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): August 5, 2021

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:

☐ 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))

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.

Item 2.02. Results of Operations and Financial Condition.

On August 5, 2021, CTI BioPharma Corp. issued a press release announcing its financial results for the quarter ended June 30, 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 August 5, 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: August 5, 2021

By: /s/ David H. Kirske

David H. Kirske
Chief Financial Officer

Exhibit 99.1

CTI BioPharma Reports Second Quarter 2021 Financial Results

– NDA for Pacritinib for the Treatment of Myelofibrosis Patients with Severe Thrombocytopenia Under 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, Aug. 5, 2021 - CTI BioPharma Corp. (Nasdaq: CTIC) today reported its financial results for the second quarter ended June 30, 2021.

“This past quarter, we continued to advance pacritinib towards a potential U.S. approval and commercial launch this year. The U.S. Food and Drug Administration’s acceptance with priority review of our NDA submission for the use of pacritinib in myelofibrosis patients with severe thrombocytopenia underscores the unmet need in this area,” said Adam R. Craig, M.D., Ph.D., President and Chief Executive Officer of CTI Biopharma. “With a PDUFA target action date of November 30, 2021, and commercial preparations already well underway, we will be well positioned for a potential U.S. launch later this year. We are working closely with the FDA during the review of our application and we continue to advance our commercial launch activities.”

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

Second Quarter Financial Results

Operating loss was $19.5 million and $36.6 million for the three and six months ended June 30, 2021, respectively, compared to operating loss of $10.0 million and $21.9 million for the corresponding periods in 2020. The increase in operating loss for the three and six months ended June 30, 2021 as compared to the comparable periods in 2020 resulted primarily from increases in research and development and general and administrative activities associated with continued development and preparation for the potential commercialization of pacritinib.

Net loss for the three months ended June 30, 2021 was $19.7 million, or $0.21 for basic and diluted loss per share, compared to net loss of $14.0 million, or $0.19 for basic and diluted loss per share, for the same period in 2020. Net loss for the six months ended June 30, 2021 was $36.9 million, or $0.44 for basic and diluted loss per share, compared to net loss of $26.2 million, or $0.38 for basic and diluted loss per share, for the same period in 2020.

As of June 30, 2021, cash, cash equivalents and short-term investments totaled $71.9 million, as compared to $52.5 million as of December 31, 2020. We expect our current cash and cash equivalents will enable 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 second quarter 2021 financial results and provide an update on business activities today, August 5 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 6891246. 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 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 more than 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 50,000 per microliter, 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 correlate with 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, creating a significant area of 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 conduct and complete clinical trials in our currently anticipated timeframes; our ability to successfully demonstrate the safety and efficacy of pacritinib; our expectations regarding the completion and outcome of our PACIFICA Phase 3 trial and our PRE-VENT Phase 3 trial; 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; the risk that the FDA may determine that the benefit/risk profile of pacritinib in the PRE-VENT Phase 3 trial does not support approval or requires additional clinical data for approval; the risk that pacritinib may fail in its development through our PACIFICA and PRE-VENT trials; our ability to receive regulatory approval for pacritinib pursuant to the accelerated approval pathway or at all; 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.

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(tables follow)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating costs and expenses:				
Research and development	$ 9,293	$ 6,199	$ 18,737	$ 9,463
General and administrative	10,213	3,797	17,839	8,264
Other operating expenses	—	—	—	4,200
Total operating costs and expenses	19,506	9,996	36,576	21,927
Loss from operations	(19,506)	(9,996)	(36,576)	(21,927)
Non-operating income (expense):				
Interest income	8	43	19	162
Interest expense	(45)	(137)	(113)	(304)
Amortization of debt discount and issuance costs	(130)	(130)	(260)	(260)
Foreign exchange loss	(2)	(6)	(11)	(83)
Loss on dissolution of majority-owned subsidiary	—	(3,774)	—	(3,774)
Total non-operating expense, net	(169)	(4,004)	(365)	(4,259)
Net loss	$ (19,675)	$ (14,000)	$ (36,941)	$ (26,186)
Basic and diluted net loss per common share	$ (0.21)	$ (0.19)	$ (0.44)	$ (0.38)
Shares used in calculation of basic and diluted net loss per common share:	92,341	73,685	84,398	68,073

Balance Sheet Data (unaudited):	(amounts in thousands)	
	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 71,881	$ 40,394
Short-term investments	—	12,057
Working capital	59,030	37,287
Total assets	77,495	58,241
Current portion of long-term debt	2,049	4,455
Total stockholders' equity	61,706	40,029