CTI BIOPHARMA CORP
Form 8-K
February 10, 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 8, 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 9, 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.

On February 8, 2016, the U.S. Food and Drug Administration (the FDA) notified the Company that a full 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 full clinical hold is a suspension of the clinical work requested under an investigational new drug application. Under the full clinical hold, all patients currently on pacritinib must discontinue pacritinib immediately, and the Company may not enroll any new patients or start pacritinib as initial or crossover treatment. In its written notification, the FDA noted interim overall survival results from PERSIST-2 showing a detrimental effect on survival consistent with the results from PERSIST-1, and that deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest.

The FDA made recommendations that supersede the recommendations made by the FDA in connection with the partial clinical hold imposed by the FDA on February 4, 2016. The current recommendations include conducting Phase 1 clinical trials for dose exploration of pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator s Brochure and informed consent documents and making certain modifications to protocols. In addition, the FDA recommended that the Company request a meeting prior to submitting a response to full clinical hold.

The Company has withdrawn its previously submitted new drug application for pacritinib until the Company has had a chance to evaluate appropriate steps for pacritinib. All clinical investigators worldwide have been delivered a notice of the full clinical hold.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of CTI Bio Pharma Corp, dated February 9, 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 9, 2016

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