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 8, 2022

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 8, 2022, CTI BioPharma Corp. issued a press release announcing its financial results for the quarter ended June 30, 2022 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 8, 2022	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 8, 2022

By: /s/ David H. Kirske

David H. Kirske
Chief Financial Officer

Exhibit 99.1

CTI BioPharma Reports Second Quarter 2022 Financial Results

– VONJO® (pacritinib) net product revenue of $12.3 million in the second quarter –

– Management to host conference call today at 4:30 p.m. ET –

SEATTLE, August 8, 2022 - CTI BioPharma Corp. (Nasdaq: CTIC) today reported its financial results for the second quarter ended June 30, 2022.

"CTI continues to make substantial headway with the U.S. commercial launch of VONJO, as we work to become the market leader in the treatment of cytopenic myelofibrosis. In the second quarter, we have performed well generating net product revenue of $12.3 million," said Adam Craig, President and Chief Executive Officer of CTI BioPharma. "With a differentiated profile, VONJO is a simple, safe and effective treatment that is a meaningful alternative to existing therapies. We look forward to extending the reach of VONJO over the coming months and years."

Recent Accomplishments and Updates

- VONJO listed as recommended treatment in the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for Myeloproliferative Neoplasms, as a first-line treatment for high-risk patients with myelofibrosis with platelet counts <50 x 10^9/L who are not candidates for transplant, and as a second-line treatment for lower-risk and higher-risk patients with myelofibrosis with platelet counts ≥50 x 10^9/L who are not candidates for transplant.
- Planned data presentations at international medical meetings by end of year that demonstrate pacritinib's activity as a potent ACVR1/ALK2 inhibitor as well as data on pacritinib's substantial anemia benefit in myelofibrosis.
- Data presented at the European Hematology Association (EHA) 2022 Congress demonstrating that full dose pacritinib achieved higher response rates and a similar, manageable safety profile compared to lower-dose ruxolitinib in patients with myelofibrosis who have moderate or severe thrombocytopenia.
- Data presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating the safety profile of pacritinib 200 mg twice a day is comparable to best available therapy, including ruxolitinib, and that pacritinib 200 mg twice daily could be a full-dose therapeutic option for patients with myelofibrosis, including those who experience severe thrombocytopenia.

- Filing of patent term extension application for the composition of matter U.S. Patent No. 8,153,632, with a requested five-year extension, which, if granted, would extend the expiration date of that patent from January 2029 to January 2034.

Second Quarter Financial Results

Net product sales of $12.3 million and $14.6 million for the three and six months ended June 30, 2022, respectively, were entirely attributable to VONJO product sales in the United States. There were no product sales for the comparable periods in 2021. Operating loss was $18.9 million and $19.5 million for the three months ended June 30, 2022 and 2021, respectively, and $54.0 million and $36.6 million for the six months ended June 30, 2022 and 2021, respectively. The decrease in operating loss between the three-month periods ended June 30, 2022 and 2021 was primarily attributable to net product sales, offset by an increase in selling, general and administrative activities related to the commercial-launch of VONJO. The increase in operating loss between the six-month periods ended June 30, 2022 and 2021 resulted primarily from an increase in selling, general and administrative activities related to the commercial launch of VONJO, as well as a $10.3 million milestone expense related to FDA approval of VONJO, which was included in other operating expenses.

Net loss for the three months ended June 30, 2022 was $22.7 million, or $0.21 for basic and diluted loss per share, compared to net loss of $19.7 million, or $0.21 for basic and diluted loss per share, for the same period in 2021. Net loss for the six months ended June 30, 2022 was $59.8 million, or $0.57 for basic and diluted loss per share, compared to net loss of $36.9 million, or $0.44 for basic and diluted loss per share, for the same period in 2021.

As of June 30, 2022, our cash, cash equivalents and short-term investments totaled $95.9 million. We expect our present financial resources, along with expected cash receipts from net product sales of VONJO and up to $25.0 million in contractual funding commitments receivable upon achievement of minimum net product sales of VONJO under the terms of the previously-announced debt and royalty transactions with DRI Healthcare Trust, will enable us to fund our operations for at least one year.

Conference Call and Webcast

CTI will host a conference call and webcast to review its second quarter 2022 financial results and provide an update on business activities today, August 8, 2022, at 4:30 p.m. ET. To access the live call by phone please dial (888) 317-6003 (domestic), (855) 669-9657 (Canada) or (412) 317-6061 (international); the conference ID is 0078819. 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 VONJO (pacritinib)

Pacritinib is an oral kinase inhibitor with activity against wild type Janus Associated Kinase 2 (JAK2), mutant $JAK2^{V617F}$ form and FMS-like tyrosine kinase 3 (FLT3), which contribute to signaling of a number of cytokines and

growth factors that are important for hematopoiesis and immune function. Myelofibrosis is often associated with dysregulated JAK2 signaling. Pacritinib has higher inhibitory activity for JAK2 over other family members, JAK3 and TYK2. At clinically relevant concentrations, pacritinib does not inhibit JAK1. Pacritinib exhibits inhibitory activity against additional cellular kinases (such as CSF1R and IRAK1), the clinical relevance of which is unknown.

VONJO is indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50×10^9/L. This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important VONJO Safety Information

Hemorrhage:

Serious (11%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts $<100 \times 10^9$/L. Serious (13%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts $<50 \times 10^9$/L. Grade ≥3 bleeding events (defined as requiring transfusion or invasive intervention) occurred in 15% of patients treated with VONJO compared to 7% of patients treated on the control arm. Due to hemorrhage, VONJO dose reductions, dose interruptions, or permanent discontinuations occurred in 3%, 3%, and 5% of patients, respectively.

Avoid use of VONJO in patients with active bleeding and hold VONJO seven days prior to any planned surgical or invasive procedures. Assess platelet counts periodically, as clinically indicated. Manage hemorrhage using treatment interruption and medical intervention.

Diarrhea:

VONJO causes diarrhea in approximately 48% of patients compared to 15% of patients treated on the control arm. The median time to resolution in VONJO-treated patients was two weeks. The incidence of reported diarrhea decreased over time, with 41% of patients reporting diarrhea in the first eight weeks of treatment, 15% in weeks 8 through 16, and 8% in weeks 16 through 24. Diarrhea resulted in treatment interruption in 3% of VONJO-treated patients. None of the VONJO-treated patients reported diarrhea that resulted in treatment discontinuation. Serious diarrhea adverse reactions occurred in 2% of patients treated with VONJO compared to no such adverse reactions in patients in the control arm.

Control pre-existing diarrhea before starting VONJO treatment. Manage diarrhea with antidiarrheal medications, fluid replacement, and dose modification. Treat diarrhea with antidiarrheal medications promptly at the first onset of symptoms. Interrupt or reduce VONJO dose in patients with significant diarrhea despite optimal supportive care.

Thrombocytopenia:

VONJO can cause worsening thrombocytopenia. VONJO dosing was reduced due to worsening thrombocytopenia in 2% of patients with pre-existing moderate to severe thrombocytopenia (platelet count $<100 \times 10^9$/L). VONJO

dosing was reduced due to worsening thrombocytopenia in 2% of patients with pre-existing severe thrombocytopenia (platelet count <50 × 10^9/L).

Monitor platelet count prior to VONJO treatment and as clinically indicated during treatment. Interrupt VONJO in patients with clinically significant worsening of thrombocytopenia that lasts for more than seven days. Restart VONJO at 50% of the last given dose once the toxicity has resolved. If toxicity recurs hold VONJO. Restart VONJO at 50% of the last given dose once the toxicity has resolved.

Prolonged QT interval:
VONJO can cause prolongation of the QTc interval. QTc prolongation of >500 msec was higher in VONJO-treated patients than in patients in the control arm (1.4% vs 1%). QTc increase from baseline by 60 msec or higher was greater in VONJO-treated patients than in control arm patients (1.9% vs 1%). Adverse reactions of QTc prolongation were reported for 3.8% of VONJO-treated patients and 2% of control arm patients. No cases of torsades de pointes were reported.

Avoid use of VONJO in patients with a baseline QTc of >480 msec. Avoid use of drugs with significant potential for QTc prolongation in combination with VONJO. Correct hypokalemia prior to and during VONJO treatment. Manage QTc prolongation using VONJO interruption and electrolyte management.

Major Adverse Cardiac Events (MACE):
Another JAK-inhibitor has increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with VONJO, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur.

Thrombosis:
Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated.

Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.

Secondary Malignancies:
Another JAK-inhibitor has increased the risk of lymphoma and other malignancies, excluding non-melanoma skin cancer (NMSC) (compared to those treated with TNF blockers), in patients with rheumatoid arthritis, a condition for which VONJO is not indicated. Patients who are current or past smokers are at additional increased risk.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with VONJO, particularly in patients with a known malignancy (other than a successfully-treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Risk of Infection:
Another JAK-inhibitor has increased the risk of serious infections compared to best available therapy (BAT) in patients with myeloproliferative neoplasms. Serious bacterial, mycobacterial, fungal and viral infections may occur in patients treated with VONJO. Delay starting therapy with VONJO until active serious infections have resolved. Observe patients receiving VONJO for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines.

Interactions with CYP3A4 Inhibitors or Inducers:
Co-administration of VONJO with strong CYP3A4 inhibitors or inducers is contraindicated. Avoid concomitant use of VONJO with moderate CYP3A4 inhibitors or inducers.

Drug interruptions due to an adverse reaction occurred in 27% patients who received VONJO 200 mg twice daily compared to 10% of patients treated with BAT. Dosage reductions due to an adverse reaction occurred in 12% of patients who received VONJO 200 mg twice daily compared to 7% of patients treated with BAT. Permanent discontinuation due to an adverse reaction occurred in 15% of patients receiving VONJO 200 mg twice daily compared to 12% of patients treated with BAT.

Please visit http://www.ctibiopharma.com/vonjo_prescribing_information for full Prescribing Information and the Medication Guide.

About Myelofibrosis
Myelofibrosis is bone marrow cancer that results in formation of fibrous scar tissue and can lead to thrombocytopenia and anemia, weakness, fatigue and an enlarged spleen and liver. Within the United States, there are approximately 21,000 patients with myelofibrosis, 7,000 of which have severe thrombocytopenia (defined as blood platelet counts of less than 50 $x10^9$/L). Severe thrombocytopenia is associated with poor survival and high symptom burden and can occur as a result of disease progression or from drug toxicity with other JAK2 inhibitors, such as JAKAFI and INREBIC.

About CTI BioPharma Corp.
We are a commercial 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. CTI has one FDA-approved product, VONJO® (pacritinib), a JAK2 and IRAK1 inhibitor, that spares JAK1. VONJO is approved for the treatment of adults with intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 10^9/L. This

indication is approved under FDA accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). CTI is conducting the Phase 3 PACIFICA study of VONJO in patients with myelofibrosis and severe thrombocytopenia as a post-marketing requirement.

VONJO® is a registered trademark of CTI BioPharma Corp.

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 commercialize VONJO and generate future revenues with respect to VONJO; our limited experience in generating revenue from product sales; 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, 2021 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.

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(tables follow)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net product sales	$ 12,329	$ —	$ 14,624	$ —
Operating costs and expenses:				
Cost of sales	917	—	1,195	—
Research and development	8,705	9,293	16,753	18,737
Selling, general and administrative	21,590	10,213	39,636	17,839
Other operating expenses	—	—	11,023	—
Total operating costs and expenses	31,212	19,506	68,607	36,576
Loss from operations	(18,883)	(19,506)	(53,983)	(36,576)
Non-operating expenses:				
Interest expense, net	(3,761)	(167)	(5,824)	(354)
Foreign exchange loss	(10)	(2)	(22)	(11)
Total non-operating expenses	(3,771)	(169)	(5,846)	(365)
Net loss	$ (22,654)	$ (19,675)	$ (59,829)	$ (36,941)
Basic and diluted net loss per common share	$ (0.21)	$ (0.21)	$ (0.57)	$ (0.44)
Shares used in calculation of basic and diluted net loss per common share:	108,529	92,341	104,205	84,398

Balance Sheet Data (unaudited):	(amounts in thousands)	
	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 66,091	$ 65,446
Short-term investments	29,779	—
Accounts receivable, net	8,159	—
Working capital	77,583	1,728
Total assets	134,534	72,434
Current portion of long-term debt	—	47,380
Total stockholders' (deficit) equity	(5,274)	3,767