Upon the implementation of the commercialization transition plan, the Company will terminate or assign certain distributor and wholesaler contracts to Servier in the Transition Territory. Each party will be responsible for the manufacture and supply of drug products and substances in their respective territories.

The Company will receive payments of €12 million from Servier, which includes €2 million for a new milestone previously achieved, and Servier is obligated to purchase a certain amount of Pixuvri drug product for an additional €900,000 within 30 days of the Restated Agreement. Subject to the achievement of certain conditions, the Company is eligible to receive additional milestone payments from Servier in the aggregate amount of up to €76 million (or approximately $82.6 million at the exchange rate as of April 24, 2017), which is comprised of the following: up to €36 million (or approximately $39.1 million at the exchange rate as of April 24, 2017) in potential regulatory milestone payments and up to €40.0 million (or approximately $43.5 million at the exchange rate as of April 24, 2017) in potential sales milestone payments. The Company is eligible to receive tiered royalty payments ranging from a low-double digit percentage up to a percentage in the low-twenties based on net sales of the Licensed Product, subject to certain reductions of up to mid-double digit percentages under certain circumstances. The Parties will no longer use a joint marketing plan, and marketing costs will no longer be shared equally between the Parties; instead Servier will be solely responsible for marketing costs within Europe. Mutually agreed upon development costs other than PIX306 will continue to be shared equally between the Parties, which represents no change to the development cost sharing.

The Restated Agreement also requires the Parties to amend the trademark license agreement entered into between the Parties on June 8, 2015 to provide for Servier’s right to use of the Company’s trademark PIXUVRI® in connection with Licensed Products worldwide, excluding the Company Territory.

The foregoing description of the terms and conditions of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Agreement, a redacted copy of which will be filed as an exhibit

to the Company's quarterly report on Form 10-Q for the quarterly period ended March 31, 2017, and upon filing will be incorporated herein by reference. The Company intends to submit a Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), requesting that it be permitted to redact certain portions of the Agreement. The omitted material will be included in the request for confidential treatment.

Item 7.01. Regulation FD Disclosure.

The information provided pursuant to this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any filing or other document filed by the Company pursuant to the Exchange Act or the Securities Act of 1933, as amended, except as shall be

expressly set forth by specific reference in such filing or document. The information provided pursuant to this Item 7.01 shall instead be deemed “furnished.”

On April 25, 2017, the Company issued a press release announcing the Company’s entry into the Restated Agreement with Servier. The full text of such press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description	Location
99.1	Press Release of CTI BioPharma Corp., dated April 25, 2017.	Furnished herewith.

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: April 25, 2017 By: /s/ Bruce J. Seeley
Bruce J. Seeley
Executive Vice President, Chief Commercial Officer and Administrative Officer

EXHIBIT INDEX

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