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 1, 2019

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 February 1, 2019, CTI BioPharma Corp. issued a press release announcing its decision to withdraw its European Marketing Authorization Application for pacritinib as a treatment for myelofibrosis following recent interactions with the European Medicine Agency's Committee for Medicinal Products for Human Use. The press release further announced that, on January 23, 2019, a planned third interim review of the PAC203 study was held by the Independent Data Monitoring Committee and the study will continue as scheduled. 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 February 1, 2019

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 1, 2019

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

CTI BioPharma Receives Results of the CHMP Oral Explanation for Pacritinib in the Treatment of Myelofibrosis and Provides Development Update

- Company announces continuation of PAC203 study following third interim review -

SEATTLE, Feb. 1, 2019 - CTI BioPharma Corp. (NASDAQ:CTIC) today announced that the Company will withdraw its European Marketing Authorization Application (MAA) for pacritinib as a treatment for myelofibrosis. The decision follows recent interactions with the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), during which the Company learned that the committee was likely to formally adopt a negative opinion in its evaluation of the application. The CHMP indicated that the risk-benefit profile for pacritinib for the intended indication has not been sufficiently established with the clinical data available to date.

The Company is continuing to develop pacritinib for both U.S. and European registration as a treatment for myelofibrosis patients with severe thrombocytopenia. CTI plans to seek scientific guidance from the EMA before beginning the planned Phase 3 study, having already discussed the protocol design with the FDA last month. The Phase 3 trial is expected to begin enrollment in the third quarter of 2019.

In addition, the Company announced that on January 23, 2019, a planned third interim review of the PAC203 study was held by the Independent Data Monitoring Committee (IDMC) and the study will continue as scheduled. The IDMC did not identify significant drug- or dose-related safety concerns and specifically did not identify any concerns around hemorrhagic or cardiac toxicity.

About Pacritinib

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development, as well as inflammatory cytokine expression and immune responses. Mutations in these kinases have been shown to be directly related to the development of a variety of blood-related cancers, including myeloproliferative neoplasms, leukemia and lymphoma. In addition to myelofibrosis, the kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as acute myeloid leukemia (AML), myelodysplastic

syndrome (MDS), chronic myelomonocytic leukemia (CMML), and chronic lymphocytic leukemia (CLL), due to its inhibition of c-fms, IRAK1, JAK2 and FLT3.

About CTI BioPharma Corp.

CTI BioPharma Corp. is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. The CTI BioPharma lead product candidate, pacritinib, is being developed for the treatment of patients with myelofibrosis. CTI BioPharma is headquartered in Seattle, Washington.

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 anticipated interactions with regulators, our ability to establish a dose for our randomized Phase 3 study of pacritinib, the anticipated trial design of the U.S. Phase 3 trial for pacritinib, the expected timing for development milestones for pacritinib, including the timing of determining the optimal dose using data from the ongoing PAC203 study, and timing expectations relating to the availability of topline efficacy and safety data from the ongoing PAC203 study as well as 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: 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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