CTI BIOPHARMA CORP
Form 8-K
February 08, 2016

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): February 4, 2016

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 240.425)

¨ 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 7.01 Regulation FD Disclosure

On February 8, 2016, CTI BioPharma Corp. (the Company) issued a press release announcing the matters discussed in Item 8.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

Partial Clinical Hold on Pacritinib IND

On February 4, 2016, the U.S. Food and Drug Administration (the FDA) notified the Company that a partial clinical hold has been placed on pacritinib (IND 078406), the Company s investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. A partial clinical hold is a delay or suspension of part of the clinical work requested under the investigational new drug (IND) application (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND). Under the partial clinical hold, the following restrictions apply until an agreement is reached with the FDA: (i) the Company may not enroll new patients or start pacritinib as an initial or crossover treatment, and (ii) patients on pacritinib not deriving benefit after 30-weeks of pacritinib treatment should stop pacritinib. In its written notification, the FDA cited the reasons for the partial clinical hold were that it identified the following fatal and life-threatening safety issues in pacritinib-treated patients: heart failure, hemorrhage including intracranial hemorrhage, and arrhythmias including sudden death, and the FDA has also noted excess mortality in pacritinib-treated patients compared to the control arm in the PERSIST-1 clinical trial evaluating pacritinib.

In connection with the partial clinical hold, the FDA has recommended that the Company make certain modifications of protocols, including modifying all protocols for randomized trials to disallow crossover to pacritinib, provide certain notifications, revise relevant statements in the related Investigator s Brochure and informed consent documents and take certain other actions. The Company has begun work to comply with the FDA request. After submission of a complete response to the items, the FDA has indicated that it would notify the Company whether it can continue the clinical study under the IND.

Completion of PERSIST-2 Phase 3 Trial

On February 8, 2016, the Company announced that as of February 3, 2016, it has completed patient enrollment in the PERSIST-2 Phase 3 clinical trial of pacritinib for the treatment of patients with myelofibrosis. PERSIST-2 is evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter (£100,000/mL). Patients currently receiving pacritinib may continue to do so unless they are not deriving benefit after 30 weeks of pacritinib treatment.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of CTI BioPharma Corp, dated February 8, 2016

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: February 8, 2016

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