

CTI BIOPHARMA CORP
Form 8-K
May 25, 2018

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): May 24, 2018
CTI BIOPHARMA CORP.
(Exact name of registrant as specified in its charter)

Delaware 001-12465 91-1533912
(State or other jurisdiction of (Commission (I.R.S. Employer
incorporation or organization) File Number) 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:

--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.

Submission of Responses to Day 120 List of Questions

As disclosed in its periodic filings, CTI BioPharma Corp. (the “Company”) previously submitted a Marketing Authorization Application (“MAA”) to the European Medicines Agency (“EMA”) for its lead development candidate, pacritinib. In July 2017, the MAA was validated by the EMA, which initiated the centralized review process by the Committee for Medicinal Products for Human Use (“CHMP”). In November 2017, as part of its review process, CHMP submitted its Day 120 List of Questions (“D120 LoQ”) to the Company and, on May 24, 2018, the Company submitted its responses to the D120 LoQ.

Final EMA GCP Inspection Report

The Company also reported that the EMA’s February 2018 final good clinical practices (“GCP”) inspection report concluded that the Company’s PERSIST-2 clinical trial of pacritinib was generally conducted in compliance with GCP and internationally accepted ethical standards, that the deficient safety reporting procedures identified did not pose a direct risk for data quality and that the results from the PERSIST-2 clinical trial can be used for the evaluation and assessment of the MAA.

In certain of the Company’s previous periodic filings, including its Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission (the “Commission”) on March 7, 2018 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 filed with the Commission on May 3, 2018, descriptions of the EMA’s January 2018 interim GCP inspection report stated that compliance was not verified in the areas of protocol compliance, safety reporting and data integrity, where significant deficiencies were cited. Such description of the January 2018 interim GCP inspection report is supplemented and updated by the information set forth in the immediately preceding paragraph.

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: May 25, 2018 By: /s/ Adam R. Craig
Adam R. Craig, M.D., Ph.D.
President and Chief Executive Officer