CTI BIOPHARMA CORP
Form 8-K
March 14, 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): March 14, 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 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 7.01 Regulation FD Disclosure

On March 14, 2016, CTI BioPharma Corp. (the "Company") provided an update regarding the availability of pacritinib to certain patients with myelofibrosis. Following the issuance of the Company's February 9, 2016, press release describing the full clinical hold issued by the U.S. Food and Drug Administration ("FDA") regarding pacritinib Phase 3 clinical studies, the FDA has been in communication with the Company regarding pacritinib. The FDA recently expressed an interest in allowing patients who were receiving benefit from pacritinib treatment at the time the clinical hold was imposed to submit requests to the FDA to resume pacritinib treatment under a Single Patient IND ("SPI") program on a case by case basis. The Company is working with the FDA on certain regulatory and logistical items necessary to assist investigators in submitting SPIs for their patients to the FDA for consideration. The Company has informed clinical investigators worldwide of the FDA's interest in allowing SPIs, and plans to continue to provide updates as meaningful details become available.

At the time the pacritinib IND was placed on full clinical hold, there were 131 patients from the PERSIST-1 trial and 187 patients from the PERSIST- 2 trial who were receiving pacritinib therapy, as well as 98 patients on various investigator sponsored trials. It is not known if any of these patients will opt to continue pacritinib or if the FDA will agree that a specific patient can continue.

As previously reported, the FDA's February 8, 2016, letter noted the interim overall survival results from PERSIST-2 show a detrimental effect on survival consistent with the results from PERSIST-1. The deaths in PERSIST-2 in pacritinib-treated patients include deaths attributed to 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 dose exploration studies for 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.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking" statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning the potential SPI/Compassionate Use program. Such statements are subject to risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of the Company's securities. Specifically, the risks and uncertainties that could affect the potential SPI/Compassionate Use program include the possibility that the FDA may not ultimately permit dosing with pacritinib under the program, may impose conditions that make it difficult to implement on reasonable terms or at all, and could modify, suspend or terminate the program at any time; and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission, including, without limitation, the Company's most recent filings on Forms 10-K, 10-Q and 8-K. The Company can give no assurances that any results or events projected or contemplated by its forward-looking statements will in fact occur and the Company cautions you not to place undue reliance on these statements. The Company undertakes no duty to update these forward-looking statements to reflect any future events, developments or otherwise.

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: March 14, 2016

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