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): December 18, 2018

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Delaware	**000-28386**	**91-1533912**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

3101 Western Avenue, Suite 800
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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On December 18, 2018, CTI BioPharma Corp. issued a press release providing a program update following regulatory feedback from the United States Food and Drug Administration on pacritinib development. A copy of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated December 18, 2018

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: December 18, 2018

By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer

CTI BioPharma Provides Program Update Following Regulatory Feedback from the U.S. FDA on Pacritinib Development

- CTI receives input on key elements of new Phase 3 trial design for patients with myelofibrosis and severe thrombocytopenia -

- Phase 3 trial of approximately 200 patients expected to begin enrollment in the third quarter of 2019 -

SEATTLE, December 18, 2018 - CTI BioPharma Corp. (NASDAQ:CTIC) announced today that it has received input from the U.S. Food and Drug Administration (FDA) at a recent Type C meeting on key elements of the design of a new randomized Phase 3 study of pacritinib in adult patients with myelofibrosis (primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis) and who have severe thrombocytopenia (as defined by patients with platelet counts of less than 50,000 per microliter), an indication that has been recognized by the medical community as an important unmet medical need.

The planned Phase 3 study is designed to evaluate the effects of pacritinib as compared to physician's choice of treatment. The primary efficacy endpoint will be the proportion of patients achieving a greater than or equal to 35% spleen volume reduction (SVR) between baseline and Week 24. Secondary efficacy endpoints of the study include total symptom score reduction and overall survival.

Before commencing the Phase 3 study, CTI plans to meet with the FDA to discuss the final optimal dose analysis from the PAC203 Phase 2 study. To expedite the transition to Phase 3, CTI intends to amend the PAC203 protocol to include a Phase 3 component. The PAC203 Phase 3 component is designed to enroll approximately 200 patients with enrollment expected to commence in the third quarter of 2019. The anticipated cost of the Phase 3 study is approximately $25 million. Taking into account the impact of recently-announced cost saving efforts and the anticipated cost of the new Phase 3 trial, the current CTI financial analysis projects a cash runway that extends into 2020.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding our expectations regarding the anticipated cost savings from the workforce reduction, anticipated interactions with regulators, the expected timing for the determination of the trial design for the planned U.S. Phase 3 trial for pacritinib, including the timing of determining the optimal dose using data from the ongoing PAC203 study, and timing expectations relating to the commencement of enrollment in the planned U.S. Phase 3 trial for pacritinib. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: cost savings from the workforce reduction may be less than anticipated; determination of the trial design for the planned U.S. Phase 3 trial for pacritinib may take longer than anticipated; clinical trials may not demonstrate safety

and efficacy of any of our or our collaborators' product candidates; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our efforts to advance the development of pacritinib may not be successful; any of our or our collaborators' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; adverse conditions in the general domestic and global economic markets; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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