

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q**

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: June 30, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 000-28386

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

91-1533912
(I.R.S. Employer
Identification No.)

3101 Western Avenue
Suite 800
Seattle
Washington
(Address of principal executive offices)

98121
(Zip Code)

(206) 282-7100
(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	CTIC	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

<u>Class</u>	<u>Outstanding at July 29, 2021</u>
Common Stock, par value \$0.001 per share	93,309,923

CTI BIOPHARMA CORP.
TABLE OF CONTENTS

	<u>PAGE</u>
<u>PART I - FINANCIAL INFORMATION</u>	
<u>ITEM 1: Financial Statements (unaudited)</u>	<u>4</u>
<u>Condensed Consolidated Balance Sheets</u>	<u>4</u>
<u>Condensed Consolidated Statements of Operations</u>	<u>5</u>
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	<u>6</u>
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity</u>	<u>7</u>
<u>Condensed Consolidated Statements of Cash Flows</u>	<u>8</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>9</u>
<u>ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>15</u>
<u>ITEM 3: Quantitative and Qualitative Disclosures about Market Risk</u>	<u>22</u>
<u>ITEM 4: Controls and Procedures</u>	<u>22</u>
<u>PART II - OTHER INFORMATION</u>	
<u>ITEM 1: Legal Proceedings</u>	<u>24</u>
<u>ITEM 1A: Risk Factors</u>	<u>24</u>
<u>ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>24</u>
<u>ITEM 3: Defaults upon Senior Securities</u>	<u>24</u>
<u>ITEM 4: Mine Safety Disclosures</u>	<u>24</u>
<u>ITEM 5: Other Information</u>	<u>24</u>
<u>ITEM 6: Exhibits</u>	<u>25</u>
<u>Signatures</u>	<u>26</u>

PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

CTI BIOPHARMA CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)
(unaudited)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 71,881	\$ 40,394
Short-term investments	—	12,057
Prepaid expenses and other current assets	2,938	1,874
Total current assets	74,819	54,325
Property and equipment, net	439	719
Other assets	2,237	3,197
Total assets	\$ 77,495	\$ 58,241
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,295	\$ 1,637
Accrued expenses	8,569	7,191
Current portion of long-term debt	2,049	4,455
Other current liabilities	3,876	3,755
Total current liabilities	15,789	17,038
Long-term liabilities	—	1,174
Total liabilities	15,789	18,212
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share:		
Authorized shares - 33,333 as of June 30, 2021 and December 31, 2020		
Series O Preferred Stock, 12,575 shares issued and outstanding as of June 30, 2021 and December 31, 2020 (Aggregate liquidation preference of \$25,150 as of June 30, 2021 and December 31, 2020)	—	—
Series X Preferred Stock, 4,429 shares issued and outstanding as of June 30, 2021 and December 31, 2020 (Aggregate liquidation preference of \$44,290 as of June 30, 2021 and December 31, 2020)	—	—
Series X ¹ Preferred Stock, 600 shares and 0 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively (Aggregate liquidation preference of \$15,000 and \$0 as of June 30, 2021 and December 31, 2020, respectively)	—	—
Common stock, \$0.001 par value per share:		
Authorized shares - 266,500,000 and 166,500,000 as of June 30, 2021 and December 31, 2020, respectively		
Issued and outstanding shares - 93,309,923 and 75,896,884 as of June 30, 2021 and December 31, 2020, respectively	93	76
Additional paid-in capital	2,426,561	2,367,958
Accumulated other comprehensive income	—	2
Accumulated deficit	(2,364,948)	(2,328,007)
Total stockholders' equity	61,706	40,029
Total liabilities and stockholders' equity	\$ 77,495	\$ 58,241

See accompanying notes.

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	<u>19,506</u>	<u>9,996</u>	<u>36,576</u>	<u>21,927</u>
Loss from operations	<u>(19,506)</u>	<u>(9,996)</u>	<u>(36,576)</u>	<u>(21,927)</u>
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	<u>(169)</u>	<u>(4,004)</u>	<u>(365)</u>	<u>(4,259)</u>
Net loss	<u>\$ (19,675)</u>	<u>\$ (14,000)</u>	<u>\$ (36,941)</u>	<u>\$ (26,186)</u>
Basic and diluted net loss per common share	<u>\$ (0.21)</u>	<u>\$ (0.19)</u>	<u>\$ (0.44)</u>	<u>\$ (0.38)</u>
Shares used in calculation of basic and diluted net loss per common share	<u>92,341</u>	<u>73,685</u>	<u>84,398</u>	<u>68,073</u>

See accompanying notes.

CTI BIOPHARMA CORP.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	\$ (19,675)	\$ (14,000)	\$ (36,941)	\$ (26,186)
Other comprehensive income (loss):				
Change in unrealized gain (loss) on available-for-sale securities	1	—	(2)	—
Other comprehensive income (loss)	1	—	(2)	—
Comprehensive loss	<u>\$ (19,674)</u>	<u>\$ (14,000)</u>	<u>\$ (36,943)</u>	<u>\$ (26,186)</u>

See accompanying notes.

CTI BIOPHARMA CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands)
(unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at January 1, 2021	17	\$ —	75,897	\$ 76	\$ 2,367,958	\$ 2	\$ (2,328,007)	\$ —	\$ 40,029
Issuance of common stock, net of issuance costs	—	—	858	1	2,961	—	—	—	2,962
Equity-based compensation	—	—	—	—	932	—	—	—	932
Cancellation of restricted stock	—	—	(4)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(17,266)	—	(17,266)
Other comprehensive loss	—	—	—	—	—	(3)	—	—	(3)
Balance at March 31, 2021	17	\$ —	76,751	\$ 77	\$ 2,371,851	\$ (1)	\$ (2,345,273)	\$ —	\$ 26,654
Issuance of common stock and Series X ¹ preferred stock, net of issuance costs	1	—	16,400	16	53,537	—	—	—	53,553
Equity-based compensation	—	—	—	—	988	—	—	—	988
Exercise of stock options and shares issued under employee stock purchase plan	—	—	159	—	185	—	—	—	185
Net loss	—	—	—	—	—	—	(19,675)	—	(19,675)
Other comprehensive income	—	—	—	—	—	1	—	—	1
Balance at June 30, 2021	18	\$ —	93,310	\$ 93	\$ 2,426,561	\$ —	\$ (2,364,948)	\$ —	\$ 61,706

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at January 1, 2020	13	\$ —	57,980	\$ 58	\$ 2,299,186	\$ —	\$ (2,275,556)	\$ (5,758)	\$ 17,930
Issuance of common stock, net of issuance costs	—	—	15,699	16	15,454	—	—	—	15,470
Conversion of Series X preferred stock to common stock	—	—	3	—	3	—	—	—	3
Equity-based compensation	—	—	—	—	1,167	—	—	—	1,167
Net loss	—	—	—	—	—	—	(12,186)	—	(12,186)
Balance at March 31, 2020	13	\$ —	73,682	\$ 74	\$ 2,315,810	\$ —	\$ (2,287,742)	\$ (5,758)	\$ 22,384
Reclassification of Series X preferred stock from mezzanine equity	4	—	—	—	43,637	—	—	—	43,637
Equity-based compensation	—	—	—	—	1,002	—	—	—	1,002
Dissolution of majority-owned subsidiary	—	—	—	—	(1,949)	—	—	5,758	3,809
Exercise of stock options and shares issued under employee stock purchase plan	—	—	35	—	31	—	—	—	31
Net loss	—	—	—	—	—	—	(14,000)	—	(14,000)
Balance at June 30, 2020	17	\$ —	73,717	\$ 74	\$ 2,358,531	\$ —	\$ (2,301,742)	\$ —	\$ 56,863

See accompanying notes.

CTI BIOPHARMA CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Six Months Ended June 30,	
	2021	2020
Operating activities		
Net loss	\$ (36,941)	\$ (26,186)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on dissolution of majority-owned subsidiary	—	3,774
Equity-based compensation	1,920	2,169
Depreciation and amortization	263	266
Provision for Italian VAT receivables and deposit	—	4,200
Other	(76)	(86)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	494	1,620
Accounts payable, accrued expenses and other liabilities	(30)	(5,766)
Net cash used in operating activities	(34,370)	(20,009)
Investing activities		
Proceeds from maturities of short-term investments	12,000	2,500
Net cash provided by investing activities	12,000	2,500
Financing activities		
Proceeds from the public offering of common stock and Series X ¹ preferred stock, net of issuance costs	53,567	—
Proceeds from at-the-market equity offering, net of issuance costs	2,754	—
Proceeds from rights offering, net of issuance costs	—	59,108
Principal payments on debt	(2,667)	(2,667)
Proceeds from stock option exercises	144	30
Proceeds from sales of common stock under employee stock purchase plan	59	4
Net cash provided by financing activities	53,857	56,475
Net increase in cash and cash equivalents	31,487	38,966
Cash and cash equivalents at beginning of period	40,394	31,144
Cash and cash equivalents at end of period	\$ 71,881	\$ 70,110
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	\$ 129	\$ 325

See accompanying notes.

CTI BIOPHARMA CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Description of Business and Summary of Significant Accounting Policies

CTI BioPharma Corp., together with its subsidiary, also referred to collectively in this Quarterly Report on Form 10-Q as “we,” “us,” “our,” the “Company” and “CTI,” is 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. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. 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 sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis. In addition, in response to the COVID-19 pandemic, we started developing pacritinib for use in hospitalized patients with severe COVID-19.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products requires approval from, and is subject to, ongoing oversight by the Food and Drug Administration, or the FDA, in the United States, the European Medicines Agency, or the EMA, in the European Union, or the EU, and comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, may take many years and may involve the expenditure of substantial resources.

Basis of Presentation

The accompanying unaudited financial information as of and for the three and six months ended June 30, 2021 and 2020 has been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to the Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial position at such dates and the operating results and cash flows for such periods. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the entire year or for any other subsequent interim period.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or the SEC. These unaudited financial statements and related notes should be read in conjunction with our audited financial statements for the year ended December 31, 2020 included in our Annual Report on Form 10-K filed with the SEC on March 17, 2021.

The condensed consolidated balance sheet at December 31, 2020 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the U.S. for complete financial statements.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of CTI and its majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus, until its dissolution in June 2020. We had an approximately 60% interest in Aequus, and the remaining interest in Aequus not held by CTI was reported as *noncontrolling interest* in the condensed consolidated financial statements until its dissolution. All intercompany transactions and balances were eliminated in consolidation through the June 2020 Aequus dissolution. The accompanying condensed consolidated financial statements do not include the accounts of subsidiaries since July 2020.

Use of Estimates

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles, or GAAP, requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures of loss contingencies in the condensed consolidated financial statements and accompanying notes. Estimates are used for, but not limited to, clinical accruals, income taxes, useful lives of equipment, commitments and contingencies, equity-based compensation forfeiture rates, collectability of receivables and impairment of investments. Given the global economic climate and additional or unforeseen effects from the ongoing COVID-19 pandemic, these estimates are becoming more challenging, and actual results could differ materially from those estimates.

Liquidity

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business within one year after the date the condensed consolidated financial statements are issued. Our management evaluates whether there are conditions or events, considered in aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

Over the next year and in the normal course of business, we will need to continue to conduct research, development, testing and regulatory compliance activities with respect to pacritinib and prepare for potential commercialization, and in the course of such activities, we will incur general and administrative expenses. Additional business activities will include procuring manufacturing and drug supply services, the costs of which, together with our projected general and administrative expenses, are expected to result in operating losses for the foreseeable future. We have incurred a net operating loss every year since our formation. As of June 30, 2021, we had an accumulated deficit of \$2.4 billion, and we expect to continue to incur net losses for the foreseeable future. Our available cash and cash equivalents were \$71.9 million as of June 30, 2021. We expect that our present financial resources will be sufficient to meet our obligations as they come due and to fund our operations into the fourth quarter of 2021. Based on our evaluation completed pursuant to Accounting Standards Update No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, these factors raise substantial doubt about our ability to continue as a going concern.

Accordingly, we will need to acquire additional funds in order to develop our business and continue the development and prepare for the potential commercialization of pacritinib. The amount of funds that we will ultimately require will depend, in part, upon: regulatory approval developments and the extent, if any, to which we are required to conduct additional clinical trials; competitive market developments which require us to alter our business practices; and other unplanned expenses or business developments. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding obtained through the sale of such shares of common stock or otherwise may not be sufficient, available on favorable terms or available at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If we fail to obtain additional capital when needed, our ability to operate as a going concern will be harmed, and we may be required to delay, scale back or eliminate some or all of our research and development programs and the commercial capabilities that we are developing to support a potential drug approval, be required to reduce our general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations at affordable rates with competitive terms, have to refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. The amount of financing we require is dependent upon many factors relating to drug approval status and our commercialization plans, as well as our clinical trials. These factors include the number of clinical trial sites in a given clinical trial, the number of patients treated in a given clinical trial, the pace of patient enrollment and other matters that may impact clinical development, including changes to a clinical trial that we may initiate or that may be requested by the FDA or other regulators. There can be no assurance as to the amount of funding necessary to fund the development of pacritinib to completion or that we will be able to obtain this funding. In addition, our ability to comply with covenants under our loan and security agreement with Silicon Valley Bank, or SVB, may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants, including a material adverse change in our business, operations or condition (financial or otherwise), could result in an event of default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable. The accompanying condensed consolidated financial statements do not include adjustments, if any, that may result from the outcome of this uncertainty.

Cash, Cash Equivalents and Short-term Investments

As of June 30, 2021, our cash and cash equivalents consisted of cash and money market funds. As of December 31, 2020, our cash, cash equivalents and short-term investments consisted of cash, money market funds and corporate debt securities. Cash equivalents and short-term investments are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. There are three levels of inputs used to measure fair value, with Level 1 having the highest priority and Level 3 having the lowest:

- Level 1—Valuations based on unadjusted quoted prices for identical assets and liabilities in active markets.

- Level 2—Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Valuations based on unobservable inputs that are supported by little or no market activity, reflecting our own assumptions. These valuations require significant judgment or estimation.

We measure the fair value of money market funds based on the closing price reported by the fund sponsor from an actively traded exchange. We value all other securities using broker quotes that utilize observable market inputs. We did not hold cash, cash equivalents and short-term investments categorized as Level 3 assets as of June 30, 2021 and December 31, 2020. The following table summarizes, by major security type, our cash, cash equivalents and short-term investments that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	June 30, 2021			December 31, 2020
	Cost or Amortized Cost	Gross Unrealized Gains / Losses	Total Estimated Fair Value	Total Estimated Fair Value
Cash	\$ 142	\$ —	\$ 142	\$ —
Level 1 securities:				
Money market funds	71,739	—	71,739	40,000
Level 2 securities:				
Corporate debt securities	—	—	—	12,000
Total cash, cash equivalents and short-term investments	\$ 71,881	\$ —	\$ 71,881	\$ 52,000

Equity-based compensation

Equity-based compensation expense is recognized over the requisite service periods on awards ultimately expected to vest. We apply estimated forfeiture rates at the time of grant and make revisions, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For performance-based stock options and restricted stock, we record compensation expense over the estimated service period once the achievement of the performance-based milestone is considered probable. We recorded equity-based compensation expense of \$1.0 million for each of the three months ended June 30, 2021 and 2020, and \$1.9 million and \$2.2 million for the six months ended June 30, 2021 and 2020, respectively. All equity-based compensation expense was related to option awards, and substantially all of the expense was included in *General and administrative* expenses for the periods presented.

Net Loss per Share

Basic net loss per common share is calculated based on the net loss attributable to common stockholders divided by the weighted average number of shares outstanding for the period. The calculation of diluted net loss per common share excludes the potential conversion of all dilutive convertible securities, such as convertible preferred stock, using the if-converted method, and the potential exercise or vesting of other dilutive securities, such as stock awards and warrants, using the treasury stock method, as their inclusion would have an anti-dilutive effect.

Common shares underlying stock awards, warrants and convertible preferred stock aggregating 76.2 million shares and 59.7 million shares for the three months ended June 30, 2021 and 2020, respectively, and 72.6 million shares and 45.0 million shares for the six months ended June 30, 2021 and 2020, respectively, were excluded from the calculation of diluted net loss per share because they were anti-dilutive.

Recently Adopted Accounting Standards

In August 2020, the FASB issued new accounting guidance for convertible instruments which eliminates two of the three models in ASC 470-20 that require separate accounting for embedded conversion features. Separate accounting is still required in certain cases. For smaller reporting companies, the guidance is effective for fiscal years beginning after December 15, 2023, including interim periods therein. Early adoption is permitted in fiscal years beginning after December 15, 2020. We early adopted this guidance as of January 1, 2021. In April 2021, as discussed in “Note 4. Equity Transactions”, we completed the public offering of our common stock and our Series X¹ Preferred Stock. No beneficial conversion feature was recognized on Series X¹ Preferred Stock upon issuance as a result of adopting this guidance.

Recently Issued Accounting Standards

In October 2020, the FASB issued new accounting guidance to provide incremental improvements to its Accounting Standards Codification on various topics. Such improvements include conforming amendments, clarifications to guidance, simplifications to wording or structure of guidance and other minor changes. For smaller reporting companies, the guidance is effective for fiscal years beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted for any annual or interim period for which financial statements have not been issued. The codification amendments do not change GAAP, therefore we do not expect the adoption of this accounting guidance to have a material impact on our condensed consolidated financial statements.

Although there were several other new accounting pronouncements issued or proposed by the FASB, we do not believe any of these have had or will have a material impact on our condensed consolidated financial statements.

2. Other Assets

Other assets consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Right-of-use assets	\$ 1,467	\$ 2,149
Clinical trial deposits	770	770
Other	—	278
Total other assets	<u>\$ 2,237</u>	<u>\$ 3,197</u>

3. Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Operating lease liabilities, current portion	\$ 1,941	\$ 2,194
End-of-facility lender fee (1)	1,440	1,440
Other current obligations	495	121
Total other current liabilities	<u>\$ 3,876</u>	<u>\$ 3,755</u>

(1) End-of-facility lender fee represents an amount payable to Silicon Valley Bank upon repayment of our secured term loan due in November 2021. See Part II, Item 8, “Notes to Consolidated Financial Statements, Note 7. Long-term Debt” of our Annual Report on Form 10-K for the year ended December 31, 2020 for additional information.

4. Equity Transactions

At-The-Market Equity Offering

In January 2021, we entered into an Open Market Sale AgreementSM with Jefferies LLC, or the Sale Agreement, to sell shares of our common stock having aggregate sales proceeds of up to \$50.0 million, from time to time, through an “at the market” equity offering program under which Jefferies will act as sales agent.

Under the Sale Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sale Agreement, Jefferies may sell the shares by methods deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or on any other existing trading market for the common stock. Jefferies will use commercially reasonable efforts in conducting such sales activities consistent with its normal trading and sales practices, applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market LLC.

We and Jefferies may each terminate the Sale Agreement at any time upon ten trading days' prior notice. We may also sell shares to Jefferies acting as principal for Jefferies' own account. The compensation to Jefferies for sales of our common stock will be an amount equal to 3% of the gross proceeds of any shares of our common stock sold under the Sale Agreement. We have no obligation to sell any shares under the Sale Agreement, and may at any time suspend solicitation and offers under the Sale Agreement.

For the six months ended June 30, 2021, we sold 0.9 million shares of our common stock for net proceeds of approximately \$2.8 million under the Sale Agreement.

Public Offering of Common Stock and Series X¹ Preferred Stock

In April 2021, we completed the public offering of our common stock and our Series X¹ Preferred Stock, or the Offering, whereby we issued 14,260,800 shares of our common stock, par value \$0.001 per share, at a public offering price of \$2.50 per share, and 600 shares of our Series X¹ Preferred Stock, par value \$0.001 per share, at a public offering price of \$25,000 per share. In addition, we granted the underwriters a 30-day option to purchase up to additional 2,139,120 shares of our common stock on the same terms and conditions, which was exercised in full in April 2021. The net proceeds to us from the Offering, after deducting underwriting discounts and offering expenses, were approximately \$53.6 million. No beneficial conversion feature was recognized upon issuance of our Series X¹ Preferred Stock due to the adoption of ASU 2020-06 in the first quarter of 2021.

At the time of issuance of our Series X¹ Preferred Stock, the carrying amount of our Series X¹ Preferred Stock was initially classified as mezzanine equity in the condensed consolidated balance sheet since we did not have an adequate number of shares of authorized common stock to satisfy the number of required shares under the conversion option of our Series X¹ Preferred Stock. In June 2021, our stockholders approved an increase in the number of shares of authorized common stock, and as such, we can now control settlement of the conversion option's exercise by delivering shares. Accordingly, the carrying amount of our Series X¹ Preferred Stock was reclassified to permanent equity as of June 2021.

BVF Partners L.P., or BVF, an existing stockholder of the Company, was one of the investors in the Offering. In connection with the Offering, BVF purchased 2.0 million shares of our common stock and 600 shares of our Series X¹ Preferred Stock. As of June 30, 2021, BVF beneficially owned approximately 9.6% of our outstanding common stock. Matthew D. Perry, a member of our Board, is the President of BVF and portfolio manager for the underlying funds managed by the firm. No shares of our Series X¹ Preferred Stock were converted into our common stock during the three and six months ended June 30, 2021. There were 600 shares of our Series X¹ Preferred Stock outstanding as of June 30, 2021.

Each share of Series X¹ Preferred Stock is convertible into 10,000 shares of our common stock at a conversion price of \$2.50 per share of common stock, at the option of the holder at any time, subject to certain limitations, including that a holder of Series X¹ Preferred Stock is prohibited from converting Series X¹ Preferred Stock into common stock if, as a result of such conversion, such holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock issued and outstanding immediately after giving effect to such conversion.

Shares of Series X¹ Preferred Stock generally have no voting rights, except as otherwise expressly provided in the Certificate of Designation of Preferences, Rights and Limitations of Series X¹ Convertible Preferred Stock, or Certificate of Designation, or as otherwise required by law. However, as long as any shares of Series X¹ Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of Series X¹ Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X¹ Preferred Stock or alter or amend this Certificate of Designation, amend or repeal any provision of, or add any provision to, the Certificate of Incorporation or bylaws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X¹ Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to the Certificate of Incorporation or by merger, consolidation or otherwise, (ii) issue further shares of Series X¹ Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X¹ Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

In the event of our liquidation, dissolution or winding up, holders of Series X¹ Preferred Stock will participate pari passu with any distribution of proceeds to holders of our common stock. Holders of Series X¹ Preferred Stock are entitled to receive dividends on shares of Series X¹ Preferred Stock equal (on an as-converted to common stock basis, without regard to the Beneficial Ownership Limitation (as defined in the Certificate of Designation)) to and in the same form as dividends actually paid on shares of common stock, plus an additional amount equal to any dividends declared but unpaid on such shares, before any payments shall be made or any assets distributed to holders of any class of Junior Securities (as defined in the Certificate of Designation).

5. Contingencies

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI - Sede Secondaria, or CTI (Europe), based on the ITA's audit of CTI (Europe)'s value added tax, or VAT, returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2006 and 2007 are €0.6 million, €2.8 million and €0.9 million, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have appealed all of the assessments and are defending ourselves against the assessments both on procedural grounds and on the merits of the cases, although we can make no assurances regarding the ultimate outcome of these cases. There have been no changes to the status of the legal proceedings surrounding each respective VAT year return at issue since the filing of our Annual Report on Form 10-K for the year ended December 31, 2020. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 14. Commitments and Contingencies" of our Annual Report on Form 10-K for the year ended December 31, 2020 for additional information.

If the final decision of the Italian Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to €4.3 million, or approximately \$5.2 million converted using the currency exchange rate as of June 30, 2021, including interest and penalties for the period lapsed between the date in which the assessments were issued and the date of effective payment. We have not recorded this contingent liability in the financial statements as we do not believe the potential payment to the ITA is probable at this time.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical fact in this Quarterly Report are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as "anticipates," "assume," "believes," "continue," "could," "estimates," "expects," "forecast," "goal," "intends," "may," "plans," "potential," "predicts," "projects," "should," "target" or "will" or the negative thereof, variations thereof and similar expressions. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding sufficiency of cash resources, cash expenditures, sources of cash flows and other projections, product manufacturing and sales, research and development expenses, general and administrative expenses and additional losses;
 - our ability to obtain funding for our operations;
 - the timing of, and our ability to develop, commercialize, and obtain regulatory approval of pacritinib, including potential accelerated approval of pacritinib as a treatment for myelofibrosis patients with severe thrombocytopenia, and other development programs we may pursue in the future;
 - the design of our clinical trials and anticipated enrollment, and the progress and potential of pacritinib and other development programs we may pursue in the future;
 - the safety, effectiveness and potential benefits and indications of pacritinib and any other product candidates we may develop in the future;
 - the timing of and results from clinical trials and pre-clinical development activities, including those related to pacritinib and any other product candidates we may develop in the future;
 - our ability to advance product candidates, including pacritinib and any other product candidates we may develop in the future, into, and the successful completion of, clinical trials;
 - our ability to achieve profitability, including our ability to effectively implement cost reduction strategies and realize anticipated cost savings from those efforts;
 - our expectations regarding federal, state and foreign regulatory requirements;
 - the rate and degree of market acceptance and clinical utility of pacritinib or any other product candidates we may develop in the future;
 - our and our collaborators' ability to obtain and maintain regulatory approvals for pacritinib or any other product candidates we may develop in the future, and the timing of such approvals;
 - our ability to maintain and establish collaborations;
 - our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
 - our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
 - the impact of government laws and regulations;
 - our ability to negotiate, integrate, and implement collaborations, acquisitions and other strategic transactions;
 - our ability to engage and retain the employees required to advance our development activities and grow our business;
 - developments relating to our competitors and our industry, including the success of competing therapies that are or become available;
 - our expectations regarding business disruptions and related risks resulting from the ongoing worldwide coronavirus pandemic known as COVID-19;
- and

- other risks and uncertainties, including those listed under the heading Risk Factors and in other filings we periodically make with the U.S. Securities and Exchange Commission, or the SEC.

Such statements are based on management’s current expectations and are subject to risks and uncertainties, which may cause actual results to differ materially from those set forth in the forward-looking statements. There can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. We urge you to carefully review the disclosures we make concerning risks and other factors that may affect our business and operating results and cause them to differ materially from our current expectations, including those discussed below and elsewhere in this Quarterly Report on Form 10-Q and those made under Part I, Item 1, “Business,” Part I, Item 1A, “Risk Factors,” Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and elsewhere in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and any risk factors contained in our subsequent Quarterly Reports on Form 10-Q that we file with the SEC.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

We do not intend to update any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q.

In this Quarterly Report on Form 10-Q, all references to “we,” “us,” “our,” the “Company” and “CTI” mean CTI BioPharma Corp. and our subsidiaries, except where it is otherwise made clear.

OVERVIEW

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. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. 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 sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis. In addition, in response to the COVID-19 pandemic, we started developing pacritinib for use in hospitalized patients with severe COVID-19.

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, IRAK1 and CSF1R. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development, as well as inflammatory cytokine expression and immune responses. Mutations in these kinases have been shown to be directly related to the development of a variety of blood-related cancers, including myeloproliferative neoplasms, leukemia and lymphoma. In addition to myelofibrosis, the kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as acute myeloid leukemia, or AML, myelodysplastic syndrome, or MDS, chronic myelomonocytic leukemia, or CMML, prevention of graft versus host disease, or GvHD, and chronic lymphocytic leukemia, or CLL, due to its inhibition of JAK2, IRAK1 and CSF1R. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

In September 2020, we reached an agreement with the U.S. Food and Drug Administration, or FDA, to submit a New Drug Application, or NDA, for the potential accelerated approval of pacritinib as a treatment for myelofibrosis patients with severe thrombocytopenia, and in March 2021 we completed our rolling NDA submission. The NDA is based on the available data from our completed Phase 3 PERSIST-1 and PERSIST-2 trials and the Phase 2 PAC203 dose-ranging trial. As agreed with the FDA, the PACIFICA Phase 3 trial will be completed as a post-approval commitment. In May 2021, the FDA accepted our NDA and granted pacritinib Priority Review, with the Prescription Drug User Fee Act target action date set for November 30, 2021. The FDA is not currently planning to hold an advisory committee meeting to discuss the NDA.

PACIFICA Phase 3 Trial

In January 2020, we received the FDA's preliminary comments from a Type A meeting request and reached an agreement on the final design changes to our PACIFICA pivotal Phase 3 clinical trial, including changes to the statistical analysis plan that would allow for an accelerated approval pathway for pacritinib. We have amended our PACIFICA Phase 3 trial protocol, to allow for the primary analysis of Spleen Volume Reduction, or SVR, rate on the first 168 patients, with an end-of-study analysis of Total Symptom Score, or TSS, and Overall Survival, or OS, following the full enrollment of 348 patients. Enrollment in this trial has recently improved due to the abatement of the COVID-19 pandemic, and we now expect to report top-line data in 2022.

PRE-VENT Phase 3 Trial

In April 2020, in response to the public health crisis due to the global COVID-19 pandemic, we initiated PRE-VENT, a Phase 3 trial evaluating pacritinib in hospitalized patients with severe COVID-19. PRE-VENT, a randomized, double-blind, placebo-controlled multicenter study will compare pacritinib plus Standard of Care, or SOC, versus placebo plus SOC in hospitalized patients with severe COVID-19, including those with a current or prior diagnosis of cancer. The primary endpoint of the trial will assess the proportion of patients who progress to invasive mechanical ventilation and/or extracorporeal membrane oxygenation or die by Day 28. We commenced enrollment of PRE-VENT in the second quarter of 2020 in the United States and currently anticipate the reporting of interim analysis from the PRE-VENT trial in the third quarter of 2021.

Patients enrolled in PRE-VENT will be randomized 1:1 to receive pacritinib (400 mg once on Day 1, then 200 mg twice daily from Day 2 to Day 14) plus SOC or placebo plus SOC. Assigned treatment will continue for up to Day 14 or until the patient experiences intolerable adverse events, withdraws consent, initiates another investigational therapy or until the study is terminated. Assigned therapy may be given for an additional 7 days (for a total of 21 days) at the discretion of the investigator and with medical monitor approval. In the event of hospital discharge, patients will complete treatment with the assigned therapy as an outpatient.

As a JAK2, IRAK1 and CSF1R inhibitor, pacritinib may ameliorate the effects of cytokine storm, a pathological immune reaction that can be triggered in COVID-19 leading to serious complications, including acute respiratory distress syndrome, or ARDS. Multiple inflammatory cytokines are upregulated in patients with severe COVID-19, including IL-1 and IL-6, and some patients have evidence of over-active macrophage activation. As a JAK2/IRAK1 inhibitor, pacritinib may ameliorate the effects of cytokine storm via inhibition of IL-6 and IL-1 signaling. Furthermore, as a CSF1R inhibitor, pacritinib may mitigate effects of macrophage activation syndrome.

aGvHD Phase 1 Trial

In March 2021, results were published from an Investigator Sponsored Phase 1 study conducted by Joseph Pidala, MD, PhD (Moffitt Cancer Center), and Brian C. Betts, MD (Masonic Cancer Center at the University of Minnesota), evaluating pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, for the prevention of acute graft-versus-host disease (aGvHD). The results demonstrated that pacritinib, combined with sirolimus and low-dose tacrolimus (PAC/SIR/TAC), has a promising safety profile and exhibits preliminary therapeutic activity in preventing aGvHD after allogeneic hematopoietic cell transplantation from HLA matched related and unrelated donors. The Phase 2 portion of the trial, designed to evaluate the therapeutic effect of pacritinib in combination with sirolimus and low-dose tacrolimus for aGvHD prevention, is ongoing.

We face numerous risks in connection with clinical development of pacritinib generally and with respect to the potentially expedited FDA regulatory approval process specifically. For more information, see Part I, Item 1A, "Risk Factors – Risks Related to the Development, Clinical Testing and Regulatory Approval of Our Product Candidates" of our Annual Report on Form 10-K for the year ended December 31, 2020.

We have historically funded our operations through the sale of equity securities, funding received from our licensees and collaborators and debt financing. We do not expect to achieve or sustain profitability for the foreseeable future. We had a net loss of \$36.9 million for the six months ended June 30, 2021 and an accumulated deficit of \$2.4 billion as of June 30, 2021, primarily from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations. We believe that our cash and cash equivalents will be sufficient to fund our projected operations into the fourth quarter of 2021. This raises substantial doubt about our ability to continue as a going concern. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information on our assessment.

We have incurred significant operating losses to date and expect to continue to incur significant expenses and operating losses for at least the next 12 to 24 months. We anticipate that our expenses will increase as we:

- prepare for and execute the commercialization of pacritinib;
- continue our research and clinical development of pacritinib;
- seek regulatory and marketing approvals for pacritinib if we successfully complete the remainder of its anticipated clinical development paths; and
- maintain, protect and expand our intellectual property portfolio.

Factors Affecting Performance

Research and Development Activities

We will need to commit significant time and resources to develop our current and any future product candidates. Our sole product candidate currently in active development, pacritinib, is currently in clinical development in two clinical trial pathways. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. We are unable to provide the nature, timing and estimated costs of the efforts necessary to complete the development of pacritinib because, among other reasons, we cannot predict with any certainty the pace of patient enrollment of our clinical trials, which is a function of many factors, including the availability and proximity of patients with the relevant condition and the availability of the compounds for use in the applicable trials. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards.

Additionally, we continue to evaluate and manage the impact of the global COVID-19 pandemic on our operations and the conduct of our clinical trials, including considerations of the vulnerable nature of the patient population participating in our trials, reduced or halted activities at our clinical trial sites, and an increase in fatalities or other adverse events due to medical problems related to the COVID-19 pandemic and the benefits of continued patient access to pacritinib. Even after a clinical trial is enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process.

Regulatory agencies, including the FDA and EMA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. In addition, based on our interactions with regulatory authorities, we have sought, and may in the future seek, changes to the protocol of clinical trials if we believe such changes may enhance the probability of approval or are necessary to protect patient safety. Such changes, if any, would impact the size, timing and cost of clinical development. Even if a product candidate progresses successfully through initial human testing in clinical trials, it may fail in later stages of development, including as a result of a failure to adequately demonstrate safety or efficacy to the satisfaction of applicable regulatory authorities. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. For these reasons, among others, we cannot estimate the date on which clinical development of any product candidate will be completed, if ever, or when we will be able to begin commercializing pacritinib to generate material net cash inflows. In order to generate revenue from any of these compounds, any product candidate needs to be developed to a stage that will enable us to commercialize, sell or license related marketing rights to third parties.

We may also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products. Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of any of our product candidates or the ultimate product development costs.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in our risk factors, which can be found in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020.

Financial Summary

Loss from operations was \$19.5 million and \$10.0 million for the three months ended June 30, 2021 and 2020, respectively, and \$36.6 million and \$21.9 million for the six months ended June 30, 2021 and 2020, respectively. Results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

As of June 30, 2021, our cash and cash equivalents were \$71.9 million.

RESULTS OF OPERATIONS

Three and Six Months Ended June 30, 2021 and 2020

Operating Costs and Expenses

Research and development expenses. Our research and development expenses for compounds under development and preclinical development were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Pacritinib	\$ 7,454	\$ 4,856	\$ 15,423	\$ 6,591
Unallocated operating expenses	1,839	1,343	3,314	2,872
Total research and development expenses	\$ 9,293	\$ 6,199	\$ 18,737	\$ 9,463

Costs for our compounds include external direct expenses such as principal investigator fees, charges from contract research organizations, or CROs, and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, the EMA or other regulatory agencies outside the United States and Europe, as well as upfront license fees for acquired technology. Operating expenses include our personnel costs and an allocation of occupancy, depreciation and amortization expenses associated with developing our compounds. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. Cumulative to date external direct costs incurred by us as of June 30, 2021 were \$198.8 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S*BIO in May 2012 and \$29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S*BIO).

Research and development expenses were \$9.3 million and \$18.7 million for the three and six months ended June 30, 2021, respectively, compared to \$6.2 million and \$9.5 million for the same periods in 2020. The increase between the three-month periods ended June 30, 2021 and 2020 was primarily attributable to a \$3.6 million increase in regulatory and other costs which included activities related to the NDA submission for pacritinib and continued development of pacritinib, and a \$0.5 million increase in additional staffing, offset by a \$0.9 million decrease in the PRE-VENT Phase 3 trial and a \$0.1 million decrease in costs related to the PACIFICA Phase 3 trial. The increase between the six-month periods ended June 30, 2021 and 2020 was primarily attributable to a \$1.3 million increase in costs related to the PACIFICA Phase 3 trial, a \$7.4 million increase in professional services which included regulatory and other costs related to the NDA submission for pacritinib, and a \$0.5 million increase in costs related to the PRE-VENT Phase 3 trial.

General and administrative expenses. General and administrative expenses were \$10.2 million and \$17.8 million for the three and six months ended June 30, 2021 compared to \$3.8 million and \$8.3 million for the same periods in 2020. Substantially all of the increase between the three-month and six-month periods ended June 30, 2021 and 2020 was attributable to activities associated with preparation for the potential commercialization of pacritinib, which included, among other things, additional staffing, professional services, legal and consulting, and infrastructure.

Other operating expenses. Other operating expense of \$4.2 million for the six months ended June 30, 2020 was related to a full provision for the uncollectability of our Italian VAT receivables and deposit. There was no such expense for the three and six months ended June 30, 2021 or for the three months ended June 30, 2020.

Non-Operating Income and Expenses

Interest income. Interest income was \$8,000 and \$19,000 for the three and six months ended June 30, 2021, respectively, and \$43,000 and \$0.2 million for the three and six months ended June 30, 2020, respectively. Interest income was related to our short-term investments and cash equivalent securities. The change was primarily related to decreases in cash equivalent securities and interest rates between periods.

Interest expense. Interest expense was \$45,000 and \$0.1 million for the three and six months ended June 30, 2021, respectively, and \$0.1 million and \$0.3 million for the three and six months ended June 30, 2020, respectively. Interest expense was related to our secured term loan. The change between periods was primarily related to a lower average loan principal balance outstanding.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of \$0.1 million and \$0.3 million for each of the three and six months ended June 30, 2021 and 2020, respectively, was related to our secured term loan.

Loss on dissolution of majority-owned subsidiary. A loss of \$3.8 million for the three and six months ended June 30, 2020 was related to a loss recognized upon dissolution of our majority-owned subsidiary, Aequus Biopharma, Inc. There was no such expense for the comparable periods in 2021.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have funded our operations from proceeds from the sales and the issuance of equity securities, payments pursuant to license and collaboration agreements and the incurrence of debt. As of June 30, 2021, we had \$71.9 million in cash and cash equivalents.

Public Offering of Common Stock and Series X¹ Preferred Stock. In April 2021, we issued 16.4 million shares of our common stock at a \$2.50 per share price and 600 shares of our Series X¹ Preferred Stock at a \$25,000 per share price, collecting net proceeds of approximately \$53.6 million upon completion of the public offering.

Rights Offering. In March 2020, we issued 15.7 million shares of our common stock at a \$1.00 per share price and 4,429 shares of our Series X Preferred Stock at a \$10,000 per share price, collecting net proceeds of \$59.1 million.

At-The-Market Equity Offering. In November 2019, we entered into an Open Sale Agreement with Jefferies LLC to sell shares of our common stock, having aggregate sales proceeds of up to \$15.0 million, from time to time, through an “at the market” equity offering program under which Jefferies acted as sales agent. In November and December 2020, we sold 2.1 million shares of our common stock for net proceeds of approximately \$7.2 million after compensation to Jefferies. In January 2021 we entered into a new Open Sale Agreement with Jefferies LLC to sell shares of our common stock having aggregate sales proceeds of up to \$50.0 million. We sold 0.9 million shares of our common stock for net proceeds of approximately \$2.8 million during the first quarter of 2021.

Loan Agreement. In November 2017, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB. As of June 30, 2021, we had an outstanding principal balance under our secured term loan agreement of \$2.2 million. We are required to pay interest plus principal payments in the approximate amount of \$0.5 million per month until November 1, 2021, with the final principal plus interest payment totaling approximately \$0.4 million as well as a back-end fee of \$1.4 million. These borrowings are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions. In addition, the secured term loan agreement requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required loan payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

Historical Cash Flows

Net cash used in operating activities. Net cash used in operating activities increased to \$34.4 million during the six months ended June 30, 2021 compared to \$20.0 million for the same period in 2020. The increase was primarily due to increases in research and development and general and administrative expenses associated with continued development and preparation for the potential commercialization of pacritinib.

Net cash provided by investing activities. Net cash provided by investing activities was \$12.0 million and \$2.5 million during the six months ended June 30, 2021 and 2020, respectively. The change was due to the amounts of short-term investments matured between periods.

Net cash provided by financing activities. Net cash provided by financing activities was \$53.9 million and \$56.5 million during the six months ended June 30, 2021 and 2020, respectively. The change was primarily attributable to the net proceeds from the completion of our public offering of common stock and Series X¹ Preferred Stock in April 2021 and from the completion of our rights offering in March 2020.

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement. We currently have no commitments for additional financing to fund the development and commercial launch of pacritinib, and we may need to seek additional funding. The development and commercialization of a major product candidate like pacritinib without a collaborative partner will require a substantial amount of our time and financial resources, and as a result, we could experience a decrease in our liquidity and a new demand on our capital resources. For additional information relating to the Pacritinib License Agreement, see Part I, Item 1, “Business – License Agreements – Baxalta” of our Annual Report on Form 10-K for the year ended December 31, 2020.

Capital Resources

We have prepared our condensed consolidated financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, we believe that, as of the date of the filing of this Quarterly Report on Form 10-Q, our present financial resources will be sufficient to fund our operations into the fourth quarter of 2021. This raises substantial doubt about our ability to continue as a going concern and we will need to raise substantial additional capital in the near term in order to fund our operations through and beyond the fourth quarter of 2021 and to continue as a going concern thereafter. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information on our assessment. Further, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for pacritinib. Because of our reacquisition of worldwide rights for pacritinib, we are no longer eligible to receive cost sharing or milestone payments for pacritinib’s development from Baxalta, and losses related to research and development for pacritinib have increased. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of June 30, 2021, our available cash and cash equivalents totaled \$71.9 million, and we had an outstanding principal balance under our secured term loan agreement of \$2.2 million.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, developments in and expenses associated with our clinical trials and the other factors identified under “*Capital Requirements*” below may consume capital resources earlier than planned. Due to these and other factors, the foregoing forecast for the period for which we will have sufficient resources to fund our operations may be inaccurate.

Capital Requirements

We will need to acquire additional funds in order to develop our business and continue the development and commercialization of pacritinib. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If we fail to obtain additional capital when needed, our ability to operate as a going concern will be harmed, and we may be required to delay, scale back or eliminate some or all of our research and development programs and/or reduce our general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, refrain from making our contractually required payments when due (including debt payments) and/or be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Our future capital requirements will depend on many factors, including:

- disruptions or other delays to our business and clinical trials resulting from the ongoing worldwide COVID-19 pandemic;
- developments in and expenses associated with our research and development activities;
- changes in manufacturing;
- our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators;

- regulatory approval developments;
- our ability to generate sales of any approved product;
- our ability to execute appropriate collaborations for development and commercialization activities;
- our ability to reach milestones triggering payments under certain of our contractual arrangements;
- acquisitions of compounds or other assets;
- litigation and other disputes;
- competitive market developments; and
- other unplanned business developments.

LICENSE AGREEMENTS AND MILESTONE ACTIVITIES

For information regarding our license agreements and milestone activities, please see Part I, Item 1, “Business – License Agreements” of our Annual Report on Form 10-K for the year ended December 31, 2020.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in conformity with GAAP requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses and related disclosures in the preparation of our condensed consolidated financial statements and accompanying notes. Our critical accounting policies are those that significantly impact our financial condition and results of operations and require the most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of this uncertainty, actual results may vary from these estimates. For a discussion of our critical accounting estimates, please see Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes to our critical accounting policies and estimates discussed therein.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305(e) of Regulation S-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our President and Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the second fiscal quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

See Part I, Item 1, “Notes to Condensed Consolidated Financial Statements, Note 5. Contingencies” of this report for information regarding material pending legal proceedings.

Item 1A. Risk Factors

Our business is subject to various risks, including those described in Part I, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes from the risk factors disclosed in Item 1A of our Annual Report on Form 10-K.

This report contains forward-looking statements that involve risks and uncertainties. The occurrence of any of the risks described in our Annual Report on Form 10-K could materially adversely affect our business, financial condition, liquidity, operating results or prospects and the trading price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also harm our business, financial condition, operating results and prospects and the trading price of our securities.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		
			File No.	Exhibit Number	Filing Date
3.1	Certification of Designation of Preferences, Rights and Limitations of Series X1 Convertible Preferred Stock	8-K	000-28386	3.1	April 6, 2021
3.2	Amended and Restated Certificate of Incorporation of CTI BioPharma Corp.	S-8	333-257174	4.1	June 17, 2021
10.1*	CTI BioPharma Corp. Amended and Restated 2017 Equity Incentive Plan	8-K	000-28386	10.1	June 7, 2021
10.2*	CTI BioPharma Corp. Amended and Restated 2007 Employee Stock Purchase Plan	8-K	000-28386	10.2	June 7, 2021
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith.
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Furnished herewith.
101	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity, (v) Condensed Consolidated Statements of Cash Flows and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.				
104	Cover page interactive data file (formatted in Inline XBRL and contained in Exhibit 101).				

* Indicates a management contract or compensatory plan.

SIGNATURES

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 thereunto duly authorized:

CTI BIOPHARMA CORP.

(Registrant)

Dated: August 5, 2021

By: /s/ Adam R. Craig
Adam R. Craig
President, Chief Executive Officer and Interim Chief
Medical Officer

Dated: August 5, 2021

By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adam R. Craig, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CTI BioPharma Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions) of internal control over financial reporting:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 5, 2021

By: /s/ Adam R. Craig
Adam R. Craig
President, Chief Executive Officer and Interim Chief
Medical Officer

**CERTIFICATION OF PRINCIPAL CHIEF FINANCIAL OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David H. Kirske, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CTI BioPharma Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions) of internal control over financial reporting:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 5, 2021

By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer

