
**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): June 1, 2021

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:

- 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))
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Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	CTIC	Nasdaq Capital Market

- Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.
 - 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.
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Item 2.02. Results of Operations and Financial Condition.

On June 1, 2021, CTI BioPharma Corp. issued a press release announcing its financial results for the quarter ended March 31, 2021 and certain other information. The full text of the press release is set forth in Exhibit 99.1 hereto. The information in this Current Report on Form 8-K and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.***(d) Exhibits***

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

Exhibit No.	Description	Location
99.1	Press Release of CTI BioPharma Corp., dated June 1, 2021	Furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

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: June 1, 2021

By:

/s/ David H. Kirske

David H. Kirske
Chief Financial Officer



CTI BioPharma Reports First Quarter 2021 Financial Results

- NDA for Pacritinib for the Treatment of Myelofibrosis Patients with Severe Thrombocytopenia Accepted with Priority Review by FDA with PDUFA Target Action Date of November 30, 2021 –*
- Commercialization Activities on Track to Support a Potential Approval and Launch of Pacritinib in the United States in 2021 –*
- Management to Host Conference Call Today at 4:30 PM ET –*

SEATTLE, June 1, 2021 - CTI BioPharma Corp. (Nasdaq: CTIC) today reported its financial results for the first quarter ended March 31, 2021.

“The U.S. Food and Drug Administration’s (FDA) acceptance of our New Drug Application (NDA) for pacritinib with priority review and a Prescription Drug User Fee Act (PDUFA) action date of November 30, 2021 brings us one step closer to providing pacritinib to myelofibrosis patients with severe thrombocytopenia who are underserved by existing therapies,” said Adam R. Craig, M.D., Ph.D., President and Chief Executive Officer of CTI BioPharma. “We continue to work diligently on our commercial preparedness and expect to be ready to launch pacritinib in the United States this year, pending approval by the FDA. To that end, over the last quarter, we progressed key pre-commercial activities to prepare for a successful and rapid launch upon approval, including market access, distribution and supply chain, disease education and field force planning and deployment. We look forward to continuing these efforts, and to work closely with the FDA during its review of our application.”

Expected Milestones

- PDUFA action date – November 30, 2021
- Expected U.S. commercial launch of pacritinib – by the end of 2021
- Reporting of interim analysis from the Phase 3 PRE-VENT trial in hospitalized patients with severe COVID-19 – Q3 2021

First Quarter Financial Results

Operating loss was \$17.1 million and \$11.9 million for the three months ended March 31, 2021 and 2020, respectively. The increase in operating loss resulted primarily from increases in research and development and general and administrative activities associated with continued development and preparation for the commercialization of pacritinib.

Net loss for the three months ended March 31, 2021 was \$17.3 million, or \$0.23 for basic and diluted loss per share, as compared to a net loss of \$12.2 million, or \$0.20 for basic and diluted loss per share, for the same period in 2020.

As of March 31, 2021, cash, cash equivalents and short-term investments totaled \$37.2 million, as compared to \$52.5 million as of December 31, 2020. On April 6, 2021 we completed an equity financing with net proceeds of \$53.8 million, which enables us to fund our operations into the fourth quarter of 2021.

Conference Call and Webcast

CTI will host a conference call and webcast to review its first quarter 2021 financial results and provide an update on business activities today, June 1 at 4:30 PM ET. To access the live call by phone please dial (877) 735-2860 (domestic) or (602) 563-8791 (international); the conference ID is 9343326. A live audio webcast of the event may also be accessed through the "Investors" section of CTI's website at www.ctibiopharma.com. A replay of the webcast will be available for 30 days following the event.

About Myelofibrosis and Severe Thrombocytopenia

Myelofibrosis is a type of bone marrow cancer that results in formation of fibrous scar tissue and can lead to severe thrombocytopenia and anemia, weakness, fatigue and enlarged spleen and liver. Patients with severe thrombocytopenia are estimated to make up one-third of patients treated for myelofibrosis, or approximately 17,000 people in the United States and Europe. Severe thrombocytopenia, defined as blood platelet counts of less than $50 \times 10^9/L$, has been shown to result in overall survival rates of just 15 months. Thrombocytopenia in patients with myelofibrosis is associated with the underlying disease but has also been shown to result from treatment with ruxolitinib, which can lead to dose reductions, and as a result, may potentially reduce clinical benefit. Survival in patients who have discontinued ruxolitinib therapy is further compromised, with an average overall survival of seven to 14 months. Myelofibrosis patients with severe thrombocytopenia have limited treatment options, and represent an area of significant unmet medical need.

About CTI BioPharma Corp.

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers that offer a unique benefit to patients and their healthcare providers. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our product candidate currently in active late-stage development, for the treatment of adult patients with myelofibrosis, and in response to the COVID pandemic, severe COVID-19 disease. We are headquartered in Seattle, Washington.

Forward-Looking Statements

Statements included in this press release that are not historical in nature are 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 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 include, but are not limited to: our ability to successfully demonstrate the safety and efficacy of, and receive regulatory approval for, pacritinib; the risk that the FDA may determine that the benefit/risk profile of pacritinib at the dose selected for the PACIFICA Phase 3 trial does not support approval; our expectations regarding the completion and outcome of our PRE-VENT Phase 3 trial; the risk that pacritinib may be delayed to a point where it is not commercially viable; the accuracy of our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations; risks and uncertainties related to the COVID-19 pandemic as it relates to our operations and ongoing clinical trials; and those risks more fully discussed in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020 and subsequent quarterly reports on Form 10-Q. 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. "CTI BioPharma" and the CTI BioPharma logo are registered trademarks or trademarks of CTI BioPharma Corp. in various jurisdictions. All other trademarks belong to their respective owner.

CTI BioPharma Investor Contacts:

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(tables follow)

CTI BioPharma Corp.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating costs and expenses:		
Research and development	\$ 9,444	\$ 3,264
General and administrative	7,626	4,467
Other operating expenses	—	4,200
Total operating costs and expenses	17,070	11,931
Loss from operations	(17,070)	(11,931)
Non-operating income (expense):		
Interest income	11	119
Interest expense	(68)	(167)
Amortization of debt discount and issuance costs	(130)	(130)
Foreign exchange loss	(9)	(77)
Total non-operating expense, net	(196)	(255)
Net loss	\$ (17,266)	\$ (12,186)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.20)
Shares used in calculation of basic and diluted net loss per common share:	76,367	62,461

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	March 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 33,105	\$ 40,394
Short-term investments	4,060	12,057
Working capital	23,790	37,287
Total assets	42,789	58,241
Current portion of long-term debt	3,252	4,455
Total stockholders' equity	26,654	40,029