CTI BIOPHARMA CORP
Form 8-K
September 17, 2014

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): September 17, 2014 (September 16, 2014)

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 (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 September 16, 2014 (the Effective Date), CTI BioPharma Corp. and its wholly-owned subsidiary, CTI Life Sciences Limited (collectively, the Company), entered into an Exclusive License and Collaboration Agreement (the Agreement) with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, Servier) for the development and commercialization of Pixantrone dimaleate (PIXUVRI®) (the Compound). Under the Agreement, the Company has granted Servier an exclusive and sublicensable (subject to certain conditions) royalty-bearing license to develop and commercialize the Compound for use in any pharmaceutical product containing the Compound as an active ingredient or in combination with other active ingredients (the Compound , and together with any such pharmaceutical product, the Licensed Product) in all countries other than the following, as to which the Company has retained such rights: Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the United Kingdom and the United States (collectively, such specified countries constitute the CTI Territory , and all other countries constitute the Servier Territory).

The Company will receive an upfront payment, and, subject to the achievement of certain conditions, is eligible to receive milestone payments, under the Agreement in the aggregate amount of up to 103.0 million (or $133.5 million at the exchange rate as of September 12, 2014), which is comprised of the following: an upfront payment of 14.0 million (or $18.1 million); up to 49.0 million (or $63.5 million) in potential clinical and regulatory milestone payments (of which 9.5 million (or $12.3 million) is payable upon the occurrence of certain enrollment events in connection with the ongoing confirmatory Phase 3 clinical trial for the Compound); and up to 40.0 million (or $51.9 million) in potential sales milestone payments. For a number of years following the first commercial sale of a Licensed Product in the respective country, regardless of patent expiration or expiration of regulatory exclusivity rights, the Company is eligible to receive tiered royalty payments ranging from a low-double digit percentage up to a percentage in the mid-twenties based on net sales of the Licensed Product, subject to certain reductions of up to mid-double digit percentages under certain circumstances.

Unless otherwise agreed by the parties, (i) certain development costs incurred pursuant to a development plan and (ii) certain marketing costs incurred pursuant to a marketing plan, will be shared equally by the parties, subject to a maximum dollar obligation of each party.

Joint executive and steering committees with representatives from the Company and Servier will be established pursuant to the Agreement. The Agreement will expire on a country-by-country basis upon the expiration of the royalty terms in the countries in the Servier Territory, at which time all licenses granted to Servier would become perpetual and royalty-free. Each party may terminate the Agreement in the event of an uncured repudiatory breach (as defined under English law) of the other party s obligations. Servier may terminate the Agreement on a country-by-country basis upon written notice within a specified period of time to the Company without cause or upon written notice within a certain period of days in the event of (i) certain safety or public health issues relating to the Licensed Product or (ii) cessation of certain marketing authorizations. In the event of a termination prior to the expiration date, rights granted to Servier will terminate, subject to certain exceptions.

The Agreement also requires the parties to enter into an agreement providing for the manufacture of the Licensed Product and an agreement governing the quality control, quality assurance, pharmacovigilance and validation of the Licensed Product to Servier. The parties will also enter into a trademark license agreement for the use of the trademark PIXUVRI® in connection with Licensed Products in the Servier Territory.

The foregoing is a brief description of the terms and conditions of the Agreement and is intended to summarize those that are material to the Company. The Company intends to file the Agreement with the Securities and Exchange Commission as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2014 or a future Current Report on Form 8-K, together with a request for confidential treatment of certain terms of the Agreement.

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 Securities Exchange Act of 1934, as amended (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 September 17, 2014, the Company issued a press release announcing the Company s entry into the 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 September 17, 2014.	Furnished herewith.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CTI BIOPHARMA CORP.

Date: September 17, 2014

By: /s/ Louis A. Bianco
Louis A. Bianco
Executive Vice President, Finance and Administration

EXHIBIT INDEX

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