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, 2022

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	**91-1533912**
(State or other jurisdiction of incorporation or organization)	**(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:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CTIC	The Nasdaq Stock Market LLC

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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:

Class	Outstanding at August 1, 2022
Common Stock, par value $0.001 per share	114,385,307

CTI BIOPHARMA CORP.

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PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,091	$ 65,446
Short-term investments	29,779	—
Accounts receivable, net	8,159	—
Inventories	702	—
Prepaid expenses and other current assets	2,641	2,933
Total current assets	107,372	68,379
Property and equipment, net	—	176
Intangible assets, net	24,289	—
Other assets	2,873	3,879
Total assets	$ 134,534	$ 72,434
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 3,097	$ 3,891
Accrued expenses	25,967	12,720
Current portion of long-term debt	—	47,380
Other current liabilities	725	2,660
Total current liabilities	29,789	66,651
Long-term debt	47,662	—
Royalty financing obligation	59,716	—
Other liabilities	2,641	2,016
Total liabilities	139,808	68,667
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share:		
Authorized shares - 33,333 as of June 30, 2022 and December 31, 2021		
Series O Preferred Stock, 12,575 shares issued and outstanding as of June 30, 2022 and December 31, 2021 (Aggregate liquidation preference of $25,150 as of June 30, 2022 and December 31, 2021)	—	—
Series X Preferred Stock, 3,383 shares and 3,794 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively (Aggregate liquidation preference of $33,830 and $37,940 as of June 30, 2022 and December 31, 2021, respectively.)	—	—
Series X[1] Preferred Stock, 600 shares issued and outstanding as of June 30, 2022 and December 31, 2021 (Aggregate liquidation preference of $15,000 as of June 30, 2022 and December 31, 2021)	—	—
Common stock, $0.001 par value per share:		
Authorized shares - 266,500,000 as of June 30, 2022 and December 31, 2021		
Issued and outstanding shares - 114,130,834 and 99,763,922 as of June 30, 2022 and December 31, 2021, respectively	114	100
Additional paid-in capital	2,480,427	2,429,582
Accumulated other comprehensive loss	(71)	—
Accumulated deficit	(2,485,744)	(2,425,915)
Total stockholders' (deficit) equity	(5,274)	3,767
Total liabilities and stockholders' equity	$ 134,534	$ 72,434

See accompanying notes.

CTI BIOPHARMA CORP.
CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(unaudited)

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

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (22,654)	$ (19,675)	$ (59,829)	$ (36,941)
Other comprehensive (loss) income:				
Change in unrealized (loss) gain on marketable securities	(71)	1	(71)	(2)
Other comprehensive (loss) income	(71)	1	(71)	(2)
Comprehensive loss	$ (22,725)	$ (19,674)	$ (59,900)	$ (36,943)

See accompanying notes.

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2022	17	$ —	99,764	$ 100	$ 2,429,582	$ —	$ (2,425,915)	$ 3,767
Issuance of common stock, net (At-the-market equity facility)	—	—	794	1	3,750	—	—	3,751
Equity-based compensation	—	—	—	—	1,679	—	—	1,679
Exercise of stock options	—	—	60	—	61	—	—	61
Net loss	—	—	—	—	—	—	(37,175)	(37,175)
Balance at March 31, 2022	17	$ —	100,618	$ 101	$ 2,435,072	$ —	$ (2,463,090)	$ (27,917)
Issuance of common stock, net (At-the-market equity facility)	—	—	8,587	8	41,459	—	—	41,467
Conversion of Series X preferred stock to common stock	—	—	4,110	4	(4)	—	—	—
Equity-based compensation	—	—	—	—	2,539	—	—	2,539
Exercise of stock options and shares issued under employee stock purchase plan	—	—	816	1	1,361	—	—	1,362
Net loss	—	—	—	—	—	—	(22,654)	(22,654)
Other comprehensive loss	—	—	—	—	—	(71)	—	(71)
Balance at June 30, 2022	17	$ —	114,131	$ 114	$ 2,480,427	$ (71)	$ (2,485,744)	$ (5,274)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	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 (At-the-market equity facility)	—	—	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

See accompanying notes.

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

	Six Months Ended June 30,	
	2022	**2021**
Operating activities		
Net loss	$ (59,829)	$ (36,941)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	4,218	1,920
Imputed interest expense on royalty financing obligation	2,885	—
Depreciation and amortization	887	263
Other	4	(76)
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,159)	—
Inventories	(702)	—
Prepaid expenses and other assets	751	494
Accounts payable, accrued expenses and other liabilities	9,724	(30)
Net cash used in operating activities	(50,221)	(34,370)
Investing activities		
Milestone payment to S*BIO Pte Ltd.	(25,000)	—
Purchases of short-term investments	(29,788)	—
Proceeds from maturities of short-term investments	—	12,000
Net cash (used in) provided by investing activities	(54,788)	12,000
Financing activities		
Gross proceeds from public offering of common stock and Series X[1] preferred stock	—	56,000
Cash paid for offering costs (public offering of common stock and Series X[1] preferred stock)	—	(2,433)
Gross proceeds from common stock sales under at-the-market equity facility	46,936	3,064
Cash paid for issuance costs (at-the-market equity facility)	(1,409)	(310)
Gross proceeds from DRI Royalty Financing Agreement	60,000	—
Cash paid for issuance costs (DRI Royalty Financing Agreement)	(1,284)	—
Principal payments on Silicon Valley Bank debt	—	(2,667)
Proceeds from stock option exercises	660	144
Proceeds from sales of common stock under employee stock purchase plan	751	59
Net cash provided by financing activities	105,654	53,857
Net increase in cash and cash equivalents	645	31,487
Cash and cash equivalents at beginning of period	65,446	40,394
Cash and cash equivalents at end of period	$ 66,091	$ 71,881
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 2,843	$ 129
Supplemental disclosure of noncash activities		
Conversion of preferred stock to common stock	$ 4,110	$ —

See accompanying notes.

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

1. Description of Business and Summary of Significant Accounting Policies

CTI BioPharma Corp., also referred to in these interim financial statements as "we," "us," "our," the "Company" and "CTI," is a commercial biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers where there is a significant unmet medical need. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We have one commercially approved product, VONJO® (pacritinib), which received accelerated approval on February 28, 2022 from the U.S. Food and Drug Administration, or FDA, in the United States, for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. We commercially launched VONJO in March 2022. We are conducting the Phase 3 PACIFICA study of VONJO in patients with myelofibrosis and severe thrombocytopenia as a post-marketing requirement.

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 FDA, the European Medicines Agency, or the EMA, in 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, 2022 and 2021 has been prepared in accordance with accounting principles generally accepted in the U.S., or U.S. GAAP, 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, 2022 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 U.S. GAAP have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or the SEC. These unaudited condensed financial statements and related notes should be read in conjunction with our audited financial statements for the year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the SEC on March 31, 2022.

The condensed balance sheet at December 31, 2021 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the condensed financial statements and accompanying notes. Estimates are used for, but not limited to, evaluation of going concern and classification of liabilities, net product sales, clinical accruals, intangible assets, interest expense on royalty financing obligation, income taxes, commitments and contingencies, equity-based compensation and the collectability of receivables. 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. See Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates" in this Quarterly Report on Form 10-Q for further information.

Liquidity

The accompanying condensed 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 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.

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*, we expect that our present financial resources, along with expected cash receipts from net product sales of VONJO and up to $25.0 million in contractual funding commitments from DRI receivable upon achieving minimum net product sales of VONJO, will be sufficient to meet our obligations as they come due and to fund our operations for at least one year after the date that this Quarterly Report on Form 10-Q is filed with the SEC. Accordingly, the conditions that previously raised substantial doubt about our ability to continue as a going concern as of the date of the filing of our Quarterly Report on Form 10-Q as of and for the three months ended March 31, 2022, have been alleviated.

Over the next year and in the normal course of business, we expect to conduct research, development, testing and regulatory compliance activities with respect to other development pathways for pacritinib. We expect continued increases in revenues from VONJO as wholesalers build supply to manage patient refills and new subscriber demand. While we have seen strong refill demand, we may not be able to accurately predict the market acceptance or growth trajectory of VONJO's revenues. We project operating expenses, when offset against our projected revenues, will result in operating losses for the foreseeable future. We have incurred a net operating loss every year since our formation and expect to continue to incur net losses for the foreseeable future. As of June 30, 2022, we had an accumulated deficit of $2.5 billion, and our available cash, cash equivalents and short-term investments were $95.9 million.

While we expect to operate as a going concern for at least one year after the date that this Quarterly Report on Form 10-Q is filed with the SEC, we will require additional capital in order to pursue our longer-term strategic objectives. We expect to satisfy our capital needs through existing capital balances, revenues from VONJO, and some combination of public or private equity financings, partnerships, collaborations, joint ventures, 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 commercialization efforts and/or reduce our selling, 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, be unable to or elect to 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: our ability to generate sales of VONJO; the cost of ongoing organization of our commercial infrastructure and distribution capabilities; our ability to reach milestones triggering payments to be made or received under certain of our contractual arrangements; the cost of manufacturing VONJO; the cost of manufacturing clinical supplies of our product candidates or of establishing commercial supplies of any products that we may develop in the future; developments in and expenses associated with our research and development activities; our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators as we seek approval for products that we may develop in the future; acquisitions or collaborations with respect to compounds or other assets; competitive market developments; disruptions or other delays to our business and clinical trials resulting from ongoing worldwide current events; and other unplanned business developments.

In addition, our ability to comply with covenants under our Credit Agreement, or the Credit Agreement, with Drug Royalty III LP 2, or DRI, 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 Credit Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable. The Credit Agreement also contains a minimum liquidity covenant requiring us to maintain at least $10.0 million of unrestricted cash and cash equivalents, subject to certain exceptions. The accompanying condensed financial statements do not include adjustments, if any, that may result from the outcome of this uncertainty. See Part II, Item 8, “Notes to Consolidated Financial Statements, Note 7. Debt Financing Arrangements” of our Annual Report on Form 10-K for the year ended December 31, 2021 for additional information regarding the Credit Agreement with DRI.

Cash, Cash Equivalents and Short-Term Investments

As of June 30, 2022, our cash, cash equivalents and short-term investments consisted of cash, money market funds and corporate debt securities. As of December 31, 2021, our cash and cash equivalents consisted of cash and money market funds. 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, 2022 and December 31, 2021. 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, 2022			December 31, 2021
	Cost or Amortized Cost	Gross Unrealized Losses	Total Estimated Fair Value	Total Estimated Fair Value
Cash	$ 444	$ —	$ 444	$ 137
Level 1 securities:				
Money market funds	45,681	—	45,681	65,309
Level 2 securities:				
Corporate debt securities	49,816	(71)	49,745	—
Total cash, cash equivalents and short-term investments	$ 95,941	$ (71)	$ 95,870	$ 65,446

Concentrations of Credit Risk and Uncertainties

Cash, cash equivalents, short-term investments and accounts receivables are financial instruments that potentially subject us to concentrations of credit risk. All of our accounts receivable relate to VONJO product sales. We have not experienced any significant credit losses on cash, cash equivalents, short-term investments or accounts receivables to date and do not require collateral on accounts receivables. To estimate credit losses for accounts receivable, we consider our historical experience and other currently available information, including customer financial condition, as well as current and forecasted economic conditions affecting our customers. We consider the risk of potential credit losses to be low at this time in light of the creditworthiness of our customers who are specialty distributors and specialty pharmacies.

We source our drug products for commercial operations and clinical trials from a concentrated group of third-party contractors. If we are unable to obtain sufficient quantities of source materials, manufacture or distribute our products to customers from existing suppliers and service providers, or obtain the materials or services from other suppliers or manufacturers, certain sales and research and development activities may be delayed.

Accounts Receivable

Accounts receivable, net consist of amounts due from customers, net of customer allowances for prompt-pay discounts, chargebacks, rebates and product returns, as well as distribution service fees. Accounts receivable are stated at amortized cost less allowance for credit losses. Our standard credit terms range from 30 days to 66 days, and all arrangements are payable within one year of the transfer of control of the product; as such, we do not adjust our revenues for the effects of a significant financing component. We analyze past due accounts for collectability and periodically evaluate the creditworthiness of our customers. As of June 30, 2022, we determined that an allowance for credit losses was not required based on our review of customer accounts and individual circumstances.

Inventories

Prior to regulatory approval, we expense costs related to the production of inventories as research and development expenses in the period in which they are incurred because product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. Subsequent to regulatory approval, we capitalize costs incurred to manufacture our products as inventories when the related costs are expected to be recoverable through the commercialization of the product.

VONJO inventory that is deployed for clinical, research or development purposes is charged to research and development expense.

As of June 30, 2022, $0.7 million of manufacturing costs, primarily related to shipping, packaging and labeling costs incurred subsequent to FDA approval of VONJO, were capitalized as inventories, substantially all of which were classified as work-in-progress. As of June 30, 2022, we had $18.5 million of previously-expensed VONJO inventory and related material on-hand.

Inventories are recorded at the lower of cost and net realizable value with the cost of inventories determined on a specific identification basis in a manner that approximates the first-in, first-out method. We perform an assessment of the recoverability of capitalized inventory during each reporting period and write down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified.

Intangible Assets

Intangible assets as of June 30, 2022 consist of a capitalized milestone payment incurred upon FDA approval and commercialization of VONJO during the first quarter of 2022. See "Note 6. Milestone Payments - *S*BIO Pte Ltd.*" for additional details. Intangible assets are amortized on a straight-line basis over the patent life of the VONJO product compound, which was 11.9 years upon FDA approval, with a remaining amortization period of 11.5 years as of June 30, 2022. For the six months ended June 30, 2022, we recognized $0.7 million of amortization expense, which was included in *Cost of sales*. The gross carrying amount and accumulated amortization were $25.0 million and $0.7 million as of June 30, 2022, respectively.

We review for impairment when events or circumstances indicate that the carrying value of intangible assets may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. Such estimated undiscounted future cash flows are derived from projected sales of VONJO and other competitive factors. The amount of impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

Revenue Recognition

ASC 606 *Revenue from Contracts with Customers* applies to all contracts with customers, except for contracts that are within the scope of other authoritative literature. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) we satisfy a performance obligation. We apply the five-step model to arrangements that meet the definition of a contract under ASC 606 including when it is probable that we will collect the consideration we are entitled to in exchange for goods or services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. Prior to recognizing revenue, we make estimates of the transaction price, including any variable consideration that is subject to a constraint. Variable consideration is included in the transaction price to the extent that it is probable that there will not be a significant reversal in the amount of cumulative revenue recognized and when the uncertainty associated with the variable consideration is subsequently resolved. We recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation as the performance obligation is satisfied.

Net Product Sales

On February 28, 2022, the FDA granted accelerated approval of VONJO for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. We commercially launched VONJO in March 2022. We entered into a limited number of distribution arrangements with specialty distributors and specialty pharmacies in the United States to distribute VONJO. Our specialty pharmacy customers resell VONJO directly to patients while our specialty distributor customers resell VONJO to healthcare entities, who then resell to patients. Such specialty distributors and specialty pharmacies are referred to as our customers in the context of ASC 606.

We recognize revenue for product sales when our customers obtain control of the product, which generally occurs upon delivery. Upon receipt of the product by our customers, we recognize revenues net of variable consideration, which relates to

allowances for customer credits, distribution service fees, product returns, chargebacks, rebates and co-payment assistance programs as discussed below. The reserves for these allowances are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than the customer). Taxes collected from the customer relating to product sales and remitted to governmental authorities are excluded from product sales.

Customer Credits and Distribution Service Fees: Our customers are offered prompt payment discounts. We expect our customers will pay timely enough to utilize prompt payment discounts and therefore we deduct the full amount of these discounts from total product sales when revenues are recognized. In addition, we pay a fee to our customers for their sales order management, data, and distribution services to us. Distribution service fees are also deducted from total product sales as they are incurred.

Returns: We offer our customers and other indirect purchasers a limited right of return for purchased units of VONJO for damaged, defective, in-dated or expired product beginning six months prior to the product's expiration date and ending 12 months after the product's expiration date. We estimate the amount of product returns initially based on data from similar products and other qualitative considerations, such as visibility into the inventory remaining in the distribution channel.

Chargebacks: Chargebacks result from our contractual commitments to provide our product to discount-eligible healthcare entities, group purchasing organizations, 340B eligible covered entities and federal government entities purchasing via the Federal Supply Schedule, at prices lower than the list prices charged to our customers. Our customers charge us back for the discount provided to the contracted entities. Our reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventory, which we expect will be sold to the contracted entities, as well as chargebacks that customers have claimed, but for which we have not yet issued a credit. We record reserves for chargebacks based on contractual terms in the same period that the related revenue is recognized.

Rebates: We are subject to discount and rebate obligations under government programs such as the Medicaid Drug Rebate Program, the Medicare Part D Coverage Gap Discounts Program and the 340B Drug Pricing Program, as well as under commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on data received from our customers and historical utilization rates observed subsequent to product launch.

Our accrual for these rebates consists of invoices received for claims from prior and current quarters that have not been paid or for which an invoice has not yet been received as well as estimates of claims for the current period's shipment to our customers, which include estimated future claims that will be made for product that has been recognized as revenue but which remains in distribution channel inventories at the end of the reporting period.

Co-payment Assistance: We offer co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption based on data provided by the third-party administrator.

Cost of Sales

Cost of sales includes the cost of manufacturing inventories that are related to product sales, including overhead costs, amortization expense for intangible assets, and third-party royalties payable on net product sales. In addition, shipping and handling costs for product shipments are recorded in cost of sales as incurred. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs and manufacturing variances. For the three and six months ended June 30, 2022, cost of sales primarily consisted of amortization expense for intangible assets, shipping and handling costs, and third-party royalty costs. The manufacturing costs of VONJO product sold during the current period were previously expensed as research and development expenses.

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 $2.5 million and $1.0 million for the three months ended June 30, 2022 and 2021, respectively, and $4.2 million and $1.9 million for the six months ended June 30, 2022 and 2021, respectively. Substantially all of equity-based compensation expense was related to option awards and was included in *Selling, general and administrative* expenses for the periods presented.

Net Loss per Share

Basic net loss per common share is calculated based on net loss 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 for each of the three months ended June 30, 2022 and 2021, and 75.2 million shares and 72.6 million shares for the six months ended June 30, 2022 and 2021, respectively, were excluded from the calculation of diluted net loss per share because they were anti-dilutive.

Recently Issued Accounting Standards

In March 2020, the Financial Accounting Standards Board, or FASB, issued accounting guidance to provide temporary optional expedients to ease the potential burden in accounting for reference rate reform. The guidance includes an optional expedient that simplifies accounting for contract modifications to loans receivable and debt, by prospectively adjusting the effective interest rate. The accounting guidance is effective as of January 7, 2021 through December 31, 2022. In August 2021, we entered into the Credit Agreement, which has an interest rate referenced to the London Interbank Offered Rate, or LIBOR. We plan to elect the optional expedient for our credit facility by prospectively adjusting the effective interest rate if the cessation of the LIBOR occurs. We do not expect the adoption of this guidance to have a material impact on our condensed 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 financial statements.

Reclassification

Certain prior year items have been reclassified to conform to current year presentation.

2. Other Assets

Other assets consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Operating lease right-of-use assets	$ 2,361	$ 3,109
Clinical trial deposits	512	770
Total other assets	$ 2,873	$ 3,879

3. Other Liabilities

Other liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Operating lease liabilities, non-current	$ 1,641	$ 2,016
End-of-facility lender fee (1)	1,000	—
Total other liabilities	$ 2,641	$ 2,016

(1) The end-of-facility lender fee as of June 30, 2022 represents an amount payable to DRI upon repayment of our secured term loan under the Credit Agreement with DRI.

4. Debt Financing Arrangements

Drug Royalty III LP 2

Credit Agreement

All amounts due under the Credit Agreement, which include a term loan in the principal amount of $50.0 million and the end-of-facility lender fee of $1.0 million, have been reclassified from current liabilities to long-term liabilities on the condensed balance sheet as of June 30, 2022 since the conditions relating to a material adverse effect provision under the Credit Agreement, which could accelerate repayment if not cured, have been alleviated as discussed in "Note 1. Description of Business and Summary of Significant Accounting Policies - *Liquidity*" above. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 7. Debt Financing Arrangements" of our Annual Report on Form 10-K for the year ended December 31, 2021 for additional information regarding the Credit Agreement.

Royalty Financing Agreement

In August 2021, we entered into the Royalty Financing Agreement, pursuant to which we sold to DRI the right to receive certain royalty payments from us for a purchase price of up to $85.0 million in cash. Under the Royalty Financing Agreement, DRI is entitled to receive tiered royalties based on net product sales of VONJO in the United States in an amount equal to: (i) 9.60% of annual net sales of VONJO in the United States for annual net sales up to $125 million, (ii) 4.50% of annual net sales of VONJO in the United States for annual net sales between $125 million and $175 million, and (iii) 0.50% of annual net sales of VONJO in the United States for annual net sales between $175 million and $400 million. No royalty payments are payable on annual net sales of VONJO in the United States over $400 million.

In March 2022, DRI funded the upfront purchase price of $60.0 million following FDA approval of VONJO in February 2022 and will be required to provide up to $25.0 million of additional funding if certain minimum VONJO sales thresholds are met in 2023, or sooner.

We are required to make payments of amounts owed to DRI each calendar quarter from and after the first commercial sale of the applicable product in the United States until the patent expiry of the VONJO product compound.

Under the Royalty Financing Agreement, we agreed to specified affirmative and negative covenants, including without limitation covenants regarding periodic reporting of information by us to DRI, obligations to use commercially reasonable efforts to commercialize VONJO in the United States and restrictions on our ability to incur certain indebtedness, which restrictions are eliminated after the earliest of: (a) the date on which the trailing twelve months' of VONJO sales equals at least $200 million, (b) the date on which the Company's market capitalization (determined on an as-converted basis) is at least $1.0 billion for 20 consecutive trading days or (c) DRI receiving royalty payments in an amount equal to 100% of their purchase price. The Royalty Financing Agreement also contains representations and warranties, other covenants, indemnification obligations, settlement clauses and other provisions customary for transactions of this nature. Certain of these provisions would, if deemed probable, result in the recognition of an embedded feature. However, we do not believe such provisions are probable at this time. The Royalty Financing Agreement does not contain subjective acceleration clauses or provisions that would require repayment of funding.

We evaluated the terms of the Royalty Financing Agreement and concluded that the features of the funding from DRI are similar to those of a debt instrument. Accordingly, the funding from DRI is recorded as *Royalty Financing Obligation* on our condensed balance sheet. In connection with the Royalty Financing Agreement, we recorded debt issuance costs of $1.8 million, of which $1.8 million remained unamortized as of June 30, 2022. The royalty financing obligation is amortized over the expected repayment term using an effective interest rate method that is calculated based on the rate that would enable the debt to be repaid in full over the patent life of the VONJO product compound, which was 11.8 years upon funding, with a remaining amortization period of 11.5 years as of June 30, 2022. The effective interest rate may vary during the term of the agreement depending on a number of factors, including the amount and timing of forecasted net product sales which affects the repayment timing and ultimate amount of repayment. As of June 30, 2022, the effective interest rate was 15.7%. We recognized non-cash interest expense of $2.9 million related to the royalty financing obligation for the six months ended June 30, 2022. We will evaluate the effective interest rate quarterly based on our current revenue forecasts utilizing the prospective method.

The activities related to the royalty financing obligation for the six months ended June 30, 2022 were as follows (in thousands):

Royalty financing obligation - initial funding	$	60,000
Less: debt issuance costs		(1,814)
Royalty financing obligation - beginning balance	$	58,186
Accretion of imputed interest on the royalty financing obligation balance		2,885
Amortization of debt issuance costs		49
Less: Royalty paid to DRI		(220)
Less: Royalty payable to DRI (classified in accrued expenses)		(1,184)
Royalty financing obligation - ending balance	$	59,716

5. Equity Transactions

At-The-Market Equity Offering

In January 2021, we entered into an Open Market Sale Agreement℠ 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 acted as sales agent. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 8. Equity Transactions" of our Annual Report on Form 10-K for the year ended December 31, 2021 for additional information. For the six months ended June 30, 2022, we sold 9.4 million shares of our common stock for net proceeds of approximately $45.5 million under the Sale Agreement. As of June 30, 2022, there was no more available facility under the Sale Agreement.

Series X Preferred Stock

In March 2020, we completed a rights offering whereby we issued 15.7 million shares of our common stock and 4,429 shares of our Series X Preferred Stock convertible into our common stock. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 8. Equity Transactions" of our Annual Report on Form 10-K for the year ended December 31, 2020 for additional information. During the three months ended June 30, 2022, 411 shares of our Series X Preferred Stock were converted into 4.1 million shares of our common stock. There were 3,383 shares of our Series X Preferred Stock outstanding as of June 30, 2022.

6. Milestone Payments

For additional information regarding the agreements discussed below, see Part II, Item 8, "Notes to Consolidated Financial Statements, Note 9. Collaboration, Licensing and Milestone Agreements" of our Annual Report on Form 10-K for the year ended December 31, 2021.

Baxalta

Pursuant to the Asset Return and Termination Agreement, or Baxalta Termination Agreement, entered into with Baxalta in 2016, we are required to make a payment to Takeda in the amount of approximately $10.3 million, upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib. Baxalta was acquired by Shire plc in 2016, and Shire plc was subsequently acquired by Takeda in 2019. Upon FDA approval of VONJO on February 28, 2022, the $10.3 million payment became payable to Takeda and is included within *Accrued expenses* as of June 30, 2022. The payment was originally due 60 days following FDA approval; however, the due date was subsequently amended such that the payment is now required to be made in full on or prior to March 15, 2023, subject to our timely payment of monthly interest on the outstanding amount due at an applicable interest rate specified in the amendment. Interest payments on the amount owed were $0.1 million in aggregate as of June 30, 2022. Since the $10.3 million payment does not relate to our intellectual property and arose from a contingency in the Baxalta Termination Agreement that was resolved in the first quarter of 2022, it was recorded in *Other operating expenses* during the six months ended June 30, 2022. Under the terms of the Baxalta Termination Agreement, we will have no further obligations to Takeda after settlement of this payment.

*S*BIO Pte Ltd.*

Under our agreement with S*BIO Pte Ltd., or S*BIO, we are required to make milestone payments to S*BIO up to an aggregate amount of $132.5 million if certain U.S., EU and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any compound that we

acquired from S*BIO for use for specific diseases, infections or other conditions. S*BIO will also be entitled to receive royalty payments from us at incremental rates in the low single-digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis. Upon FDA approval of VONJO on February 28, 2022, a $25.0 million milestone payment became payable to S*BIO, which is recorded in *Intangible assets, net* due to the fact that this payment represents contingent consideration for the acquired pacritinib compound that became marketable and capable of generating cash flows from sales during the first quarter of 2022. At our election, we may pay up to 50% of any milestone payments to S*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock.

7. 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).

In January 2018, the Italian Supreme Court issued decision No. 02250/2018 regarding the 2005 VAT return, which (i) rejected the April 2013 appeal of the ITA, (ii) confirmed the October 2012 decision of the Regional Tax Court (127/31/2012), which fully accepted the merits of our earlier appeal and confirmed that no penalties could be imposed against us, and (iii) due to the novelty of the arguments at stake, compensated the legal expenses incurred by the parties. The ITA may not use any ordinary means of appeal against the Italian Supreme Court decision, and we have applied for a refund based on the guidance from the ITA.

The assessments, including interest and penalties, for the years 2003, 2006 and 2007 were €0.7 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 were correct as originally filed. We appealed all of the assessments and defended ourselves against the assessments both on procedural grounds and on the merits of the cases.

In April 2022, we were notified that the Italian Supreme Court ruled in our favor for the 2006 and 2007 VAT year returns but ruled in the ITA's favor for the 2003 VAT year return. With respect to the 2006 and 2007 VAT year returns, on March 31, 2022, the Italian Supreme Court issued decision No. 10355/22 which (i) rejected the appeal of the ITA, (ii) confirmed the decision of the Regional Tax Court which ruled fully in our favor, and (iii) due to a change of law, compensated the legal expenses incurred by the parties for the appeals. We have applied for refunds based on the guidance from the ITA.With respect to the 2003 VAT year return, on April 12, 2022, the Italian Supreme Court rejected our arguments both on procedural grounds and on the merits of the case. Accordingly, we recorded €0.7 million for the 2003 VAT assessment, including interest and penalties, or approximately $0.7 million converted using the currency exchange rate as of June 30, 2022, in *Accrued expenses* and *Other operating expenses* as of and for the six months ended June 30, 2022.

There have been no changes to the status of the legal proceedings surrounding the status of our application for a refund related to the 2005 VAT return for which the court ruled in our favor since the filing of our Annual Report on Form 10-K for the year ended December 31, 2021.

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, selling, general and administrative expenses and additional losses;
- our ability to obtain funding for our operations;
- the commercialization of VONJO as a treatment for adult myelofibrosis patients with severe thrombocytopenia;
- our ability to develop, commercialize and obtain regulatory approval of pacritinib for other development programs we may pursue in the future;
- the design of our clinical trials and their anticipated enrollment;
- the safety, effectiveness and potential benefits and indications of VONJO and any other product candidates we may develop in the future;
- the rate and degree of market acceptance and clinical utility of VONJO or 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 VONJO and any other product candidates we may develop in the future;
- our ability to advance product candidates, including VONJO 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;
- our and our collaborators' ability to obtain and maintain regulatory approvals, and the timing of such approvals, for VONJO or any other product candidates we may develop in the future;
- 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, 2021 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., except where it is otherwise made clear.

OVERVIEW

We are a commercial biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers where there is a significant unmet medical need. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We have one commercially approved product, VONJO® (pacritinib), which has received accelerated approval in the United States by the U.S. Food and Drug Administration, or the FDA, for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L.

Pacritinib is an oral kinase inhibitor with activity against wild type Janus Associated Kinase 2 (JAK2), mutant $JAK2^{V617F}$ form and FMS-like tyrosine kinase 3 (FLT3), which contribute to signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. Pacritinib has higher inhibitory activity for JAK2 over other family members, JAK3 and TYK2. At clinically relevant concentrations, pacritinib does not inhibit JAK1. Pacritinib exhibits inhibitory activity against additional cellular kinases (such as CSF1R and IRAK1), the clinical relevance of which is unknown. 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. Myelofibrosis is often associated with dysregulated JAK2 signaling. 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, graft versus host disease, or GvHD, and chronic lymphocytic leukemia, or CLL, due to its inhibition of JAK2, IRAK1, FLT3 and CSF1R. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

U.S. FDA Approval of VONJO

In September 2020, we reached an agreement with the FDA to submit a New Drug Application, or NDA, for the potential accelerated approval of VONJO as a treatment for myelofibrosis patients with severe thrombocytopenia, and in March 2021 we completed our rolling NDA submission. The NDA was based on the available data from our completed Phase 3 PERSIST-1 and PERSIST-2 trials and the Phase 2 PAC203 trial. 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, which was

subsequently extended by three months to February 28, 2022. On February 28, 2022, the FDA granted accelerated approval of VONJO for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. This indication is approved under FDA accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). As agreed with the FDA, the PACIFICA Phase 3 trial will be completed as a post-marketing requirement.

PACIFICA Phase 3 Trial

As part of the accelerated approval of VONJO, we agreed with the FDA to amend the design of PACIFICA to have co-primary endpoints of Spleen Volume Reduction, or SVR, and modified Total Symptom Score, or TSS, with both endpoints being analyzed after the complete enrollment of the study. To ensure sufficient study powering this change resulted in an increase in study size to 399 patients. This change will be implemented in the next study amendment. In addition to co-primary endpoints SVR and TSS, overall survival is a secondary endpoint. Enrollment in this trial is progressing despite the challenges of conducting clinical trials during the COVID-19 pandemic. Additionally, enrollment at sites in Russia, Ukraine and Belarus has been indefinitely paused in response to the conflict in the region. As agreed with the FDA, following the accelerated approval of VONJO, we plan to complete the PACIFICA Phase 3 trial as a post-marketing requirement, with expected results in mid-2025.

Patent Term Extension Applications

In February 2022, we filed patent term extension applications for U.S. Patent No. 8,153,632 and U.S. Patent No. 9,573,964. For U.S. Patent No. 8,153,632, we requested five years of extension, which, if granted, would extend the expiration date of that patent from January 2029 to January 2034. For U.S. Patent No. 9,573,964, we requested 1,085 days of extension, which, if granted, would extend the expiration date of that patent from May 2028 to April 2031. The U.S. Patent and Trademark Office, or USPTO, can often take several years to respond to patent term extension applications. If the USPTO determines that both applications are eligible for extension of patent term, we will be required to elect which of these two patents will receive the requested extension of term. We will be required to make this election after we receive notice that the applications are eligible. If we fail to make an election, the USPTO will apply the extension to U.S. Patent No. 8,153,632, the longer of the two extension requests.

Operations

We have historically funded our operations through the sale of equity securities, debt financing and funding received from our licensees and collaborators. We had a net loss of $22.7 million and $59.8 million for the three and six months ended June 30, 2022, respectively, and an accumulated deficit of $2.5 billion as of June 30, 2022, primarily from expenses incurred in connection with our research programs and from selling, general and administrative costs associated with our operations. We believe that our cash, cash equivalents and short-term investments, along with expected cash receipts from net product sales of VONJO and up to $25.0 million in contractual funding commitments from DRI receivable upon achieving minimum net product sales of VONJO, will be sufficient to meet our obligations as they come due and to fund our operations for at least one year after the date that this Quarterly Report on Form 10-Q is filed with the SEC.

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:

- continue our commercialization efforts for VONJO;
- 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

Product Sales

Following FDA approval of VONJO on February 28, 2022, we commenced shipping of VONJO to a limited number of specialty distributor customers and specialty pharmacy customers in March 2022. Product sales are recognized upon delivery of our product to our customers and are recorded net of applicable deductions, including trade discounts, distribution service fees,

product returns, chargebacks and discounts, rebates and other incentives such as co-pay assistance. Our realization of product sales will be dependent, in part, upon our commercialization efforts and the market acceptance of VONJO among physicians, patients, healthcare payers and the medical community.

Cost of Sales

Cost of sales for the three and six months ended June 30, 2022 primarily consisted of shipping and distribution costs of VONJO, amortization expense for intangible assets and third-party royalty costs. Cost of sales will reflect only a portion of the costs related to the manufacture of VONJO and related materials, since, prior to FDA approval, these costs were expensed as research and development expenses. We expect to utilize zero cost inventory with respect to VONJO for an extended period of time.

Research and Development

We expect to commit significant time and resources to research and development activities relating to our current and any future product candidates. Pacritinib has received accelerated approval for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L and is being marketed as VONJO. However, a confirmatory study, PACIFICA, is ongoing and we expect to continue to devote resources to the completion of this study.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel costs, expenses for outside consulting and professional services, allocated facilities costs and costs required to support the marketing and sales operations of our commercialized product. Following FDA approval of VONJO in February 2022, we anticipate that selling, general and administrative expenses will increase as we expand our commercial activities in support of our expected growth in the United States.

Impact of COVID-19

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, 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 VONJO.

Financial Summary

Our net product sales reflect sales from our product VONJO, which was commercially launched in the United States in March 2022 following FDA approval on February 28, 2022. Total net product sales were $12.3 million and $14.6 million for the three and six months ended June 30, 2022, respectively. We did not have any product sales for the three and six months ended June 30, 2021. Loss from operations was $18.9 million and $19.5 million for the three months ended June 30, 2022 and 2021, respectively, and $54.0 million and $36.6 million for the six months ended June 30, 2022 and 2021, respectively. 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, 2022, our cash, cash equivalents and short-term investments were $95.9 million.

RESULTS OF OPERATIONS

Three and Six Months Ended June 30, 2022 and 2021

Net product sales. We began recognizing product sales in March 2022 following FDA approval of VONJO on February 28, 2022 and its subsequent commercial launch in the United States. Net product sales were $12.3 million and $14.6 million for the three and six months ended June 30, 2022, respectively. We did not have any product sales for the comparable periods in 2021.

The activities and ending reserve balances for significant categories of allowances for VONJO (which constitute variable consideration that is deducted from gross product sales) during the six months ended June 30, 2022 were as follows (in thousands):

	Chargebacks and rebates	Service fees, returns, co-pay assistance and other	Total
Balance, January 1, 2022	$ —	$ —	$ —
Provision related to current year sales	1,254	1,028	2,282
Payments / credits for current year sales	(645)	(592)	(1,237)
Balance, June 30, 2022	$ 609	$ 436	$ 1,045

Chargebacks and rebates are expected to be the most significant component of our total gross-to-net deductions. Future gross-to-net deductions will fluctuate based on the volume of purchases eligible for government mandated discounts and rebates as well as changes in the discount percentage which is impacted by the rate of inflation and other factors. We expect gross-to-net deductions to increase for the remainder of 2022, driven by anticipated growth in our gross product sales.

Operating Costs and Expenses

Cost of sales. During the three and six months ended June 30, 2022, we recorded $0.9 million and $1.2 million of cost of sales, respectively, which primarily consisted of amortization expense for intangible assets, shipping and distribution costs as well as third-party royalty costs. We did not have any cost of sales for the comparable periods in 2021. The manufacturing costs for VONJO incurred prior to FDA approval on February 28, 2022 were not capitalized as inventory but were expensed as research and development costs since product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, cost of sales reflects only a portion of the costs related to the manufacture of VONJO and related materials. If cost of sales had included such previously-expensed inventory that was sold during the current period, cost of sales for the three and six months ended June 30, 2022 would have been $1.2 million and $1.5 million, respectively.

The time period over which reduced-cost VONJO inventory is consumed will depend on a number of factors, including the amount of future sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date. At this time, we expect that cost of sales in relation to net product sales will progressively increase towards 2025 as VONJO product manufactured and expensed prior to capitalization is sold.

Research and development expenses. Our research and development expenses were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Pacritinib	$ 5,843	$ 7,454	$ 11,071	$ 15,423
Operating expenses	2,862	1,839	5,682	3,314
Total research and development expenses	$ 8,705	$ 9,293	$ 16,753	$ 18,737

Costs for our compound include external direct expenses such as principal investigator fees, charges from contract research organizations, 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. Cumulative to date external direct costs incurred by us through June 30, 2022 were $226.3 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S*BIO Pte Ltd. or 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 $8.7 million and $16.8 million for the three and six months ended June 30, 2022, respectively, compared to $9.3 million and $18.7 million for the same periods in 2021. The decrease between the three-month periods ended June 30, 2022 and 2021 was primarily attributable to a $0.3 million decrease in the PRE-VENT Phase 3 trial, a $0.4 million decrease in the PACIFICA Phase 3 trial and a $0.9 million decrease in professional services, partially offset by a $1.0 million increase for additional staffing. The decrease between the six-month periods ended June 30, 2022 and 2021 was primarily attributable to a $1.8 million decrease in the PRE-VENT Phase 3 trial, a $1.1 million decrease in the PACIFICA Phase 3 trial and a $1.5 million decrease in professional services, partially offset by a $2.4 million increase for additional staffing.

Selling, general and administrative expenses. Selling, general and administrative expenses were $21.6 million and $39.6 million for the three and six months ended June 30, 2022, respectively, compared to $10.2 million and $17.8 million for the same periods in 2021. Substantially all of the increases between periods were attributable to activities associated with the commercial launch of VONJO. The increase between the three-month periods ended June 30, 2022 and 2021 was primarily attributable to a $7.7 million increase in additional staffing and personnel costs, a $2.6 million increase in professional services, a $0.2 million increase in infrastructure including sales-related service agreements and a $0.9 million increase in travel and other expenses. The increase between the six-month periods ended June 30, 2022 and 2021 was primarily attributable to a $15.2 million increase in additional staffing and personnel costs, a $4.5 million increase in professional services, a $0.6 million increase in infrastructure including sales-related service agreements and a $1.5 million increase in travel and other expenses.

Other operating expenses. Other operating expenses for the six months ended June 30, 2022 were attributable to a $10.3 million expense relating to resolution of a contingency in the Baxalta Asset Return and Termination Agreement, which became payable to Takeda upon FDA approval of VONJO, as well as a $0.7 million expense regarding the 2003 Italian VAT assessment. See Part I, Item 1, "Notes to Condensed Financial Statements, Note 6. Milestone Payments - *Baxalta* and Note 7. Contingencies" of this Quarterly Report on Form 10-Q for additional details. There were no such expenses during the three months ended June 30, 2022 or during the three and six months ended June 30, 2021.

Non-Operating Expenses

Interest expense, net. Interest expense, net was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Interest income	$ 212	$ 8	$ 227	$ 19
Interest expense	(1,520)	(45)	(2,836)	(113)
Imputed interest expense (royalty financing obligation)	(2,274)	—	(2,885)	—
Amortization of debt discount and issuance costs	(179)	(130)	(330)	(260)
Interest expense, net	$ (3,761)	$ (167)	$ (5,824)	$ (354)

Interest income was $0.2 million and $8,000 for the three months ended June 30, 2022 and 2021, respectively and $0.2 million and $19,000 for the six months ended June 30, 2022 and 2021, respectively. Interest income was primarily related to our cash equivalent securities and short-term investments. The change was primarily due to increases in cash equivalent securities and short-term investments during the three and six months ended June 30, 2022 as compared to the same periods in 2021.

Interest expense was $1.5 million and $45,000 for the three months ended June 30, 2022 and 2021, respectively and $2.8 million and $0.1 million for the six months ended June 30, 2022 and 2021, respectively. Interest expense for the three and six months ended June 30, 2022 was primarily related to the $50 million Credit Agreement we entered into with Drug Royalty III LP 2, or DRI, in August 2021 whereas interest expense for the three and six months ended June 30, 2021 was related to our secured term loan with Silicon Valley bank, which was repaid in full in August 2021. The increase was primarily due to the higher average loan principal balance outstanding during the three and six months ended June 30, 2022 compared to the same periods in the prior year.

Imputed interest expense (royalty financing obligation) for the three and six months ended June 30, 2022 was related to non-cash interest expense recognized on the royalty financing obligation for the sale of the right to receive certain royalty payments from us under the Purchase and Sale Agreement entered into in August 2021 with DRI, or the Royalty Financing Agreement. See "Item 1, Notes to Condensed Financial Statements, Note 4. Debt Financing Arrangements" of this report for additional information. There was no such expense for the three and six months ended June 30, 2021.

Amortization of debt discount and issuance costs for the three and six months ended June 30, 2022 was related to the Credit Agreement and Royalty Financing Agreement with DRI. Amortization of debt discount and issuance costs for the three and six months ended June 30, 2021 was related to our term loan with Silicon Valley Bank.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have funded our operations from proceeds from the sales and the issuance of equity securities, the incurrence of debt and payments pursuant to license and collaboration agreements. As of June 30, 2022, we had $95.9 million in cash, cash equivalents and short-term investments.

Product Sales. We commercially launched VONJO in March 2022 following the accelerated approval of VONJO by the FDA on February 28, 2022. We intend to rely on cash flows from product sales as our source of liquidity in the near future as we expand our commercialization efforts with respect to VONJO.

Public Offering of Common Stock and Series X^1 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 X^1 Preferred Stock at a $25,000 per share price, collecting net proceeds of approximately $53.6 million.

At-The-Market Equity Offering. In January 2021, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or the Sale Agreement, 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 $2.7 million during the year ended December 31, 2021. For the six months ended June 30, 2022, we sold 9.4 million shares of our common stock for net proceeds of approximately $45.5 million under the Sale Agreement. There is no more available facility under the Sale Agreement.

Credit Agreement. In August 2021, we entered into the Credit Agreement with DRI as lender and administrative agent, which provided for a loan in the principal amount of $50 million funded by DRI at closing. As of June 30, 2022, we had an outstanding principal balance under the Credit Agreement of $50.0 million. We are required to pay quarterly interest-only payments until August 25, 2026, or the maturity date, with the unpaid principal amount of the outstanding loan due and payable on the maturity date. The loan bears interest at a rate equal to 8.25% per annum, plus the greater of (i) 1.75% and (ii) the three-month LIBOR rate and requires a back-end fee of $1.0 million. These borrowings are secured by a first priority security interest on substantially all of our assets, subject to certain exceptions. In addition, the Credit Agreement contains a minimum liquidity covenant requiring us to maintain at least $10.0 million of unrestricted cash and cash equivalents, subject to certain exceptions. The Credit Agreement also 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 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.

Royalty Financing Agreement. In connection with the Credit Agreement discussed above, we and DRI entered into the Royalty Financing Agreement, pursuant to which we sold to DRI the right to receive certain royalty payments from us for a purchase price of up to $85.0 million in cash. In March 2022, DRI funded the upfront purchase price of $60.0 million following the FDA approval of VONJO on February 28, 2022 and will be required to provide up to $25.0 million of additional funding to us if certain minimum VONJO sales thresholds are met in 2023, or sooner. Under the Royalty Financing Agreement, DRI is entitled to receive tiered, sales-based royalties on net product sales of VONJO in the United States.

Historical Cash Flows

Net cash used in operating activities. Net cash used in operating activities increased to $50.2 million during the six months ended June 30, 2022 compared to $34.4 million for the same period in 2021. The increase was primarily due to increases in payments for selling, general and administrative expenses associated with the commercialization of VONJO, partially offset by cash receipts from VONJO product sales.

Net cash (used in) provided by investing activities. Net cash used in investing activities during the six months ended June 30, 2022 was attributable to a $25.0 million milestone payment to S*BIO and purchases of short-term investments. See “Note 6. Milestone Payments - *S*BIO Pte Ltd.*” for additional details. Net cash provided by investing activities during the six months ended June 30, 2021 was related to the maturity of short-term investments.

Net cash provided by financing activities. Net cash provided by financing activities was $105.7 million and $53.9 million during the six months ended June 30, 2022 and 2021, respectively. Net cash provided during the six months ended June 30, 2022 was primarily attributable to net proceeds from the Royalty Financing Agreement with DRI and the utilization of the at-the-market equity facility. Net cash provided during the six months ended June 30, 2021 was primarily attributable to net proceeds from the public offering of common stock and Series X^1 preferred stock.

Capital Resources

We have prepared our condensed 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. We believe that, as of the date of the filing of this Quarterly Report on Form 10-Q, our present financial resources, along with expected cash receipts from net product sales of VONJO and up to $25.0 million in contractual funding commitments from DRI receivable upon achieving minimum net product sales of VONJO, will be sufficient to meet our obligations as they come due and to fund our operations for at least one year after the date that this Quarterly Report on Form 10-Q is filed with the SEC. 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, 2022, our available cash, cash equivalents and short-term investments totaled $95.9 million, and we had an outstanding principal balance of $50.0 million under our Credit Agreement with DRI.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in our commercialization efforts, 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

While we expect to operate as a going concern for at least one year from the date of filing of this Quarterly Report on Form 10-Q, we will require additional capital in order to pursue our longer-term strategic objectives. We expect to satisfy our capital needs through existing capital balances, revenues from VONJO and a combination of 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 commercialization efforts and/or reduce our selling, 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: our ability to generate sales of VONJO; the cost and timing of establishing our commercial infrastructure and distribution capabilities; our ability to reach milestones triggering payments under certain of our contractual arrangements; the cost of manufacturing VONJO; the cost of manufacturing clinical supplies or of establishing commercial supplies of any products that we may develop in the future; developments in and expenses associated with our research and development activities; our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators as we seek product approval; acquisitions or collaborations with respect to compounds or other assets; competitive market developments; disruptions or other delays to our business and clinical trials resulting from the ongoing worldwide COVID-19 pandemic; 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, 2021.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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 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. The following estimates are considered material updates to our critical accounting policies and estimates disclosed in 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, 2021:

Revenue Recognition

Under Accounting Standards Codification 606, *Revenue from Contracts with Customers*, or ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. As part of accounting for these arrangements, we make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (i.e., the transaction price discussed in *Revenue Recognition* above), which includes estimates of variable consideration. We establish reserves for such variable consideration which results from customer credits, service fees, returns, chargebacks, discounts, rebates and co-pay assistance that are offered within contracts between us and our customers and other indirect healthcare entities relating to our product sales. These reserves are based on the amounts earned or to be claimed on the related sales. Where appropriate, our estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical data, current contractual and statutory requirements, specific known market trends and industry data, and forecasted customer purchase and payment patterns. These reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product sales and earnings in the period such variances become known.

Royalty Financing Obligation

The royalty financing obligation is eligible to be repaid based on royalties from net sales of VONJO. Interest expense is accrued using the effective interest rate method over the estimated repayment period of the obligation. This requires us to estimate the total amount of future royalty payments to be generated from VONJO product sales over the life of the agreement. We impute interest on the carrying value of the royalty financing obligation and record interest expense using an imputed effective interest rate. We will reassess the expected royalty payments at each reporting period and account for any changes through an adjustment to the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the royalty financing obligation require that we make estimates which could impact the carrying value of the liability. A significant increase or decrease in forecasted product sales could materially impact the liability balance, the amount of interest expense and the timing of repayment.

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, 2022 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 Financial Statements, Note 7. Contingencies” of this Quarterly Report on Form 10-Q 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, 2021. 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	Incorporated by Reference			
		Form	File No.	Exhibit Number	Filing Date
10.1*	CTI BioPharma Corp. Amended and Restated 2017 Equity Incentive Plan.	8-K	000-28386	10.1	June 3, 2022
10.2*	CTI BioPharma Corp. Amended and Restated 2007 Employee Stock Purchase Plan.	8-K	000-28386	10.2	June 3, 2022
10.3	Amendment No 1. to the Asset Return and Termination Agreement, by and between Baxalta Incorporated and CTI BioPharma Corp., dated as of May 31, 2022				Filed herewith
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[(1)]	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, 2022, formatted in Inline XBRL: (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations, (iii) Condensed Statements of Comprehensive Loss, (iv) Condensed Statements of Changes in Stockholders' Equity, (v) Condensed Statements of Cash Flows and (vi) Notes to Condensed 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 management contract or compensatory plan or arrangement.

(1) The certifications on Exhibit 32 hereto are deemed not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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 8, 2022

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

Dated: August 8, 2022

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

AMENDMENT NO. 1 TO THE ASSET RETURN AND TERMINATION AGREEMENT

THIS AMENDMENT NO. 1 TO THE ASSET RETURN AND TERMINATION AGREEMENT (the "Amendment"), is effective as of the 31st day of May 2022 (the "Effective Date"), by and between **BAXALTA INCORPORATED**, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, with offices at 1200 Lakeside Drive, Bannockburn, IL 60015 ("BI"), **BAXALTA GmbH**, with offices located at Thurgauerstrasse 130, 8152 Glattpark-Opfikon (Zürich), Switzerland ("BGMBH"), **BAXALTA US Inc.**, with offices located at 1200 Lakeside Drive, Bannockburn, IL 60015 ("BUSI" and, together with BI and BGMBH, collectively, "Takeda") and **CTI BioPharma Corp. (F/k/a Cell Therapeutics, Inc.)** with offices located at 3101 Western Ave., #800, Seattle WA 98121 ("CTI"). For the purposes of this Amendment, each of Takeda and CTI may be referred to as a "Party" and together as the "Parties".

WHEREAS, Takeda and CTI have entered into that certain Asset Return and Termination Agreement with an effective date as of the 21st day of October 2016 and as may be amended (the "Agreement"); and

WHEREAS, the Parties now desire to amend the Agreement as of the Effective Date.

NOW THEREFORE, for and in exchange of the mutual promises contained herein and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the Parties hereto agree as follows:

1. The Parties acknowledge and agree that CTI has received accelerated approval of the drug product VONJO on February 28, 2022, and as a result, CTI was required under the Agreement to make a one-time payment of $10,290,687 to Takeda within 60 days following FDA approval of VONJO (the "Approval Payment"). CTI has not yet made the Approval Payment and the Parties are now agreeing to an amended payment schedule as set forth in this Amendment.

2. In consideration for the waiver of any breach under the Agreement arising from the failure to make the Approval Payment by April 29, 2022 (i.e., 60 days from the VONJO approval date), CTI now agrees to instead make a one-time approval payment in the sum of $10,290,687 by no later than March 15, 2023, with interest thereon in accordance with the milestone payment schedule in Annex 1 ("Milestone Payments") of this Amendment, which shall be made part of the Agreement as of the Amendment Effective Date. It will be considered a breach of this Amendment if CTI fails to make any of the Milestone Payments. On each interest payment date (or the next business day thereafter) CTI shall send Takeda a monthly statement of interest along with the interest payment, so that Takeda may verify the accuracy of the payments. In consideration for extending the payment due date, CTI agrees to pay the full amount due notwithstanding whether there is any further regulatory action related to VONJO (e.g. full FDA approval is granted or denied, VONJO is removed from the market for any reason, etc.). For sake of clarity, this means that CTI agrees to pay Takeda $10,290,687 by or before March 15, 2023, plus the interest described below, without any further conditions or requirements. Any late payments shall be subject to the interest rate set forth on Annex 1.

2. Except as otherwise set forth in this Amendment, all other terms and conditions of the Agreement shall remain in full force and effect. Each capitalized term used herein shall have the same meaning assigned to it in the Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed by their duly authorized representatives as of the Effective Date.

BAXALTA INCORPORATED

BY: _____

John Bathery

Name

Head, Business Development Operations

Title

CTI BioPharma Corp.

BY: _____

David Kirske

Name

Chief Financial Officer

Title

BAXALTA GmbH

BY: i.V. _____

Andrea Herrmann

Name

Authorised Signatory

Title

BAXALTA GmbH

BY: i.V. _____

Naomi de Roo

Name

Authorized Signatory

Title

BAXALTA US INC.

BY: _____

John Bathery

Name

Head, Business Development Operations

Title

ANNEX I
MILESTONE PAYMENTS

Payment Due Date	Payment Amount Due
July 1, 2022	• Three interest payments due (first payment originally due May 1, 2022; second payment due on June 1, 2022; and third interest payment due on July 1, 2022). • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 90-day period, plus two percent per annum.
August 1, 2022	• Fourth interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
September 1, 2022	• Fifth interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
October 1, 2022	• Sixth interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
November 1, 2022	• Seventh interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
December 1, 2022	• Eighth interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
January 1, 2023	• Ninth interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
February 1, 2023	• Tenth interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
March 1, 2023	• Eleventh interest payment due. • Amount to be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, over the prior 30-day period, plus two percent per annum.
March 15, 2023	• Full payment amount of $10,290,687 per the contract due on or before this date.

An additional payment penalty will apply to any payments not received by the due date as indicated above. Monthly penalty amount will be equal to the monthly interest due.

Exhibit 31.1

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 8, 2022

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

Exhibit 31.2

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 8, 2022

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

Exhibit 32

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam R. Craig, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of CTI BioPharma Corp., that, to my knowledge, the Quarterly Report of CTI BioPharma Corp. on Form 10-Q for the fiscal quarter ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of CTI BioPharma Corp.

A signed original of this written statement required by Section 906 has been provided to CTI BioPharma Corp. and will be retained by CTI BioPharma Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: August 8, 2022

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

I, David H. Kirske, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of CTI BioPharma Corp., that, to my knowledge, the Quarterly Report of CTI BioPharma Corp. on Form 10-Q for the fiscal quarter ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of CTI BioPharma Corp.

A signed original of this written statement required by Section 906 has been provided to CTI BioPharma Corp. and will be retained by CTI BioPharma Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: August 8, 2022

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