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): March 6, 2023

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 March 6, 2023, CTI BioPharma Corp. issued a press release announcing its financial results for the quarter and year ended December 31, 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 March 6, 2023	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: March 6, 2023

By: /s/ David H. Kirske

David H. Kirske
Chief Financial Officer

Exhibit 99.1

CTI BioPharma Reports Fourth Quarter and Full Year 2022 Financial Results

– Growing physician awareness and usage of VONJO® (pacritinib) drove quarterly double-digit revenue growth –

– VONJO® net product revenue exceeded year-end goal with a total of $54 million for 2022 and $21.1 million in the fourth quarter, a 16% increase compared to the third quarter –

– ASH 2022 oral presentation featured new data on pacritinib's ACVR1 inhibition and anemia benefit in myelofibrosis patients –

– Management to host webcast and conference call at updated time today at 8:30 a.m. ET –

SEATTLE, Wash., March 6, 2023 - CTI BioPharma Corp. (Nasdaq: CTIC), a commercial biopharmaceutical company focused on the development and commercialization of novel targeted therapies for blood-related cancers, today reported its financial results for the fourth quarter and full year ended December 31, 2022.

"CTI is now established as a market leader in the treatment of cytopenic myelofibrosis following the accelerated approval and U.S. commercial launch of VONJO® (pacritinib) over the past year," said Adam Craig, M.D., Ph.D., M.B.A., President, Chief Executive Officer and Interim Chief Medical Officer. "With the launch of VONJO in March 2022, we exceeded our year-end revenue goal by achieving $54 million in net sales in 2022 with strong quarter-over-quarter growth."

"As of year-end 2022, more than 1,000 patients were treated with VONJO, which is a significant milestone for this rare disease. Importantly, we have also achieved over 90% insurance coverage with both Medicare and Commercial plans. To further increase the market penetration of VONJO, our commercial team continues to reinforce the VONJO clinical value proposition for cytopenic myelofibrosis patients leveraging peer-to-peer interactions and education. New data presented at the 64th American Society of Hematology (ASH) Annual Meeting suggests the potential to strengthen the clinical differentiation for pacritinib through its potent Activin A receptor type 1 (ACVR1) inhibitor and anemia benefit. We look forward to continuing activities focused on market expansion in 2023, which are intended to drive quarter-over-quarter net sales increases," concluded, Dr. Craig.

2022 Key Accomplishments and Recent Highlights

- FDA approval of VONJO (pacritinib) 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.
- $54 million in net sales in the first nine months following VONJO launch.
- Over 1,000 patients commercially treated with VONJO in 2022.

- Inclusion in the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for Myeloproliferative Neoplasms, with a recommendation for VONJO as a: First-line treatment option for higher-risk myelofibrosis patients with platelet counts <50 x 10^9/L who are not candidates for transplant; Second-line treatment option for: patients with higher-risk myelofibrosis who are not candidates for transplant with platelet counts ≥50 x 10^9/L with no response or loss of response to one prior JAK inhibitor and for patients with symptomatic lower-risk myelofibrosis with platelet counts <50 x 10^9/L with no response or loss of response to initial treatment.
- Oral presentation at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition highlighted pacritinib as a potent activin A receptor type 1 (ACVR1) inhibitor with significant anemia benefit in patients with myelofibrosis.
- On February 7, 2023, VONJO was granted seven years of orphan-drug exclusive approval by the FDA for 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 x10^9/L. The seven-year exclusive approval began on February 28, 2022.

Fourth Quarter and Full Year 2022 Financial Results

- **Net Product Sales:** Net product sales of $21.1 million and $53.9 million for the three months and year ended December 31, 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:** Operating loss was $13.6 million and $35.4 million for the three months ended December 31, 2022 and 2021, respectively, and $79.8 million and $95.3 million for the years ended December 31, 2022 and 2021, respectively. The decrease in operating loss between the three-month periods ended December 31, 2022 and 2021 was primarily attributable to VONJO product sales. The decrease in operating loss between the years ended December 31, 2022 and 2021 resulted primarily from VONJO product sales, partially offset by 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:** Net loss for the three months ended December 31, 2022 was $17.5 million, or $0.14 for basic and diluted loss per share, compared to net loss of $36.8 million, or $0.38 for basic and diluted loss per share, for the same period in 2021. Net loss for the year ended December 31, 2022 was $93.0 million, or $0.81 for basic and diluted loss per share, compared to net loss of $97.9 million, or $1.09 for basic and diluted loss per share, for the same period in 2021.
- **Cash Position:** As of December 31, 2022, cash, cash equivalents and short-term investments totaled $79.9 million, compared to $65.4 million as of December 31, 2021. Subsequent to the end of the quarter, the Company received $6.5 million in additional contractual funding from DRI Healthcare Trust in January 2023.

Conference Call and Webcast

CTI will host a webcast and conference call at 8:30 a.m. ET today to review its fourth quarter and full year 2022 financial results and provide a corporate update. The live and archived webcast may be accessed on the CTI BioPharma website under the Investors & Media section: Events and Presentations. To participate via telephone, please register in advance using the link provided in the event listing. The Company suggests participants log in 15 minutes in advance of the event.

About VONJO® (pacritinib) capsules

VONJO® (pacritinib) is an oral kinase inhibitor with activity against wild type Janus Associated Kinase 2 (JAK2), mutant $JAK2^{V617F}$ form, IRAK1, ACVR1 (ALK2) and 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. At clinically relevant concentrations, pacritinib does not inhibit JAK1.

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). CTI is conducting the Phase 3 PACIFICA study of VONJO in patients with myelofibrosis and severe thrombocytopenia as a post-marketing requirement.

Important VONJO Safety Information

- Hemorrhage: Serious (11%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts <100 × 10^9/L. Serious (13%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts <50 × 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 × 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 click here 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.

About CTI BioPharma Corp.

CTI BioPharma is a commercial biopharmaceutical company focused on the 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, ACVR1, 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 x10^9/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. For more information, please visit www.ctibiopharma.com.

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, including marketing plans to drive adoption of VONJO and sales growth, 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; 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, 2022 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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SOURCE: CTI BioPharma Corp.

(tables follow)

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Net product sales	$ 21,083	$ —	$ 53,948	$ —
Operating costs and expenses:				
Cost of sales	1,167	—	3,514	—
Research and development	11,922	10,682	36,895	39,136
Selling, general and administrative	23,692	24,693	84,826	56,196
Other operating (income) expenses	(2,102)	—	8,510	—
Total operating costs and expenses	34,679	35,375	133,745	95,332
Loss from operations	(13,596)	(35,375)	(79,797)	(95,332)
Non-operating expenses:				
Interest expense, net	(3,751)	(1,408)	(13,139)	(2,415)
Other non-operating expenses	(111)	(5)	(56)	(161)
Total non-operating expenses	(3,862)	(1,413)	(13,195)	(2,576)
Net loss	$ (17,458)	$ (36,788)	$ (92,992)	$ (97,908)
Basic and diluted net loss per common share	$ (0.14)	$ (0.38)	$ (0.81)	$ (1.09)
Shares used in calculation of basic and diluted net loss per common share:	128,426	97,663	114,694	90,117

Balance Sheet Data (unaudited):	(amounts in thousands)	
	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 30,420	$ 65,446
Short-term investments	49,519	—
Accounts receivable, net	15,387	—
Working capital	18,262	1,728
Total assets	125,925	72,434
Current portion of long-term debt	47,943	47,380
Total stockholders' (deficit) equity	(17,577)	3,767