

**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): November 26, 2018

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

000-28386
(Commission
File Number)

91-1533912
(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.

As disclosed in its periodic filings, CTI BioPharma Corp. (the “Company”) previously submitted to the European Medicines Agency (“EMA”) a marketing authorization application (“MAA”) for its primary development candidate, pacritinib. The Company received a second round of questions relating to the Day 180 List of Outstanding Issues for the MAA and the Company plans to submit responses to the EMA, which will include data from the ongoing open label PAC203 trial, by the end of the year. In addition, the Company is preparing for an Oral Explanation meeting before the Committee for Medicinal Products for Human Use (“CHMP”). A decision by CHMP on the MAA is expected in the first quarter of 2019.

On November 26, 2018, the Company issued a press release regarding these matters. 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

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated November 26, 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: November 26, 2018

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



CTI BioPharma Provides Program Update Following Regulatory Feedback on Pacritinib Development from the European Medicines Agency

- European regulatory opinion on marketing authorization application (MAA) for pacritinib now expected in the first quarter of 2019 -

SEATTLE, November 26, 2018 - CTI BioPharma Corp. (NASDAQ:CTIC) today announced that the Company has received a second round of questions related to the Day 180 List of Outstanding Issues, for the marketing authorization application (MAA) for pacritinib, from the European Medicines Agency (EMA). The Company plans to submit responses to the EMA, which will include data from the ongoing open label PAC203 trial, by the end of the year. In addition, the Company is preparing for an Oral Explanation meeting before the Committee for Medicinal Products for Human Use (CHMP). A decision by CHMP on the MAA is expected in the first quarter of 2019.

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 timing of and results from clinical trials and development activities related to pacritinib, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of pacritinib, the anticipated timing of regulatory submissions and our interactions with regulators, the efficacy of, and potential changes to, our clinical trial designs and anticipated enrollment, including timing thereof, our ability to successfully develop and achieve milestones in the development of pacritinib, and the anticipated benefits of 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: 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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