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: March 31, 2020

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**	**98121**
(Address of principal executive offices)	**(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 Capital Market

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

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

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

Large accelerated filer	☐	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 April 30, 2020
Common Stock, par value $0.001 per share	73,681,593

CTI BIOPHARMA CORP.

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PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,149	$ 31,144
Short-term investments	—	2,522
Prepaid expenses and other current assets	1,490	1,914
Total current assets	82,639	35,580
Property and equipment, net	1,102	1,235
Other assets	4,240	9,465
Total assets	$ 87,981	$ 46,280
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 905	$ —
Accrued expenses	6,565	11,606
Current portion of long-term debt	4,812	4,812
Other current liabilities	2,123	2,070
Total current liabilities	14,405	18,488
Long-term debt, less current portion	3,252	4,455
Other liabilities	4,295	5,407
Total liabilities	21,952	28,350
Commitments and contingencies		
Mezzanine equity:		
Series X Preferred Stock, 4,429 shares and 0 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively (Aggregate liquidation preference of $44,290 and $0 as of March 31, 2020 and December 31, 2019, respectively)	43,645	—
Stockholders' equity:		
Preferred stock, $0.001 par value per share:		
Authorized shares - 33,333		
Series O Preferred Stock, 12,575 shares issued and outstanding as of March 31, 2020 and December 31, 2019 (Aggregate liquidation preference of $25,150 as of March 31, 2020 and December 31, 2019)	—	—
Common stock, $0.001 par value per share:		
Authorized shares - 131,500,000 as of March 31, 2020 and December 31, 2019		
Issued and outstanding shares - 73,681,593 and 57,979,725 as of March 31, 2020 and December 31, 2019, respectively	74	58
Additional paid-in capital	2,315,810	2,299,186
Accumulated other comprehensive loss	(11,993)	(11,993)
Accumulated deficit	(2,275,749)	(2,263,563)
Total CTI stockholders' equity	28,142	23,688
Noncontrolling interest	(5,758)	(5,758)
Total stockholders' equity	22,384	17,930
Total liabilities, mezzanine equity and stockholders' equity	$ 87,981	$ 46,280

See accompanying notes.

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

	Three Months Ended March 31,	
	2020	**2019**
License and contract revenues	$ —	$ 640
Operating costs and expenses:		
Research and development	3,264	5,172
General and administrative	4,467	5,206
Restructuring expenses	—	794
Other operating expenses	4,200	—
Total operating costs and expenses	11,931	11,172
Loss from operations	(11,931)	(10,532)
Non-operating income (expense):		
Interest income	119	380
Interest expense	(167)	(294)
Amortization of debt discount and issuance costs	(130)	(130)
Foreign exchange loss	(77)	(238)
Total non-operating expense, net	(255)	(282)
Net loss	$ (12,186)	$ (10,814)
Basic and diluted net loss per common share	$ (0.20)	$ (0.19)
Shares used in calculation of basic and diluted net loss per common share	62,461	57,973

See accompanying notes.

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

	Three Months Ended March 31,	
	2020	2019
Net loss before noncontrolling interest	$ (12,186)	$ (10,814)
Other comprehensive income (loss):		
Foreign currency translation adjustments	—	662
Unrealized foreign exchange loss on intercompany balance	—	(679)
Net unrealized gain on available-for-sale securities	—	26
Other comprehensive income	—	9
Comprehensive loss	(12,186)	(10,805)
Comprehensive loss attributable to noncontrolling interest	—	—
Comprehensive loss attributable to CTI	$ (12,186)	$ (10,805)

See accompanying notes.

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

	Series O Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Noncontrolling	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Interest	Equity
Balance at January 1, 2020	13	$ —	57,980	$ 58	$ 2,299,186	$ (11,993)	$ (2,263,563)	$ (5,758)	$ 17,930
Issuance of common stock, net of issuance costs	—	—	15,699	16	15,454	—	—	—	15,470
Conversion of Series X preferred stock to common stock	—	—	3	—	3	—	—	—	3
Equity-based compensation	—	—	—	—	1,167	—	—	—	1,167
Net loss	—	—	—	—	—	—	(12,186)	—	(12,186)
Balance at March 31, 2020	13	$ —	73,682	$ 74	$ 2,315,810	$ (11,993)	$ (2,275,749)	$ (5,758)	$ 22,384

	Series O Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Noncontrolling	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Interest	Equity
Balance at January 1, 2019	13	$ —	57,986	$ 58	$ 2,294,025	$ (10,643)	$ (2,224,746)	$ (5,755)	$ 52,939
Cumulative effect adjustments	—	—	—	—	(7)	—	1,203	—	1,196
Equity-based compensation	—	—	(7)	—	1,257	—	—	—	1,257
Net loss	—	—	—	—	—	—	(10,814)	—	(10,814)
Other comprehensive income	—	—	—	—	—	9	—	—	9
Balance at March 31, 2019	13	$ —	57,979	$ 58	$ 2,295,275	$ (10,634)	$ (2,234,357)	$ (5,755)	$ 44,587

See accompanying notes.

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

	Three Months Ended March 31,	
	2020	**2019**
Operating activities		
Net loss before noncontrolling interest	$ (12,186)	$ (10,814)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	1,167	1,257
Depreciation and amortization	133	140
Provision for Italian VAT receivables and deposit	4,200	—
Other	(38)	215
Changes in operating assets and liabilities:		
Receivables from license and development services arrangements	—	12,846
Prepaid expenses and other assets	1,038	972
Accounts payable, accrued expenses and other liabilities	(4,756)	(8,072)
Net cash used in operating activities	(10,442)	(3,456)
Investing activities		
Proceeds from maturities of short-term investments	2,500	9,000
Net cash provided by investing activities	2,500	9,000
Financing activities		
Proceeds from rights offering, net of issuance costs	59,280	—
Principal payments on debt	(1,333)	(1,333)
Cash paid for at-the-market equity offering costs	—	(45)
Net cash provided by (used in) financing activities	57,947	(1,378)
Effect of exchange rate changes on cash and cash equivalents	—	(12)
Net increase in cash and cash equivalents	50,005	4,154
Cash and cash equivalents at beginning of period	31,144	36,439
Cash and cash equivalents at end of period	$ 81,149	$ 40,593
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 179	$ 301

See accompanying notes.

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

1. Description of Business and Summary of Significant Accounting Policies

CTI BioPharma Corp., together with its subsidiary, also referred to collectively in this Quarterly Report on Form 10-Q as "we," "us," "our," the "Company" and "CTI," is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers that offer a unique benefit to patients and their healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis.

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

Basis of Presentation

The accompanying unaudited financial information as of and for the three months ended March 31, 2020 and 2019 has been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to 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 date and the operating results and cash flows for such periods. Operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the entire year or for any other subsequent interim period.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or the SEC. These unaudited financial statements and related notes should be read in conjunction with our audited financial statements for the year ended December 31, 2019 included in our Annual Report on Form 10-K filed with the SEC on March 13, 2020.

The condensed consolidated balance sheet at December 31, 2019 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the U.S. for complete financial statements.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of CTI and its wholly-owned subsidiary, CTI Life Sciences Limited, or CTILS, until its dissolution in November 2019. As of March 31, 2020, we also had an approximately 60% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. The remaining interest in Aequus not held by CTI is reported as *noncontrolling interest* in the condensed consolidated financial statements.

All intercompany transactions and balances are eliminated in consolidation.

Use of Estimates

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

Liquidity

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

We will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, are expected to result in operating losses for the foreseeable future. In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Development, Commercialization and License Agreement, or the Pacritinib License Agreement, with Baxalta and are no longer eligible to receive cost sharing or milestone payments for pacritinib's development. We have incurred a net operating loss every year since our formation. As of March 31, 2020, we had an accumulated deficit of $2.3 billion, and we expect to continue to incur net losses for the foreseeable future.

Our available *cash and cash equivalents* were $81.1 million as of March 31, 2020. We completed the evaluation about our ability to continue as a going concern as required by 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.* Based on this analysis, we expect that our present financial resources will be sufficient to meet our obligations as they come due and to fund our operations into the fourth quarter of 2021.

We will need to acquire additional funds in order to develop our business and continue the development of pacritinib. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding obtained through the sale of such shares or otherwise may not be sufficient, 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, reduce our general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. The amount of financing we require is dependent on many factors, such as the number of clinical trial sites, the number of patients in a trial, the pace of patient enrollment and other matters that may impact clinical development, including changes to a trial that we may initiate or that may be requested by the FDA or other regulators, and there can be no assurance as to the amount of funding necessary to fund the development of pacritinib to completion. In addition, our ability to comply with covenants under the loan and security agreement with Silicon Valley Bank, or SVB, may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants, including a material adverse change in our business, operations or condition (financial or otherwise) could result in an event of default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable. The accompanying condensed consolidated financial statements do not include adjustments, if any, that may result from the outcome of this uncertainty.

Cash, Cash Equivalents and Short-term Investments

As of March 31, 2020 and December 31, 2019, our cash, cash equivalents and short-term investments consisted of cash, money market funds, U.S. government and agency securities and corporate debt securities. Cash equivalents and short-term investments are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

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

We measure the fair value of money market funds based on the closing price reported by a 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 March 31, 2020 and December 31, 2019. 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):

	March 31, 2020		December 31, 2019
	Cost or Amortized Cost	Total Estimated Fair Value	Total Estimated Fair Value
Cash	$ 343	$ 343	$ 188
Level 1 securities:			
Money market funds	80,806	80,806	28,957
Level 2 securities:			
U.S. government and agency securities	—	—	2,522
Corporate debt securities	—	—	1,999
Total cash, cash equivalents and short-term investments	$ 81,149	$ 81,149	$ 33,666

Italian Value Added Tax Receivable

We historically carried out research and development activities in Italy and incurred value added tax, or VAT, from Italian suppliers on the acquisition of goods and services in Italy. This VAT should be considered as an input VAT credit. We treated the majority of our sales made in Italy without output VAT (on the basis that the supplies should be considered outside the scope of Italian VAT). This resulted in the value of input VAT exceeding the value of output VAT, and accordingly we submitted a refund claim for the VAT. The Italian Tax Authority, or the ITA, has challenged the treatment of the sales transactions and claimed that the sales transactions made by us should have been subject to output VAT. Our Italian VAT receivable was approximately €3.9 million as of March 31, 2020 and December 31, 2019. While we believe that our refund claim is valid, we have concluded that the recent COVID-19 global pandemic negatively impacted the collectability of our Italian VAT receivables and deposit. Accordingly, we have recorded a full provision against our Italian VAT receivables and deposit outstanding as of March 31, 2020 in the amount of $4.2 million, which is included in *Other operating expenses* for the three months ended March 31, 2020.

In addition, as disclosed in Note 5. Contingencies, the ITA assessed us for additional VAT payments for services we provided in Italy, which we do not believe we owe. We have not recorded an amount in the financial statements for this contingent liability as we do not believe the potential payment of up to €4.3 million (or approximately $4.8 million converted using the currency exchange rate as of March 31, 2020), to the ITA is probable at this time.

Leases

Under ASC 842 - *Leases*, we determine if an arrangement is a lease at inception. We recognize a right-of-use asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as operating or finance at lease commencement, which will affect the pattern and classification of expense recognition in our condensed consolidated statements of operations.

Right-of-use assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our leases do not provide a readily determinable implicit rate of return, we use our incremental borrowing rate to derive the present value of lease payments, which is the rate of interest that we would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

An operating lease right-of-use asset is measured at the amount of the lease liability, adjusted for prepaid or accrued lease payments, lease incentives received, unamortized initial direct costs and the impairment of the right-of-use asset. A lease may include options to extend or terminate the lease. When it is reasonably certain that we will exercise such an option, it is considered in the lease term. Right-of-use assets are tested for impairment in the same manner as long-lived assets used in operations. Leasehold improvements are capitalized at cost and amortized over the lesser of their expected useful life or the lease term.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as part of *Research and development* expenses and *General and administrative* expenses in our condensed consolidated statements of operations. Right-of-use assets are included in *Other assets*, and the current portion of lease liabilities and the non-current portion of lease liabilities are included in *Other current liabilities* and *Other liabilities*, respectively, in our condensed consolidated balance sheets.

Accumulated Other Comprehensive Loss

As of March 31, 2020 and December 31, 2019, the balance of accumulated other comprehensive loss was related to foreign currency translation adjustments.

Equity-based Compensation

Equity-based compensation expense is recognized over the requisite service periods on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, 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. For the three months ended March 31, 2020 and 2019, we recorded equity-based compensation expense of $1.2 million and $1.3 million, respectively. Substantially all of equity-based compensation expense was related to option awards and was included in *General and administrative* expenses for the periods presented.

Net Loss per Share

Basic net loss per share is calculated based on the net loss attributable to common stockholders divided by the weighted average number of our common shares outstanding for the period. Diluted net income per share assumes the conversion of all dilutive convertible securities using the if-converted method and assumes the exercise or vesting of other dilutive securities, such as warrants and stock awards, using the treasury stock method. In periods when we have a net loss, stock awards, warrants and convertible securities are excluded from our calculation of net loss per share as their inclusion would have an anti-dilutive effect.

Common shares underlying stock awards, warrants and convertible preferred stock aggregating 29.6 million shares and 16.9 million shares for the three months ended March 31, 2020 and 2019, respectively, were excluded from the calculation of diluted net loss per share because they were anti-dilutive.

Recently Adopted Accounting Standards

In August 2018, the FASB issued new accounting guidance which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. We adopted this guidance on January 1, 2020. The adoption of this accounting guidance did not have a material impact on our condensed consolidated financial statements.

Recently Issued Accounting Standards

In June 2016, the FASB issued new accounting guidance which amends the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans and other financial instruments, the standard requires the use of a new forward-looking "expected credit loss" model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. We do not expect the adoption of this accounting guidance to have a material impact on our condensed consolidated financial statements.

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

2. Other Assets

Other assets consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Right-of-use assets	$ 3,088	$ 3,379
Italian VAT receivables, net	—	4,390
Italian VAT deposit, net	—	483
Clinical trial deposits	720	720
Refundable security deposit	194	194
Other	238	299
Other assets	$ 4,240	$ 9,465

During the three months ended March 31, 2020, we recorded full provisions against our Italian VAT receivables and deposit outstanding as of March 31, 2020. See Note 1. Description of Business and Summary of Significant Accounting Policies - *Italian Value Added Tax Receivable* for further details.

3. Other Liabilities

Other liabilities consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Lease liabilities, non-current	$ 2,480	$ 2,993
End-of-facility lender fee	1,440	1,440
Other long-term obligations	375	974
Total other liabilities	$ 4,295	$ 5,407

End-of-facility lender fee as of March 31, 2020 and December 31, 2019 represents an amount payable to Silicon Valley Bank upon repayment of our secured term loan. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 7. Long-term Debt" of our Annual Report on Form 10-K for the year ended December 31, 2019 for additional information.

4. Equity Transactions

In March 2020, we completed a rights offering through the distribution of subscription rights to holders of our common stock and Series O Preferred Stock, or the Rights Offering. Under the Rights Offering, we issued a total of 15.7 million shares of our common stock and 4,429 shares of our Series X Preferred Stock, which shares of Series X Preferred Stock are convertible into 44.3 million shares of our common stock, for aggregate gross proceeds of approximately $60.0 million. Total offering costs were approximately $0.9 million. There was no beneficial conversion feature on our Series X Preferred Stock. Due to the revocable nature of the Rights Offering prior to closing, there was no separate accounting for the subscription rights and purchase guarantees made by certain of our stockholders prior to the closing date.

As of March 31, 2020, since we do not have an adequate number of authorized common stock to satisfy the number of required shares under the conversion option of our Series X Preferred Stock, the carrying amount of Series X Preferred Stock has been classified as mezzanine equity in the condensed consolidated balance sheet until such time that our stockholders approve an increase in the number of authorized common shares so that settlement of the conversion option's exercise can be controlled.

During the three months ended March 31, 2020, 0.2873 of a share of our Series X Preferred Stock converted into 2,873 shares of our common stock. There were 4,429 shares of our Series X Preferred Stock outstanding as of March 31, 2020.

Each share of our Series X Preferred Stock has a stated value of $10,000 per share and is convertible into 10,000 shares of our common stock at the option of the holder at any time except as described above; subject to certain limitations, including, that the holder will be prohibited from converting Series X Preferred Stock into common stock, if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock. In the event of our liquidation, dissolution or winding up, holders of Series X Preferred Stock will participate *pari passu* with any distribution of proceeds to holders of our common stock and holders of our Series O Preferred Stock. Holders of our Series X Preferred Stock are also entitled to receive

dividends on shares of Series X Preferred Stock equal (on an as-if-converted-to common stock basis) to and in the same form as dividends actually paid on our common stock or other junior securities of the Company. Shares of Series X Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series X Preferred Stock will be required to amend the terms of the Series X Preferred Stock.

5. Contingencies

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI - Sede Secondaria, or CTI (Europe), based on the ITA's audit of CTI (Europe)'s value added tax, or VAT, returns for the years 2003, 2005, 2006 and 2007, or, collectively, the VAT Assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2006 and 2007 are €0.6 million, €2.8 million and €0.9 million, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have appealed all of the assessments and are defending ourselves against the assessments both on procedural grounds and on the merits of the cases, although we can make no assurances regarding the ultimate outcome of these cases. There have been no changes to the status of the legal proceedings surrounding each respective VAT year return at issue since the filing of our Annual Report on Form 10-K for the year ended December 31, 2019. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 16. Commitments and Contingencies" of our Annual Report on Form 10-K for the year ended December 31, 2019 for additional information.

If the final decision of the Italian Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to €4.3 million, or approximately $4.8 million converted using the currency exchange rate as of March 31, 2020, including interest and penalties for the period lapsed between the date in which the assessments were issued and the date of effective payment. We have not recorded this contingent liability in the financial statements as we do not believe the potential payment to the ITA is probable at this time.

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

This Quarterly Report on Form 10-Q may contain "forward-looking statements" within the meaning of the United States federal securities laws. All statements other than statements of historical fact are forward-looking statements, including, without limitation:

- our expectations regarding business disruptions and related risks resulting from the recent worldwide coronavirus pandemic known as COVID-19;
- our expectations regarding sufficiency of cash resources, cash expenditures, sources of cash flows and other projections, product manufacturing and sales, research and development expenses, general and administrative expenses and additional losses;
- our ability to obtain funding for our operations;
- the timing of, and our ability to develop, commercialize, and obtain regulatory approval of pacritinib and other development programs we may pursue in the future;
- the design of our clinical trials and anticipated enrollment, and the progress and potential of pacritinib and other development programs we may pursue in the future;
- the safety, effectiveness and potential benefits and indications of pacritinib and any other product candidates we may develop in the future;
- the timing of and results from clinical trials and pre-clinical development activities, including those related to pacritinib and any other product candidates we may develop in the future;
- our ability to advance product candidates, including pacritinib and any other product candidates we may develop in the future, into and successfully complete clinical trials;
- our ability to achieve profitability, including our ability to effectively implement cost reduction strategies and realize anticipated cost savings from those efforts;
- our expectations regarding federal, state and foreign regulatory requirements;
- the rate and degree of market acceptance and clinical utility of pacritinib or any other product candidates we may develop in the future;
- our and our collaborators' ability to obtain and maintain regulatory approvals for pacritinib or any other product candidates we may develop in the future, and the timing of such approvals;
- our ability to maintain and establish collaborations;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the impact of government laws and regulations;
- our ability to negotiate, integrate, and implement collaborations, acquisitions and other strategic transactions;
- our ability to engage and retain the employees required to advance our development activities and grow our business;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- those risk factors identified in this Quarterly Report on Form 10-Q under the heading Risk Factors and in other filings we periodically make with the U.S. Securities and Exchange Commission, or the SEC.

In some cases, forward-looking statements can be identified by terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should" or "will" or the negative thereof, variations thereof and similar expressions. 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, 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, 2019 and any risk factors contained in our subsequent Quarterly Reports on Form 10-Q that we file with the SEC.

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

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

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

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers that offer a unique benefit to patients and their healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis.

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development, as well as inflammatory cytokine expression and immune responses. Mutations in these kinases have been shown to be directly related to the development of a variety of blood-related cancers, including myeloproliferative neoplasms, leukemia and lymphoma. In addition to myelofibrosis, the kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as acute myeloid leukemia, or AML, myelodysplastic syndrome, or MDS, chronic myelomonocytic leukemia, or CMML, and chronic lymphocytic leukemia, or CLL, due to its inhibition of c-fms, IRAK1, JAK2 and FLT3. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

In January 2020, we had a Type A meeting with the FDA and reached an agreement on the final design changes to our PACIFICA pivotal Phase 3 clinical trial, including changes to the statistical analysis plan that would allow for an accelerated approval pathway for pacritinib. We have amended our PACIFICA Phase 3 trial protocol to allow for the primary analysis of SVR rates on the first 168 patients, with an end-of-study analysis of TSS and OS following the full enrollment of 348 patients. If the primary endpoint of SVR is met following the planned review of data from the first 168 patients, we intend to submit an NDA under the FDA's regulations for the Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, 21 C.F.R. subpart H, subject to review of all available efficacy and safety data. Conversion to a regular approval of pacritinib would be anticipated following a statistically significant successful end-of-study assessment of the secondary efficacy endpoint of TSS, no survival detriment for the pacritinib arm and the completion of post-marketing requirements. We previously anticipated reporting primary SVR data by the end of 2021 with a potential NDA filing in early 2022 and final study efficacy data expected in 2023; however, as a result of the worldwide coronavirus pandemic known as COVID-19, we currently anticipate at least a three-month delay in the PACIFICA Phase 3 trial timeline.

In April 2020, in response to the public health crisis due to the global COVID-19 pandemic, we initiated PRE-VENT, a Phase 3 study evaluating pacritinib in hospitalized non-cancer and cancer patients with severe COVID-19. PRE-VENT, a randomized, double-blind, placebo-controlled multicenter study will compare pacritinib plus standard of care, or SOC, versus placebo plus SOC in hospitalized patients with severe COVID-19, including those with a current or prior diagnosis of cancer. The primary endpoint of the trial will assess the proportion of patients who progress to invasive mechanical ventilation and/or

extracorporeal membrane oxygenation or die by Day 28. We expect to commence enrollment of PRE-VENT in the second quarter of 2020 at sites in the United States and in Europe.

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

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

We face numerous risks in connection with clinical development of pacritinib generally and with respect to attempts to expedite the FDA regulatory approval process specifically. For more information, see Item 1A-Risk Factors-Risks Related to the Development, Clinical Testing and Regulatory Approval of Our Product Candidates.

We have historically funded our operations through the sale of equity securities, funding received from our licensees and collaborators and debt financing. For the three months ended March 31, 2019, we recognized revenues of approximately $0.6 million consisting of license and contract revenues, while no revenue was recognized during the three months ended March 31, 2020. We do not expect to achieve or sustain profitability for the foreseeable future. We had a net loss of $12.2 million for the three months ended March 31, 2020 and an accumulated deficit of $2.3 billion as of March 31, 2020, primarily from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations. We believe that our cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into the fourth quarter of 2021. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

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

Factors Affecting Performance

Research and Development Activities

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

Additionally, we continue to evaluate and manage the impact of the COVID-19 global pandemic on our operations and the conduct of our clinical trials, including considerations of the vulnerable nature of the patient population participating in our trials, reduced or halted activities at our clinical trial sites, and an increase in fatalities or other adverse events due to medical problems related to the COVID-19 global pandemic and the benefits of continued patient access to pacritinib. Even after a

clinical trial is enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process.

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

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

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in our risk factors, which can be found in Part II, Item 1A, "Risk Factors" of this report.

Financial Summary

Our license and contract revenues reflect the earned amount of upfront payments and milestone payments under our product collaborations. Total revenues were $0.6 million for the three months ended March 31, 2019 while there was no revenue for the three months ended March 31, 2020. Loss from operations was $11.9 million and $10.5 million for the three months ended March 31, 2020 and 2019, 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 March 31, 2020, cash and cash equivalents were $81.1 million.

RESULTS OF OPERATIONS

Three months ended March 31, 2020 and 2019

License and Contract Revenues

License and contract revenues are summarized as follows (in thousands):

		Three Months Ended March 31,	
		2020	2019
Servier	Development services revenue	$ —	$ 99
	Royalty revenue	—	162
	Other revenue	—	379
Total		$ —	$ 640

License and contract revenue for the three months ended March 31, 2019 includes $0.1 million of development services revenue relating to the reimbursement of certain regulatory agency costs under the terms of the Amended and Restated Exclusive License and Collaboration Agreement, or the Restated Agreement, with Servier. Other revenue of $0.4 million for the three months ended March 31, 2019 was related to transition period activities pursuant to the terms of the Termination and Transfer Agreement with Servier.

Operating costs and expenses

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

	Three Months Ended March 31,	
	2020	2019
Compounds:		
Pacritinib	$ 1,735	$ 3,164
PIXUVRI	—	575
Unallocated operating expenses	1,529	1,429
Research and preclinical development	—	4
Total research and development expenses	$ 3,264	$ 5,172

Costs for our compounds include external direct expenses such as principal investigator fees, charges from contract research organizations, or CROs, and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, the EMA or other regulatory agencies outside the United States and Europe, as well as upfront license fees for acquired technology. Operating expenses include our personnel costs and an allocation of occupancy, depreciation and amortization expenses associated with developing these compounds. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us as of March 31, 2020 were $164.7 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S*BIO in May 2012 and $29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S*BIO). We do not anticipate incurring additional expenses related to PIXUVRI as the Restated Agreement with Servier was terminated in February 2019, and all of our rights and responsibilities for PIXUVRI were transferred and assigned globally to Servier pursuant to the Asset Purchase Agreement with Servier during the year ended December 31, 2019.

Research and development expenses were $3.3 million for the three months ended March 31, 2020 compared to $5.2 million for the same period in 2019. The decrease between the three-month periods ended March 31, 2020 and 2019 was primarily attributable to a $1.4 million overall decrease in pacritinib development costs from the completion of PAC203 dosing clinical trial in 2019 as well as a $0.6 million decrease related to PIX306 clinical study close-out in 2019, partially offset by a $0.1 million increase in unallocated operating expenses.

General and administrative expenses. General and administrative expenses were $4.5 million for the three months ended March 31, 2020 compared to $5.2 million for the same period in 2019. The decrease between periods was primarily attributable to a $0.6 million decrease in professional and consulting services as well as a $0.1 million decrease in personnel costs and other administrative expenses.

Restructuring expenses. In December 2018, we announced a plan to reduce our workforce in order to improve efficiencies, reduce costs within the organization and preserve capital for pacritinib development. For the three months ended March 31, 2019, we recorded $0.8 million of restructuring expenses related to employee separation costs. There were no such restructuring expenses for the same period in 2020 as we fully recognized expenses during the year ended December 31, 2019.

Other operating expense. Other operating expense of $4.2 million for the three months ended March 31, 2020 relates to provisions for our Italian VAT receivables and deposit. See Part 1, Item 1, Note 1. Description of Business and Summary of Significant Accounting Policies - *Italian Value Added Tax Receivable* for further details. There was no such expense for the same period in 2019.

Non-operating income and expenses

Interest income. Interest income was $0.1 million and $0.4 million for the three months ended March 31, 2020 and 2019, respectively. The $0.3 million reduction was primarily related to a decrease in our daily average balances of short-term investments and cash equivalent for the three months ended March 31, 2020 compared to the same period in 2019.

Interest expense. Interest expense was $0.2 million and $0.3 million for the three-month periods ended March 31, 2020 and 2019, respectively, and was related to our secured term loan. The change between periods primarily relates to a lower

average loan principal balance outstanding during the three months ended March 31, 2020 compared to the same period in 2019.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of $0.1 million for each of the three months ended March 31, 2020 and 2019 related to amortization of issuance costs and a discount recorded on our secured term loans.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We have funded our operations from proceeds from sales and issuance of equity securities, payments pursuant to license and collaboration agreements and the incurrence of debt. As of March 31, 2020, we had $81.1 million in cash and cash equivalents.

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

Common Stock Offering. In February 2018, we offered and sold 23.0 million shares of common stock at a $3.00 per share price. The net proceeds from the offering, after deducting underwriting commissions and discounts and other offering costs were approximately $64.2 million.

Loan Agreement. In November 2017, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, which agreement was amended in May 2018, the proceeds of which were partially used to repay in full all outstanding indebtedness under our Loan and Security Agreement, dated March 26, 2013, as amended, with Hercules Technology Growth Capital, Inc., or Hercules (and certain of its affiliates). As of March 31, 2020, we had an outstanding principal balance under our secured term loan agreement of $8.9 million. We are required to pay interest plus principal payments in the approximate amount of $0.5 million per month until November 1, 2021, with the final principal plus interest payment totaling approximately $0.4 million as well as a back-end fee of $1.4 million. These borrowings are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions. In addition, the secured term loan agreement requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required loan payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

Historical Cash Flows

Net cash used in operating activities. Net cash used in operating activities increased to $10.4 million during the three months ended March 31, 2020 compared to $3.5 million for the same period in 2019. During the three months ended March 31, 2019, we received €3.0 million (or $3.3 million using the currency exchange rate as of the date of cash receipt) relating to the attainment of a regulatory milestone in November 2018 under the Restated Agreement with Servier and also collected $10.0 million from Teva relating to the December 2018 achievement of a worldwide net sales milestone of TRISENOX. The overall change in net cash used in operating activities was primarily due to these cash receipts in 2019, partially offset by a decrease in payments for operating expenses between periods.

Net cash provided by investing activities. Net cash provided by investing activities was $2.5 million and $9.0 million during the three months ended March 31, 2020 and 2019, respectively. The change was due to the amounts of short-term investments matured between periods.

Net cash provided by (used in) financing activities. Net cash provided by financing activities was $57.9 million during the three months ended March 31, 2020, while net cash used in financing activities was $1.4 million for the same period in 2019. The change was primarily attributable to the net proceeds from the completion of our rights offering in March 2020.

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement. We currently have no commitments for additional financing to fund the development and commercial launch of pacritinib, and we may need to seek additional funding. The development and commercialization of a major product candidate like pacritinib without a collaborative partner will require a substantial amount of our time and financial resources, and as a result, we could experience a decrease in our liquidity and a new demand on our

capital resources. For additional information relating to the Pacritinib License Agreement, see Part I, Item 1, “Business - License Agreements - Baxalta” of our Annual Report on Form 10-K for the year ended December 31, 2019.

Capital Resources

We have prepared our condensed consolidated financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. We believe that, as of the date of the filing of this Quarterly Report on Form 10-Q, our present financial resources will be sufficient to fund our operations into the fourth quarter of 2021. However, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for pacritinib. Because of our reacquisition of worldwide rights for pacritinib, we are no longer eligible to receive cost sharing or milestone payments for pacritinib’s development from Baxalta, and losses related to research and development for pacritinib have increased. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of March 31, 2020, our available cash, cash equivalents and short-term investments totaled $81.1 million. We had an outstanding principal balance under our secured term loan agreement of $8.9 million.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, developments in and expenses associated with our clinical trials and the other factors identified under “*Capital Requirements*” below may consume capital resources earlier than planned. Additionally, following our and Servier’s mutual termination of our collaborative agreement, we are no longer eligible to receive additional revenues or payments from Servier relating to PIXUVRI. Although we received a $10.0 million milestone payment from Teva in February 2019, which was recognized as revenue in 2018, relating to the achievement of a worldwide net sales milestone of TRISENOX, the achievement of the remaining milestones is uncertain at this time. Due to these and other factors, the foregoing forecast for the period for which we will have sufficient resources to fund our operations may be inaccurate.

Capital Requirements

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

- disruptions or other delays to our business and clinical trials resulting from the recent worldwide coronavirus pandemic known as COVID-19;
- developments in and expenses associated with our research and development activities;
- changes in manufacturing;
- our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators;
- regulatory approval developments;
- our ability to generate sales of any approved product;
- our ability to execute appropriate collaborations for development and commercialization activities;
- our ability to reach milestones triggering payments under certain of our contractual arrangements;
- acquisitions of compounds or other assets;

- litigation and other disputes;
- competitive market developments; and
- other unplanned business developments.

LICENSE AGREEMENTS AND MILESTONE ACTIVITIES

For information regarding our license agreements and milestone activities, please see Part I, Item 1, “Business - License Agreements” of our Annual Report on Form 10-K for the year ended December 31, 2019.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in conformity with GAAP requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses and related disclosure in the preparation of our condensed consolidated financial statements and accompanying notes. Our critical accounting policies are those that significantly impact our financial condition and results of operations and require the most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of this uncertainty, actual results may vary from these estimates. For a discussion of our critical accounting estimates, please see Part II, Item 7, "Management’s Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2019. There have been no material changes to our critical accounting policies and estimates discussed therein.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or 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

During the first fiscal quarter ended March 31, 2020, we completed the implementation of an enterprise resource planning (ERP) system. In connection with this ERP implementation, we updated our internal controls to accommodate changes to our business processes and accounting procedures.

Except as otherwise described above, there have been no other changes to our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) that occurred during the first fiscal quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

See Part I, Item 1, "Notes to Condensed Consolidated Financial Statements, Note 5. Contingencies" of this report and Part I, Item 3, “Legal Proceedings” of our Annual Report on Form 10-K for the year ended December 31, 2019 for information regarding material pending legal proceedings.

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. The occurrence of any of the risks described below and elsewhere in this document, including the risk that our actual results may differ materially from those anticipated in these forward-looking statements, 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.

Risks Related to Our Business

We expect to continue to incur net losses, and we may never achieve profitability.

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of March 31, 2020, we had an accumulated deficit of $2.3 billion, and we expect to continue to incur net losses. As part of our business plan, we will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, is expected to result in operating losses for the foreseeable future. There can be no assurances that we will ever achieve profitability.

Our prospects are dependent on the successful development, regulatory approval and commercialization of pacritinib and we may be unsuccessful in such efforts.

Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize pacritinib. Pacritinib, our sole product candidate in active development through our PACIFICA Phase 3 trial and our PRE-VENT Phase 3 trial, has not yet received regulatory approval. Our ability to discover and develop drug candidates and to commercialize additional drug products will depend on our ability to:

- hire and retain key employees;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;
- identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;
- complete laboratory testing;
- commence, conduct and complete safe and effective clinical trials on humans;
- obtain and maintain necessary intellectual property rights to our product candidates;
- obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;
- enter into arrangements with third parties to provide services or to manufacture our product candidates on our behalf;
- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions in compliance with all applicable laws; and

- obtain appropriate coverage and reimbursement levels for the cost of our products from governmental authorities, private health insurers and other third-party payors.

We have limited experience with many of the activities listed above and may not be successful in discovering, developing, or commercializing product candidates. Discovery and development of drug candidates are expensive, uncertain and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. Of the compounds that we identify as potential drug products or that we may in-license from other companies, only a few, if any, are likely to lead to successful drug development programs and commercialized drug products.

In addition, obtaining regulatory approval requires substantial time, effort and financial resources, and without additional financing, we lack sufficient resources to pursue the development of pacritinib. We currently have no commitments or arrangements for any additional financing to fund the development and commercial launch of pacritinib, and we will need to seek additional funding, which may not be available or may not be available on favorable terms. The amount of financing we require is dependent on many factors, such as the number of clinical trial sites, the number of patients in the trial, the pace of patient enrollment and other matters that may impact clinical development, including changes to the trial that we may initiate or that may be requested by the FDA or other regulators, and there can be no assurance as to the amount of funding necessary to fund the development of pacritinib to completion. We could also seek another collaborative partnership for the development and commercialization of pacritinib, which may not be available on reasonable terms or at all. If we partner pacritinib, we may have to relinquish valuable economic rights and would potentially forgo additional economic benefits that could be realized if we continued the development and commercialization activities alone. Even if pacritinib receives approval from the FDA, EMA or other regulatory authorities for one or more indications, we would need to incur significant expenses to support the commercialization and launch of pacritinib, which investment may never be realized if sales are insufficient. As our sole product candidate in active development, our prospects are dependent upon the successful development, approval and commercialization of pacritinib. If we fail to obtain regulatory approval and successfully commercialize pacritinib, our business would be materially and adversely impacted as we have no other product candidates in active clinical development.

Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 global pandemic, in regions where third parties for which we rely, as in CROs, have clinical trial sites or other business operations and may result in significant disruptions to our clinical trials, which could have a material adverse effect on our business.

Our business has been adversely affected and may continue to be adversely affected by the effects of health epidemics, including the recent worldwide COVID-19 pandemic, in regions where we have clinical trial sites or other business operations and has resulted in and may continue to result in significant disruptions to our clinical trials. On January 30, 2020, the World Health Organization (WHO) announced a global health emergency because of a new strain of novel coronavirus originating in Wuhan, China and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO declared the coronavirus outbreak a pandemic, which virus has spread throughout the world, including to geographies where we are conducting the PACIFICA Phase 3 trial and the PRE-VENT Phase 3 trial. Further, the President of the United States declared the COVID-19 pandemic a national emergency. Similarly, numerous states have declared a state of emergency related to the spread of COVID-19 and/or issued executive orders directing all individuals living in their respective states to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic. The spread of this pandemic has caused significant volatility and uncertainty in U.S. and international markets. This has resulted in an economic downturn and may disrupt our business and delay our clinical trials and timelines.

Quarantines, shelter-in-place and similar government orders have been enacted in each of the geographies in which we are conducting our clinical trials and such orders, shutdowns or other restrictions on the conduct of business operations could continue to remain in place for extended periods of time, thereby further affecting our clinical trials. The patient populations that are eligible for our clinical trials are immune-compromised and are at higher risk for becoming infected with COVID-19. As COVID-19 affects the parts of the world where we are conducting our clinical trials, and the patients involved with these clinical trials become infected with COVID-19, we may have more AEs and deaths in our clinical trials as a result.

We have faced and may continue to face difficulties enrolling patients in our clinical trials as the patient populations that are eligible for our clinical trials are impacted by COVID-19. Patient enrollment may be further delayed due to the diversion of healthcare resources, such as hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, away from the conduct of clinical trials, toward the COVID-19 pandemic.

Additionally, if our clinical trial patients are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from COVID-19, we may experience higher drop-out rates or delays in our clinical trials. Similarly, we may struggle to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have

heightened exposure to COVID-19. Any such delays in enrollment hinder our ability to obtain clinical data on the schedule we currently predict.

Travel restrictions continue to be implemented throughout the world in an effort to contain COVID-19, and several countries have expanded screenings of travelers.

We may experience additional disruptions due to the COVID-19 pandemic that could severely impact our business and clinical trials, including:

- evidence from the PRE-VENT Phase 3 trial showing increased adverse events in trial participants, which could affect the safety profile and/or acceptability of our application to the FDA;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- refusal of the FDA to accept data from clinical trials in affected geographies; and

- interruption or delays to our sourced discovery and clinical activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials, which could prevent or delay us from obtaining approval for pacritinib.

We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them.

Competition in the oncology market is intense and is accentuated by the rapid pace of technological and product development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically, if we are successful in bringing pacritinib to market for indications such as AML, MDS, CMML, or CLL, pacritinib may face competition from the currently approved JAK1/JAK2 inhibitors, Jakafi® / Jakavi® and Inrebic® (fedratinib). Celgene announced FDA approval of Inrebic® for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. Pacritinib may also face competition from momelotinib, which Sierra Oncology acquired from Gilead. In June 2019, Sierra Oncology announced that momelotinib was granted fast track designation by the FDA and launched a Phase 3 clinical trial in

November 2019. In addition, if we are successful in bringing pacritinib to market as a treatment to prevent progression to acute respiratory distress syndrome, orARDS, and medical ventilation, we expect to face competition from numerous other companies that are currently pursuing clinical development programs for COVID-19 and related conditions.

In addition to the specific competitive factors discussed above, new anti-cancer drugs or drugs for the treatment of COVID-19 that may be under development or developed and marketed in the future could compete with our various compounds.

Many of our competitors, particularly multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial and technical resources and substantially larger development and marketing teams than us, as well as significantly greater experience than we do in developing, commercializing, manufacturing, marketing and selling products. As a result, products of our competitors might come to market sooner or might prove to be more effective, less expensive, have fewer side effects or be easier to administer than ours. In any such case, sales of any potential future product would likely suffer and we might never recoup the significant investments we have made and will continue to make to develop and market these compounds.

Even if pacritinib or other compounds we may develop are successful in clinical trials and receive regulatory approvals, we or our collaboration partners may not be able to successfully commercialize them.

The development and ongoing clinical trials for pacritinib and other compounds we may develop may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products or gain market acceptance among physicians, patients, healthcare payors or the medical community. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, our products may not reach or remain in the market for a number of reasons including:

- they may be found ineffective or cause harmful side effects;
- they may be difficult to manufacture on a scale necessary for commercialization;
- they may experience excessive product loss due to contamination, equipment failure, inadequate transportation or storage, improper installation or operation of equipment, vendor or operator error, natural disasters or other catastrophic events, inconsistency in yields or variability in product characteristics;
- they may be uneconomical to produce;
- the timing of market introduction of pacritinib and other compounds we may develop and competitive products may be inopportune;
- political and legislative changes may make the commercialization of pacritinib, or any other product candidates we may develop in the future, more difficult;
- we may fail to obtain reimbursement approvals or pricing that is cost effective for patients as compared to other available forms of treatment or that covers the cost of production and other expenses;
- they may not compete effectively with existing or future alternatives;
- we may be unable to develop commercial operations and to sell marketing rights;
- they may fail to achieve market acceptance; or
- we may be precluded from commercialization of a product due to proprietary rights of third parties.

Uncertainty and speculation continue regarding the possible repeal of all or a portion of the Patient Protection and Affordable Care Act through legislative action or court ruling, as well as possible changes to the regulations implemented under the Patient Protection and Affordable Care Act by the Department of Health and Human Services. The 5th Circuit of Appeals recently upheld a federal district court ruling that the individual mandate provisions of the Patient Protection and Affordable Care Act are unconstitutional, and the U.S. Supreme Court is expected to review the constitutionality of the remaining provisions of the Patient Protection and Affordable Care Act in the Fall. The uncertainty this causes for the healthcare industry could also adversely affect the commercialization of our products. If we fail to commercialize products

or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

If we are unable to adequately prepare the market for the potential future commercialization of a product, we may not be able to generate product revenue once marketing authorization is obtained. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have limited commercialization expertise, including sales, marketing or distribution capabilities. Advancing pacritinib through Phase 3 development and regulatory approval will require us to begin commercialization preparation activities and incur related expenses before we obtain final trial results and know whether PACIFICA or PRE-VENT will support regulatory approval. These activities will include, among other things, the development of an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain qualified marketing and sales personnel. If we are unable to adequately prepare the market for the potential future commercialization of pacritinib, we may not be able to generate product revenue once marketing authorization is obtained.

Additionally, if we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements on commercially reasonable terms, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Pacritinib or other compounds we may develop may cause undesirable side effects or have other properties that could halt their development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

It is possible that the FDA or foreign regulatory authorities may not agree with our assessment of the safety profile of pacritinib or other compounds we may develop in the future. Undesirable side effects caused by pacritinib could cause us, institutional review boards, our contract research organizations, or CROs, the FDA or foreign regulatory authorities to interrupt, delay or discontinue development and could result in a clinical hold on any clinical trial, or the denial of regulatory approval by the FDA or foreign regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing pacritinib and generating revenues from its sale. In addition, if pacritinib or other compounds we may develop in the future cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of this product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy in connection with approval, if any;
- we may be required to change the way the product is administered or conduct additional preclinical studies or clinical trials; or

- we may be required to change or stop other ongoing clinical studies that may negatively impact the development of the agent for other indications.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate.

Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

We will need to raise additional funds to operate our business, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could harm our liquidity, financial condition, business, operating results and prospects.

We have substantial operating expenses associated with the development of pacritinib, and we have significant contractual payment obligations. We have incurred net operating losses every year since our formation. As of March 31, 2020, we had an accumulated deficit of $2.3 billion, and we expect to continue to incur net losses for the foreseeable future. Our available cash, cash equivalents and short-term investments were $81.1 million as of March 31, 2020. In March 2020, we received approximately $59.1 million in net proceeds from our rights offering. While we believe that our present financial resources, when combined with the net proceeds we received from the rights offering, will be sufficient to fund our operations into the fourth quarter of 2021, cash forecasts and capital requirements are subject to change as a result of a variety of risks and uncertainties. Developments in and expenses associated with our clinical trials and other research and development activities, including regulatory approval developments, our ability to consummate appropriate collaborations for development and commercialization activities, our ability to reach milestones triggering payments under applicable contractual arrangements, receive the associated payments, litigation and other disputes, competitive market developments and other unplanned expenses or business developments such as our new PRE-VENT clinical trial may consume capital resources earlier than planned. Due to these and other factors, any forecast for the period for which we will have sufficient resources to fund our operations, as well as any other operational or business projection we have disclosed, or may, from time to time, disclose, may fail.

We will need to acquire additional funds in order to develop our business and continue the development of pacritinib. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, our ability to raise capital is subject to a number of risks, uncertainties, constraints and consequences, including, but not limited to, the following:

- our ability to raise capital through the issuance of additional shares of our common stock or convertible securities is restricted by the limited number of our authorized shares available for issuance, the potential difficulty of obtaining stockholder approval to increase authorized shares and the restrictive covenants under our secured term loan agreement;

- issuance of equity-based securities will dilute the proportionate ownership of existing stockholders;

- our ability to obtain further funds from any potential loan arrangements is limited by our existing loan and security agreement;

- certain financing arrangements may require us to relinquish rights to various assets and/or impose more restrictive terms than any of our existing or past arrangements;

- we may be required to meet additional regulatory requirements, and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain funding;

- for so long as our non-affiliate public float does not exceed $75 million, our ability to file or use shelf registration statements on Form S-3 to raise capital will be limited; and

- if we are not listed on the Nasdaq or any stock exchange, whether due to a failure to regain compliance with the minimum bid price requirement (as discussed below) or otherwise, our ability to raise capital will be adversely impacted.

For these and other reasons, additional funding may not be available on favorable terms or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. If we fail to obtain additional capital when needed, we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our general and administrative expenses, be unable to attract and retain highly qualified personnel, 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. Any of these consequences could harm our business, financial condition, operating results and prospects.

We may never be able to generate significant product revenues.

We anticipate that, for at least the next several years, our ability to generate significant revenues and become profitable will be dependent on our ability to obtain regulatory approval for and successfully commercialize pacritinib. If we are unable to successfully commercialize our development stage or approved products as planned, our business, financial condition, operating results and prospects could be harmed.

We are dependent on third-party service providers for a number of critical operational activities including, in particular, for the manufacture, testing and distribution of our compounds and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships. In particular, we rely heavily on third parties for the manufacture and testing of our compounds. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of our compounds in compliance with GLP and cGMP. As a result, we rely on third parties to supply us in a timely manner with manufactured products or product candidates. We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. In particular, we depend on third-party manufacturers to conduct their operations in compliance with GLP and cGMP or similar standards imposed by U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates GLP and cGMP. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance, and could subject us to penalties.

We may not be able to obtain sufficient quantities of our compounds if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds according to our schedule and specifications or fail to comply with cGMP regulations. In particular, in connection with the transition of the manufacturing of drug supply to successor vendors, we could face logistical, scaling or other challenges that may adversely affect supply. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective compounds in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to effect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

We also rely on third-party service providers for certain warehousing, transportation, sales, order processing, distribution and cash collection services. With regard to the distribution of our compounds, we depend on third-party distributors to act in accordance with GDP, and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with GCP and in accordance with our timelines, expectations and requirements. To the extent any such third parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including, in particular, as a result of the engagement of foreign medical institutions and foreign CROs, who may be less experienced with regard to regulatory matters applicable to us and may have different standards of medical care.

With regard to certain of the foregoing clinical trial operations and stages in the manufacturing and distribution chain of our compounds, we rely on single vendors. In addition, in the event pacritinib is approved, we will initially have only one commercial supplier for pacritinib. We may in the future seek to qualify an additional manufacturer of pacritinib, but the process for qualifying a manufacturer, and seeking prior regulatory approval for a new manufacturer, can be lengthy and expensive and may not occur on a timely basis or at all. The use of single vendors for core operational activities, such as clinical trial operations, manufacturing and distribution, and the resulting lack of diversification, exposes us to the risk of a material interruption in service related to these single, outside vendors. As a result, our exposure to this concentration risk could harm our business.

Although we monitor the compliance of our third-party service providers performing the aforementioned services, we cannot be certain that such service providers will consistently comply with applicable regulatory requirements or that they will otherwise timely satisfy their obligations to us. Any such failure and/or any failure by us to monitor their services and to plan for and manage our short and long term requirements underlying such services could result in shortage of the compound, delays in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditures to resolve shortcomings. Such consequences could have a significant impact on our business, financial condition, operating results or prospects.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities and we may be required to repay the outstanding indebtedness in an event of default, which could have a material adverse effect on our business.

In November 2017, we entered into a loan and security agreement with Silicon Valley Bank, which was amended in May 2018, the proceeds of which were partially used to repay in full all outstanding indebtedness under a prior loan and security agreement.

Borrowings under this loan and security agreement are secured by substantially all of our assets except intellectual property and subject to certain other exceptions. The loan and security agreement restricts our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business assets or property, subject to limited exceptions;
- make material changes to our business or management;
- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, other than dividends paid solely in our common shares, or make distributions on and, in certain cases, repurchase our capital stock;
- enter into certain transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under our loan agreement and security agreement to comply with various affirmative covenants. The covenants and restrictions and obligations in our loan and security agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants 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 a default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

If we are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either when they mature, or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our business operations and financial condition.

If we are unable to recruit, retain, integrate and motivate senior management, other key personnel and directors, or if such persons are unable to perform effectively, our business could suffer.

Our future success depends, in part, on our ability to continue to attract and retain senior management, other key personnel and directors to enable the execution of our business plan and to identify and pursue new opportunities. Additionally, our productivity and the quality of our operations are dependent on our ability to integrate and train our new personnel quickly and effectively.

Directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and stockholder claims, as well as governmental, creditor and other claims that may be made against them. Due to these and other reasons, such persons are also becoming increasingly concerned with the availability of directors and officers liability insurance to pay on a timely basis the costs incurred in defending such claims. We currently carry directors and officers liability insurance. However, directors and officers liability insurance is expensive and can be difficult to obtain, particularly for companies like ours that have had a history of litigation. In addition, the cost of obtaining directors and officers liability insurance recently has been increasing while applicable coverage has been decreasing and self-insured retention levels have been increasing, which requires us to pay higher premiums and reserve for higher self-insurance retention levels. If we are unable to continue to provide directors and officers sufficient liability insurance at affordable rates or at all, or if directors and officers perceive our ability to do so in the future to be limited, it may become increasingly more difficult to attract and retain management and qualified directors to serve on our Board of Directors.

The loss of the services of senior management, other key personnel or directors and/or the inability to timely attract or integrate such persons could significantly delay or prevent the achievement of our development and strategic objectives and may adversely affect our business, financial condition and operating results.

We may encounter difficulties in managing our expected growth and in expanding our operations successfully.

Advancing our lead product candidate, pacritinib, through the product development and, if approved, commercialization process will require us to develop or expand our development, regulatory, manufacturing, medical affairs, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We must also successfully integrate the employees and operations related to the development of pacritinib. Maintaining additional relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to manage our development efforts and clinical trials effectively, hire, train and integrate additional management, development, medical affairs, administrative and sales and marketing personnel, improve our managerial, development, operational and finance systems, and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure. Our future financial performance will depend, in part, on our ability to manage this growth effectively. We may not be able to accomplish these tasks; which failure could prevent us from successfully developing and commercializing pacritinib.

If we are unable to in-license or acquire additional product candidates, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is the in-licensing and acquisition of drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories, such as pacritinib. Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing or acquisition opportunities and enter into arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

We may owe additional amounts for VAT related to our operations in Europe.

Our European operations are subject to the VAT which is usually applied to all goods and services purchased and sold throughout Europe. We historically carried out research and development activities in Italy and incurred value added tax, or VAT, from Italian suppliers on the acquisition of goods and services in Italy. This VAT should be considered as an input VAT credit. We treated the majority of our sales made in Italy without output VAT (on the basis that the supplies should be considered outside the scope of Italian VAT). This resulted in the value of input VAT exceeding the value of output VAT, and

accordingly we submitted a refund claim for the VAT. The Italian Tax Authority, or the ITA, has challenged the treatment of the sales transactions and claimed that the sales transactions made by us should have been subject to output VAT.

On April 14, 2009, December 21, 2009 and June 25, 2010, the ITA issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2006 and 2007 are €0.6 million, €2.8 million and €0.9 million, respectively. While we are defending ourselves against the assessments both on procedural grounds and on the merits of the case, there can be no assurances that we will be successful in such defense. The 2005 VAT assessment was decided in favor of the Company by the Italian Supreme Court, with no further potential liabilities for the Company. Further information pertaining to these cases can be found in Part I, Item 1, "Notes to Condensed Consolidated Financial Statements, Note 5. Contingencies" and is incorporated by reference herein. If the final decision of the Italian Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay to the ITA an amount up to $4.3 million, or approximately $4.8 million converted using the currency exchange rate as of March 31, 2020, including interest and penalties for the period lapsed between the date in which the assessments were issued and the date of effective payment.

We are currently subject to certain regulatory and legal proceedings, and may in the future be subject to additional proceedings and/or allegations of wrong-doing, which could harm our financial condition and operating results.

We are currently, and may in the future be, subject to regulatory matters and legal claims, including possible securities, derivative, consumer protection and other types of proceedings pursued by individuals, entities or regulatory bodies. See Part II, Item 8, "Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 16. Commitments and Contingencies," for more information regarding the regulatory matters and legal claims in which we are currently involved. Additionally, we were previously required to supply documents in response to a subpoena from the SEC in connection with an investigation into potential federal securities law violations; however, in August 2018, the SEC staff sent a letter stating that it had concluded its investigation of us, and, based on information it had as of that date, it did not intend to recommend an enforcement action against us. Litigation and regulatory proceedings are subject to inherent uncertainties, and we have had and may in the future have unfavorable rulings and settlements. Adverse outcomes may result in significant monetary damages and penalties or injunctive relief against us. It is possible that our financial condition and operating results could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable. If an unfavorable ruling were to occur in any of the legal proceedings we are or may be subject to, our business, financial condition, operating results and prospects could be harmed. The ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future.

We cannot predict with certainty the eventual outcome of any litigation or regulatory proceedings we are or may be party to in the future. In addition, negative publicity resulting from any allegations of wrong-doing could harm our business, regardless of whether the allegations are valid or whether there is a finding of liability. Furthermore, we may have to incur substantial time and expense in connection with such lawsuits and management's attention and resources could be diverted from operating our business as we respond to the litigation. Our insurance is subject to high deductibles and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages. In the event of negative publicity resulting from allegations of wrong-doing and/or an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

A variety of risks associated with international operations could materially adversely affect our business.

If we engage in significant cross-border activities, we will be subject to risks related to international operations, including:

- different regulatory requirements for initiating clinical trials and maintaining approval of drugs in foreign countries and multiple, differing and changing tax laws and regulations;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability or open conflict in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations of doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- likelihood of potential or actual violations of domestic and international anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, or of U.S. and international export control and sanctions regulations, which likelihood may increase with an increase of operations in foreign jurisdictions;
- tighter restrictions on privacy, data protection, and the collection and use of data, including genetic material, may apply in jurisdictions outside of North America; and
- business interruptions resulting from global health epidemics, including the COVID-19 pandemic, geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If any of these issues were to occur, our business could be materially harmed.

Our net operating losses may not be available to reduce future income tax liability.

We have substantial tax loss carryforwards for U.S. federal income tax purposes, but our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended, as a result of prior changes in the stock ownership of our company. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to limitations. Moreover, future changes in the ownership of our stock, including those resulting from issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

We could be subject to additional income tax liabilities.

We are subject to income taxes in the United States and certain foreign jurisdictions. We use significant judgment in evaluating our worldwide income-tax provision. During the ordinary course of business, we conduct many transactions for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by earnings being lower than anticipated in countries where we have lower statutory rates and higher than anticipated in countries where we have higher statutory rates, by changes in currency exchange rates, by changes in the valuation of our deferred tax assets and liabilities or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. We are subject to audit in various jurisdictions, and such jurisdictions may assess additional income tax against us. Although we believe our tax estimates are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income-tax provisions and accruals. The results of an audit or litigation could have a material effect on our operating results or cash flows in the period or periods for which that determination is made.

We are subject to risk regarding currency exchange rate fluctuations associated with the translation of monetary amounts in foreign currencies into U.S. dollars.

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars for financial reporting purposes. The carrying value of the assets and liabilities, as well as the reported amounts of revenues and expenses, will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Certain of our transactions denote monetary amounts in foreign currencies, and consequently, the ultimate financial impact to us from a U.S. dollar perspective is subject to significant uncertainty. Furthermore, the referendum in the United Kingdom in June

2016, in which the majority of voters voted in favor of an exit from the European Union has resulted in increased volatility in the global financial markets and caused severe volatility in global currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against the euro. Changes in the value of the U.S. dollar as compared to foreign currencies (in particular, the euro) might have an adverse effect on our reported operating results and financial condition.

Because there is a risk of product liability associated with developing and commercializing pharmaceuticals, we face potential difficulties in obtaining insurance, and if product liability lawsuits were to be successfully brought against us, our business may be harmed.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing, marketing and sale of human pharmaceutical products. If our insurance covering a compound is not maintained on acceptable terms or at all, we might not have adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim could also exceed our insurance coverage and could harm our financial condition and operating results.

The illegal distribution and sale by third parties of counterfeit versions of a product or stolen product could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of a product that do not meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit product sold under our brand name. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

We may be subject to claims relating to improper handling, storage or disposal of hazardous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations, both internationally and domestically, governing the use, manufacture, storage, handlings, treatment, transportation and disposal of such materials and certain waste products and employee safety and health matters. Although we believe that our safety procedures for handling and disposing of such materials comply with applicable law and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental, safety and health laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

We depend on sophisticated information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.

We and third parties on which we rely, including our CROs and other service providers, depend on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of such information technology systems makes them vulnerable to damage from a cyber-attack, computer virus, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such attacks or disruptions could result in the theft of intellectual property or other misappropriation of assets, result in the loss or disclosure of personal data, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. We anticipate needing to make further investments in protecting against these matters going forward. There can be no assurance that these measures and efforts will prevent future interruptions, breakdowns, security breach or other incidents. If we or the third parties on which we rely fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could find it necessary or advisable to need to notify individuals, government agencies, or others, have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other health care professionals, face private litigation, be subject to negative publicity and harm to our reputation, face regulatory investigations and have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues, be exposed to increased costs including remediation costs, disruption of operations, or increased cybersecurity protection costs, or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Further, any security breach,

interruption, or other breakdown may take longer than anticipated to remediate or otherwise address. The third parties on which we rely, including our CROs and other service providers, face similar risks with respect to interruptions, breakdowns, and other security incidents, and any incidents suffered by our service providers can result in similar impacts upon our business, results of operations, financial condition, prospects and cash flows.

While we maintain insurance, our insurance may be insufficient to cover all liabilities incurred by any security incidents. We also cannot be certain that our insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results, and reputation.

In addition, any security incident could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations and the EU General Data Protection Regulation and other regulations, the breach of which could result in significant penalties.

If we or the third parties upon whom we depend are be adversely affected by natural disasters or other events, our business continuity and disaster recovery plans may not adequately protect us from such interruptions.

Our headquarters are located in Seattle, Washington. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, power shortage, power outage, telecommunication failure, or other natural or man-made accidents or incidents could disrupt our operations. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We may not carry sufficient business interruption insurance to compensate us for all losses that may occur. The disaster recovery and business continuity plans we have in place may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of a natural disaster or other event, which could have a material adverse effect on our business, and we could potentially lose valuable data and other items. The occurrence of any of the foregoing could have a material adverse effect on our business.

We will incur a variety of costs for, and may never realize the anticipated benefits of, acquisitions, collaborations or other strategic transactions.

We evaluate and undertake acquisitions, collaborations and other strategic transactions from time to time. The process of negotiating these transactions, as well as integrating any acquisitions and implementing any strategic alliances, may result in operating difficulties and expenditures. In addition, these transactions may require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. These undertakings could also result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to intangible assets, and we may never realize the anticipated benefits. In addition, following the consummation of a transaction, our results of operations and the market price of our common stock may be affected by factors different from those that affected our results of operations and the market price of our common stock prior to such acquisition. Any of the foregoing consequences resulting from transactions of the type described above could harm our business, financial condition, operating results or prospects.

Risks Related to the Development, Clinical Testing and Regulatory Approval of Our Product Candidates

The regulatory approval process for pacritinib has been subject to delay and uncertainty associated with clinical holds placed on pacritinib clinical trials in February 2016 and the withdrawal of the MAA in Europe. While the full clinical hold on pacritinib trials has been removed and the dose-exploration trial for pacritinib has been completed, further registration of clinical trials for pacritinib could be subject to further delay or we could be prevented from further studying pacritinib or seeking its commercialization, which could have a material adverse effect on our business.

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib clinical trials; however, in January 2017, the full clinical hold was removed. In September 2019, we initiated patient enrollment in a Phase 3 clinical trial, which we refer to as the PACIFICA Phase 3 trial. The current PACIFICA Phase 3 trial protocol provides for the comparison of the safety and efficacy of 200mg of pacritinib administered twice daily to physician’s choice in adult patients with myelofibrosis and severe thrombocytopenia who are treatment-naïve or intolerant to ruxolitinib. The current PACIFICA Phase 3 protocol provides for the evaluation of 348 adult patients. Although the independent data monitoring

committee, or IDMC, completed its fourth and final interim safety review in May 2019 and recommended that the PAC203 Phase 2 trial continue without modification, we cannot be certain that the PACIFICA Phase 3 trial will be sufficient for regulatory approval. Under the current protocol for the PACIFICA Phase 3 trial, the primary endpoint is the percentage of patients who achieve at least 35 percent reduction in spleen volume at Week 24 and secondary endpoints include, among others, the efficacy of pacritinib versus physician's choice therapy as assessed by the proportion of patients achieving at least a 50 percent reduction in total symptom score between baseline and Week 24. The primary analysis of SVR rates will be conducted once the 168th randomized patient has reached week 24, and this analysis will be used as the basis for an accelerated approval filing. An end-of-study efficacy analysis of the secondary endpoints TSS and OS will be conducted once the 348th randomized patient has reached week 24. Even if the current primary endpoint of the PACIFICA Phase 3 trial is achieved, the FDA may determine that the benefit/risk profile of pacritinib at the dose selected for the PACIFICA Phase 3 trial does not support approval based on the results of such trial, previously identified FDA concerns regarding safety and dosing limitations of pacritinib, including FDA concerns identified in connection with our previous PERSIST-1 and 2 trials, or otherwise. We also cannot be certain of the anticipated timing of the results from the PACIFICA Phase 3 trial. The FDA may request additional information regarding pacritinib or require us to pursue new clinical safety trials with changes to, among other things, protocol, study design or sample size, which could cause significant delays in completion of these studies.

Additionally, in July 2019 we announced an expanded access program, or EAP, for pacritinib for patients in the PAC203 Phase 2 trial. To facilitate the EAP, we have extended the PAC203 Phase 2 trial to enable trial participants to continue receiving pacritinib through the launch of our EAP. Patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and generally have exhausted all other available therapies. The risk for serious adverse events, including those which may be unrelated to pacritinib, in this patient population is high and could have a negative impact on the safety profile of pacritinib, which could cause significant delays or impair our ability to obtain regulatory approval for pacritinib.

Further, in the EMA's initial assessment report regarding our original MAA, the CHMP determined that the current application was not approvable because of major objections in the areas of efficacy, safety (hematological and cardiovascular toxicity) and the overall risk-benefit profile of pacritinib. After the filing of the original MAA, data from the second phase 3 trial of pacritinib, PERSIST-2, were reported. Following discussions with the EMA about how PERSIST-2 data might address the major objections and how to integrate the data into the current application, we withdrew the original MAA, and submitted a new application for the treatment of patients with myelofibrosis who have thrombocytopenia (platelet counts less than 100,000 per microliter). The new MAA was validated by the EMA in July 2017; however, we withdrew the MAA in February 2019 following interactions with CHMP, during which we learned that CHMP was likely to formally adopt a negative opinion in its evaluation of the application. CHMP indicated that the risk-benefit profile for pacritinib for the intended indication has not been sufficiently established with the clinical data available to date. For additional information regarding the status of our clinical development efforts, see Part I, Item 1. "Business".

Finally, in April 2020 we announced the initiation of PRE-VENT, a Phase 3 trial evaluating pacritinib in hospitalized non-cancer and cancer patients with severe COVID-19. Patients with severe COVID-19 are at a high risk for complications from the disease, and the risk for serious adverse events, including those which may be unrelated to pacritinib, in this patient population is high and could have a negative impact on the safety profile of pacritinib, which could cause delays or impair our ability to obtain regulatory approval for pacritinib.

The submission of new marketing applications, complying with any additional requests for information from the FDA or EMA or making any changes to study design or sample size may be time-consuming, expensive and delay or prevent our ability to continue to study pacritinib. If we are unable to adequately address any previous or further recommendations, concerns, requests, or objections in a manner satisfactory to the FDA or EMA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking commercialization of pacritinib.

From time to time we may amend the clinical protocols for our product candidates to include additional objectives that could produce important clinical trial results critical to our overall development strategy. The protocol amendment process requires review and approval by several review bodies, including regulatory agencies and scientific, regulatory and ethics boards. These protocol amendments may not be accepted by the review bodies in the form submitted, or at all, which may delay our planned enhancements to the clinical development program and/or limit or change the type of information we may gather from our studies.

In early October 2019, we received correspondence from the FDA asking us to consider incorporating change in TSS at week 24 as a co-primary endpoint for the PACIFICA Phase 3 trial. In January 2020, we reached agreement on an accelerated approval pathway for pacritinib. In March 2020, we submitted an amended PACIFICA pivotal Phase 3 trial protocol to allow

for the primary analysis of SVR rates on the first 168 patients, with an end-of-study analysis of TSS and OS following the full enrollment of 348 patients. Such a change to the trial protocol will require an increase in the number of patients evaluated over the course of the trial, as well as the costs and time required to complete the trial. Making any changes to clinical protocols is time-consuming and expensive and may delay or prevent our ability to continue to study pacritinib. If our changes to the trial design do not adequately address any previous or further recommendations, concerns, requests, or objections in a manner satisfactory to the FDA or EMA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking commercialization of pacritinib.

If development and commercialization collaborations we enter into are not successful, or if we are unable to enter into additional collaborations, we may not be able to effectively develop and/or commercialize our compounds, which could have a material adverse effect on our business.

Historically, we have entered into development and commercialization collaborations to help advance the development of our product candidates. We evaluate collaboration opportunities from time to time and if we enter into such collaborations in the future, our business may become increasingly dependent on the success of such collaborations. Additionally, if we do not successfully enter into additional collaborations when needed, we may be unable to further develop and commercialize the applicable compounds, generate revenues to sustain or grow our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

Compounds that appear promising in research and development may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once existing data are more fully evaluated, which could have a material adverse effect on our business.

Successful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to failure of clinical testing to show potential products to be safe and efficacious, failure to demonstrate desired safety and efficacy characteristics in human clinical trials, and failure to demonstrate a benefit/risk profile sufficient to justify approval in the view of applicable regulatory authorities.

In addition, from time to time, we report top-line data for clinical trials. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, top-line results may differ from future results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business in general.

If the development of pacritinib is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and the ability to commercialize pacritinib may be harmed, which could harm our business, financial condition, operating results or prospects.

Pacritinib or other compounds we may develop may cause undesirable side effects or have other properties that could halt their development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

It is possible that the FDA or foreign regulatory authorities may not agree with any assessment of the safety profile of pacritinib or other compounds we may develop in the future. Undesirable side effects caused by pacritinib could cause us, institutional review boards, our CROs, the FDA or foreign regulatory authorities to interrupt, delay or discontinue development and could result in a clinical hold on any clinical trial, or the denial of regulatory approval by the FDA or foreign regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing pacritinib and generating revenues from its sale. In addition, if pacritinib or other compounds we may develop in the future cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of this product;

- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy in connection with approval, if any;
- we may be required to change the way the product is administered or conduct additional preclinical studies or clinical trials; or
- we may be required to change or stop other ongoing clinical studies that may negatively impact the development of the agent for other indications.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate.

Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including that we often face lengthy preparatory periods prior to the activation of clinical trial sites, the patient populations that are eligible for our clinical trials are small and unique and we must comply with specific regulatory requirements and timelines in each country in which we conduct our clinical trials. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including, but not limited to:

- the number and size of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocols;
- the size of the specific patient populations such as those whose have low platelet counts, if required, or other defined subsets of a larger patient population;
- the risk that disease progression will result in death or clinical deterioration before the patient can enroll in clinical trials or before sufficient data has been collected such that the patient contributes no meaningful information for the clinical trial in which the patient is enrolled;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trials, including the inclusion of a placebo or comparator arm in a trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic area as our product candidate. This competition reduces the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Moreover, because our product candidates are experimental, potential patients and their doctors may be inclined to use conventional therapies, such as surgery, radiation and chemotherapy, rather than enroll patients in any one of our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of pacritinib or other compounds we may develop in the future.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trials are not well-designed.

Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with Good Clinical Practices, or GCPs, or other applicable foreign regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, foreign regulatory authorities and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current Good Manufacturing Practices, or cGMPs. Clinical trial data may be rejected by the FDA or foreign regulatory authorities or clinical trials may be suspended by the FDA, foreign regulatory authorities, or us for various reasons, including, but not limited to:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols or to obtain or maintain clinical trial data in accordance with applicable regulatory requirements;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial designs necessary to demonstrate efficacy;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments;
- the product candidates may not appear to be more effective than current therapies;
- the quality or stability of the product candidates may fall below acceptable standards; or
- failure to adequately demonstrate study conduct oversight, ensure data integrity, and that clinical study sites complied with the principles of GCPs.

On February 8, 2016, clinical studies under the IND for pacritinib were placed on a full clinical hold issued by the FDA. The FDA removed the full clinical hold in January 2017. Although we have not been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial since that clinical hold was removed, if we elect or are forced to suspend or terminate a clinical trial of any of our current or future product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

If we are unable to expedite the regulatory approval process for pacritinib in our clinical trials, we may be required to pursue strategic alternatives for the development of pacritinib and/or our company, which could have a material adverse effect on our business.

The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint under an accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. There can be no assurance that the FDA will agree that any endpoint we suggest with respect to any of our drug candidates is an appropriate surrogate endpoint. Furthermore, there can be no assurance that any application will be accepted or that accelerated approval will be granted on any basis. Even if a product candidate is granted accelerated approval based on a surrogate endpoint, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials that demonstrate a clinical benefit. Such confirmatory trial(s) must be completed with due diligence and, in some cases, the FDA may require that the trial(s) be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons, including if the trial(s) required to verify the predicted clinical benefit of a product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug, or if the sponsor fails to promptly conduct any required post-approval trial(s) with due diligence.

A priority review designation will direct the FDA's overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The FDA decides on the review designation for every application, and an applicant may also expressly request priority review. The FDA informs the applicant of a Priority Review designation within 60 days of the receipt of an original NDA. The FDA has a goal to (but is not required to) take action on an application designated as priority within six months after it has accepted an application for filing (rather than a goal of ten months for a standard review). The FDA has broad discretion whether to grant priority review, and, while the FDA has granted priority review to other oncology product candidates, our drug candidates may not receive similar designation. Moreover, designation of a drug as priority does not alter the scientific/medical standard for approval or quality of evidence necessary for approval and does not affect the length of the clinical trial period. Also, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted six-month cycle or thereafter.

As described above, in early October 2019, we received correspondence from the FDA asking us to consider incorporating change in total symptom score, or TSS, at week 24 as a co-primary endpoint for the PACIFICA Phase 3 trial. In January 2020, we reached agreement on an accelerated approval pathway for pacritinib. In March 2020, we submitted an amended PACIFICA pivotal Phase 3 trial protocol to allow for the primary analysis of SVR rates on the first 168 patients, with an end-of-study analysis of TSS and OS following the full enrollment of 348 patients. If the primary endpoint of SVR is met following the planned review of data from the first 168 patients, we intend to submit an NDA under the FDA's regulations for the Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, 21 C.F.R. subpart H, subject to review of all available efficacy and safety data. Conversion to a regular approval of pacritinib would be anticipated following the successful end-of-study assessment of the secondary efficacy endpoints, and the completion of post-marketing requirements. We previously anticipated reporting primary SVR data by the end of 2021 with a potential NDA filing in early 2022 and final study efficacy data expected in 2023; however, as a result of the worldwide coronavirus pandemic known as COVID-19, we currently anticipate at least a three-month delay in the PACIFICA Phase 3 trial timeline.

In addition, in April 2020 we initiated PRE-VENT, a Phase 3 study evaluating pacritinib in hospitalized non-cancer and cancer patients with severe COVID-19. We expect to commence enrollment of PRE-VENT in the second quarter of 2020 at sites in the United States and in Europe.

We or any collaboration partners we may work with may not obtain or maintain the regulatory approvals required to develop or commercialize pacritinib or any other compounds we may develop in the future, which could have a material adverse effect on our business.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other jurisdictions, including the EMA in the European Union. Pacritinib is currently in clinical development. Pacritinib may not be marketed in the United States until it has been approved by the FDA and may not be marketed in other jurisdictions until it has received approval from the appropriate foreign regulatory agencies, and requires development and extensive clinical investigation before submission of any regulatory application for marketing approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of pacritinib or any other product

candidate on a timely basis, or at all. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a compound for many reasons, including, but not limited to:

- a compound may not be shown to be safe or effective;
- the clinical and other benefits of a compound may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- such regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- such regulatory agencies may not approve the manufacturing process of a compound or determine that a third-party contract manufacturers manufactures a compound in accordance with cGMPs;
- a compound may fail to comply with regulatory requirements; or
- such regulatory agencies might change their approval policies or adopt new regulations.

In particular, if pacritinib is not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, medical devices, and biologics or modifications to cleared or approved drugs, medical devices, and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement and access to drugs, which could adversely affect our future revenues and profitability.

To the extent our products are developed, commercialized and introduced to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Globally, governmental and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the United States to continue. In the United States, we are subject to substantial pricing,

reimbursement and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures.

The Patient Protection and Affordable Care Act instituted comprehensive health care reform, which includes provisions that, among other things, reduce and/or limit Medicare reimbursement and impose new and/or increased taxes. In addition, members of the Trump administration, including the President, have made public statements criticizing pricing practices within the pharmaceutical industry, indicating that they may seek to increase pricing pressures on the pharmaceutical industry. For example, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs.

In almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides and that treatment with the product works at least as well as currently available treatments. The continuing efforts of governments and insurance companies, health maintenance organizations and other payors of health care costs, to contain or reduce costs of health care may affect the availability of capital, as well as our future revenues and profitability or those of our potential customers, suppliers and collaborative partners.

Post-approval or authorization regulatory reviews and obligations often result in significant expense and marketing limitations, and any failure to satisfy such ongoing obligations could negatively affect our business, financial condition, operating results or prospects.

Even if a product receives regulatory approval or authorization, as applicable, we are and will continue to be subject to numerous regulations and statutes regulating the manner of obtaining reimbursement for and selling the product, including limitations on the indicated uses for which a product may be marketed, promoted and advertised. Approved or authorized products are subject to extensive manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping regulations. These requirements include submissions of safety and other post-marketing information and reports. In addition, such products are subject to ongoing maintenance of product registration and continued compliance with cGMPs, GCPs and good laboratory practices, or GLPs for post-approval studies. Further, distribution of products must be conducted in accordance with good distribution practices, or GDPs. The distribution process and facilities of our third-party distributors are subject to, and our wholesale distribution authorization by the UK Medicines and Healthcare Products Regulatory Agency subjects us to, continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products. Regulatory authorities may also impose new restrictions on continued product marketing or may require the withdrawal of a product from the market if adverse events of unanticipated severity or frequency are discovered following approval.

Any other failure to comply with applicable regulations could result in warning or untitled letters from the FDA, product recalls, interruption of manufacturing and commercial supply processes, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, revocation of the applicable product's approval or authorization, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditure to resolve shortcomings, which could negatively affect our business, financial condition, operating results or prospects.

We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.

Our business and future growth depend on the development, ultimate sale and use of products that are subject to FDA, EMA and or other regulatory agencies regulation, clearance and approval. Under the FDCA and other laws, we are prohibited from promoting our products for off-label uses, or uses not approved by the FDA. We may also be subject to various federal and state physician payment transparency laws, including the federal Physician Payments Sunshine Act. This means that in the United States, we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the uses of our products that are not approved by the FDA, unless otherwise allowed by the FDA by policy or other guidance.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome, generate negative publicity and may result in fines or payments of settlement awards. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities.

We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.

In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many states have also adopted laws similar to the federal Anti-Kickback Statute and False Claims Act. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business.

For our sales and operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA, as amended, U.K. Bribery Act, and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third parties, fail to comply with the FCPA and other anti-corruption and anti-bribery laws.

We leverage various third parties to sell our products and conduct our business abroad. We, our commercial partners and our other third-party intermediaries, including collaborators and licensees, may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses or sales to government owned or controlled health care facilities, universities, institutes, clinics, etc.) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, collaborators, licensees and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, representatives, contractors, partners, collaborators, licensees, agents and other third parties or intermediaries from violating or circumventing our policies and/or the law.

Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, operating results and prospects. In addition, responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have a material adverse impact on our business.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, EMA and other regulators, providing inaccurate or misleading information to the FDA,

EMA and other regulators, failure to comply with data privacy and security and healthcare fraud and abuse laws and regulations in the United States and abroad, reporting inaccurate financial information or clinical data or failing to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices.

Various laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Any misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, officers, directors, agents and representatives, including consultants, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We are subject to a variety of laws regarding data privacy and protection, which carry potentially significant penalties for non-compliance.

Laws regarding data privacy and protection may impose obligations with respect to safeguarding the privacy, use, security, transmission and other processing of individually identifiable health information and other personal data that we may collect, retain, and otherwise process.

In the United States, these laws include HIPAA and HITECH. In addition to possible civil and criminal penalties imposed by federal authorities for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In some instances, individuals also may file civil actions related to alleged data privacy and protection violations, seeking damages, injunctions, attorneys' fees, costs, and other relief.

As the General Data Protection Regulation entered into force recently, guidance on implementation and compliance practices are still being developed, updated or otherwise revised. Although the General Data Protection Regulation is intended to provide for a high level of harmonization across the European Union, Member States may still implement certain variations, and data protection authorities may enforce the General Data Protection Regulation and national laws differently, which adds to the complexity of processing personal data in the European Union.

Furthermore, there is a trend towards the public disclosure of clinical trial data in the European Union, which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation (which is replacing the EU Clinical Trials Directive), EMA disclosure initiatives, and voluntary commitments by industry, among other sources.

The uncertainty regarding the interplay between different regulatory frameworks, such as the Clinical Trials Regulation and the General Data Protection Regulation, further adds to the complexity that we face with regard to data protection regulation.

Failing to comply with these obligations could lead to government investigations and enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. For example, the General Data Protection Regulation provides for significant penalties that may be assessed in the event of noncompliance, up to the greater of $20 million or 4% of worldwide annual revenues. We may be subject to negative publicity, have increases in operating expenses, incur expenses or lose revenues, be exposed to increased costs including remediation costs and disruption of operations, or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

Additionally, we rely on the use of standard contractual clauses approved by the European Commission in order to transfer personal data from the European Union to the United States. These standard contractual clauses are subject to legal challenge in the European Union, and it is possible that they will be invalidated or modified. In such event, we could need to implement alternative measures to transfer personal data from the European Union to the United States, which we may be unable to do in a commercially reasonable manner or at all.

Risks Related to Our Intellectual Property

If any of our license agreements for intellectual property underlying our product candidates are terminated, we may lose the right to develop or market that product candidate.

We have acquired or licensed intellectual property from third parties, including patent applications and patents relating to pacritinib and other product candidates. Some of our product development programs depend on our ability to maintain rights under license agreements relating to this licensed intellectual property. Each licensor of this intellectual property has the power to terminate its agreement with us if we fail to meet our obligations under that agreement. We may not be able to meet all of our obligations under each of these agreements. If we default under any of these agreements, we may lose our right to market and sell any products based on the intellectual property licensed under these agreements and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Bankruptcy may result in the termination of these agreements.

We hold rights under numerous patents that we have acquired or licensed or that protect inventions originating from our research and development, and the expiration of any of these patents would enable our competitors to use the inventions that are the subject of such patents in competition with us.

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the United States and various other countries seeking protection of inventions originating from our research and development, and we have also obtained rights to various patents and patent applications under licenses with third parties and through acquisitions. We have pending patent applications or issued patents in the United States and foreign countries directed to pacritinib and other product candidates. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained.

Our U.S. and foreign method and composition of matter patents for pacritinib expire as follows: U.S. patents expire in May 2028 (method) / January 2029 (compound) / March 2030 (salt); foreign patents expire in November 2026 (method and compound) / December 2029 (salt). We expect our U.S. and foreign patent applications for use of pacritinib for treating transplant rejection will expire in 2036.

Certain patents may be eligible for future patent term restoration of up to five years under certain circumstances. However, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before such candidates are commercialized which may prevent us from obtaining any regulatory extensions if all the patents covering our candidates are expired prior to regulatory approval of the corresponding product candidate. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Also, regulatory exclusivity tied to the protection of clinical data may be complementary to patent protection. During a period of regulatory exclusivity, competitors generally may not use the original applicant’s data as the basis for a generic application. In the United States, the data protection generally runs for five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication. Pacritinib has orphan drug designation for myelofibrosis in the United States and the European Union.

In addition to our patent rights, we rely, to the extent possible, trade secret and contractual protections for our know-how and other unpatented technology. Ultimately, to the extent any of our product candidates are not protected by patent rights our competitors would be free to use inventions embodied in our product candidates to which they have access to compete with us.

If we fail to adequately protect our intellectual property, our competitive position and the potential for long-term success could be harmed.

Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies, including the inventions embodied in our product candidates. Our success depends in part on our ability to:

- obtain and maintain patent protection for our product candidates and technologies both in the United States and other countries;

- maintain our know-how, unpatented technologies and trade secrets; and
- prevent others from infringing on our patent and other intellectual rights.

The patent position of pharmaceutical and biotechnology firms, including ours, generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office, the U.S. PTO, has not established a consistent policy regarding the breadth of claims that it will allow in pharmaceutical and biotechnology patents. If the U.S. PTO allows broad claims in patents that are issued, the number and cost of patent interference or derivation proceedings in the United States and the risk of infringement litigation may increase. If the U.S. PTO allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our product candidates or technologies. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated, circumvented or found unenforceable. Litigation, interference or derivation proceedings or other governmental proceedings that we may become involved in with respect to our patent rights or our proprietary technologies or the proprietary technologies of others could result in substantial cost to us.

We also rely upon trade secrets to protect our proprietary know-how and continuing technological innovation to enable us to remain competitive. Third parties may independently develop such know-how or innovations or otherwise obtain access to such know-how or technology. While we require our employees, consultants, corporate partners and other third parties with access to our proprietary information to enter into confidentiality agreements, these agreements may not be honored and may be difficult to enforce.

Patent litigation is widespread in the pharmaceutical and biotechnology industry, and any patent litigation in which we become involved could harm our business.

Costly litigation might be necessary for us to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology. With respect to our in-licensed patents, if we attempt to initiate a patent infringement suit against an alleged infringer, it is possible that our applicable licensor will not participate in or assist us with the suit, and as a result, we may not be able to effectively enforce the applicable patents against the alleged infringers.

We may be unable to obtain or protect our intellectual property rights and we may be liable for infringing upon the intellectual property rights of others, which may cause us to engage in costly litigation and, if unsuccessful, could cause us to pay substantial damages and prohibit us from selling our products.

At times, we may monitor patent filings for patents that might be relevant to some of our product candidates in an effort to guide the design and development of our products to avoid infringement, but we may not conduct a search or, if we do, it may not be an exhaustive search. We may not be able to successfully challenge the validity of third-party patents and could be required to pay substantial damages, possibly including treble damages, for past infringement and attorneys' fees if it is ultimately determined that our products infringe such patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties.

Moreover, third parties may challenge the patents that have been issued or licensed to us. We do not believe that pacritinib infringes upon the rights of any third parties of which we are aware nor do we believe that third parties are materially infringing any of our owned or licensed patents; however, there can be no assurance that our product candidates or technologies will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements or redesign our compounds so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from any third parties. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Even if infringement claims against us are without merit, or if we challenge the validity of issued patents that are asserted against us, lawsuits in which such claims could be asserted or challenges could be made take significant time, may, even if resolved in our favor, be expensive and divert management attention from other business activities requiring attention. Uncertainties resulting from the initiation and continuation of any litigation relating to intellectual property could limit our ability to continue our operations.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers.

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we or our employees may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of these employees. Litigation may be necessary to defend against these claims. If we are unsuccessful in our defense of such claims, in addition to paying monetary damages, we may lose the right to use valuable intellectual property rights relating to our product candidates or technologies. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, the litigation involving these claims could result in substantial costs and be a distraction to management.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing patents is costly, time consuming, and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our product or product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product and product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Risks Related to Our Common Stock

The market price of shares of our common stock is extremely volatile, which may affect our ability to raise capital in the future and may subject the value of your investment in our securities to sudden decreases.

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended April 30, 2020, our stock price ranged from a low of $0.62 to a high of $1.93. Fluctuations in the market price or liquidity of our common stock may harm the value of your investment in our common stock. Factors that may have an impact, which, depending on the circumstances, could be significant, on the market price and marketability of our securities include:

- announcements by us or others of results of clinical trials and regulatory actions, such as the imposition of a clinical trial hold or required amendments to our clinical trial protocols;
- announcements by us or others of serious adverse events that have occurred during administration of our products to patients;
- announcements by us or others relating to our ongoing development and commercialization activities;
- halting or suspension of trading in our common stock on the Nasdaq;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt or equity securities, which we expect to pursue to generate additional funds to operate our business, or any perception from time to time that we will issue such securities;
- our quarterly operating results;
- liquidity, cash position or financing needs;
- developments or disputes concerning patent or other proprietary rights;
- developments in relationships with collaborative partners;
- acquisitions or divestitures;
- our ability to realize the anticipated benefits of our compounds;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling of our securities;
- changes in health care policies and practices;
- a failure to achieve previously announced goals and objectives as or when projected; and
- general economic and market conditions.

We may not be able to maintain our listing on the Nasdaq Capital Market, or the Nasdaq, or trading on the Nasdaq may otherwise be halted or suspended, which may make it more difficult for investors to sell shares of our common stock and consequently may negatively impact the price of our common stock.

We regained compliance in December 2019 with the minimum $1.00 bid price requirement, after receiving notice of non-compliance from the Nasdaq in June 2019.

We have in the past and may in the future fail to comply with the Nasdaq requirements. If our common stock ceases to be listed for trading on the Nasdaq for failure to comply with the minimum $1.00 per share closing bid price requirement or for any other reason, it may harm our stock price, increase the volatility of our stock price, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. Our failure to maintain a listing on the Nasdaq may constitute an event of default under our loan and security agreement and any future indebtedness, which would accelerate the maturity date of such debt or trigger other obligations. In addition, certain institutional investors that are not permitted to own securities of non-listed companies may be required to sell their shares adversely affecting the market price of our common stock. If we are not listed on the Nasdaq, our ability to raise capital will be adversely impacted. Additionally, for so long as our non-affiliate public float does not exceed $75 million, the amount of securities that we may sell pursuant to registration statements on Form S-3 will be limited to the equivalent of one-third of our public float, which will limit our ability to file or use shelf registration statements on Form S-3 and further limit our ability to raise capital. We have relied significantly on shelf registration statements on Form S-3 for most of our financings in recent years, so any such limitations may harm our ability to raise the capital we need. Trading in our common stock has been halted or suspended on the Nasdaq in the past and may also be halted or suspended in the future on the Nasdaq due to market or trading conditions at the discretion of the Nasdaq. Any halt or suspension in the trading in our common stock may negatively impact the market price of our common stock.

Future financing, strategic and other activities may require us to increase the number of authorized shares in our certificate of incorporation. An inability to secure requisite stockholder approval for such increases could materially and adversely impact our ability to fund our operations.

At our 2018 annual meeting of stockholders, we sought and received approval of an amendment to our certificate of incorporation to increase the total number of authorized shares and the total number of authorized shares of our common stock by 20 million shares. We proposed the increase in authorized shares due to the fact that we anticipate the need to issue additional shares of common stock in the future in connection with one or more of the following:

- financing transactions, such as public or private offerings of common stock or derivative securities;
- our equity incentive plans and employee stock purchase plan;
- debt, warrant or other equity restructuring or refinancing transactions, such as debt or warrant exchanges or offerings of new convertible debt or modifications to existing securities, or as payments of interest on debt securities;
- acquisitions, strategic partnerships, collaborations, joint ventures, restructurings, divestitures, business combinations and strategic investments;
- corporate transactions, such as stock splits or stock dividends; and
- other corporate purposes that have not yet been identified.

At our 2019 annual meeting of stockholders, our stockholders approved an amendment to our certificate of incorporation to increase the total number of authorized shares and the total number of authorized shares of common stock by 30 million and we may seek approval to increase the number of authorized shares again in the future. Without such increases in the number of authorized shares, we may be constrained in our ability to raise capital when needed, and may lose important business opportunities, including to competitors, which could adversely affect our financial performance, growth and ability to continue our operations. As opportunities or circumstances that require prompt action frequently arise, we believe that the delay necessitated for stockholder approval of a specific issuance could result in a material and adverse impact on our business.

Even if we obtain approval to further increase the number of authorized shares, we are required under the Nasdaq Marketplace Rules to obtain stockholder approval for any issuance of additional equity securities that would comprise more than 20 percent of the total shares of our common stock outstanding before the issuance of such securities sold at a discount to a minimum price as set forth in the Nasdaq Marketplace Rules in an offering that is not deemed to be a “public offering” by the Nasdaq Marketplace Rules, as well as under certain other circumstances. We have in the past and may in the future issue additional equity securities that would comprise more than 20 percent of the total shares of our common stock outstanding in order to fund our operations. However, we might not be successful in obtaining the required stockholder approval for any future issuance that requires stockholder approval pursuant to applicable rules and regulations. If we are unable to obtain financing or

our financing options are limited due to stockholder approval difficulties, such failure may harm our ability to continue operations.

Anti-takeover provisions in our charter documents, under Delaware law and in other applicable instruments could make removal of incumbent management or an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our certificate of incorporation and bylaws may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, to commence proxy contests or to effect changes in control. These provisions include:

- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without stockholder approval; and
- the ability of our Board of Directors to issue shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a Delaware corporation, we are subject to Delaware's anti-takeover statute, which imposes restrictions on some transactions between a corporation and certain interested stockholders. Other existing provisions applicable to us that could have an anti-takeover effect include our executive employment agreements and certain provisions of our outstanding equity-based compensatory awards that allow for acceleration of vesting in the event of a change in control. Our shareholder rights plan expired pursuant to its terms on December 2, 2018, and was not replaced; however, the Board may, subject to its fiduciary duties under applicable law, choose to implement a similar plan in the future. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

The foregoing provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

If we fail to maintain effective internal controls over financial reporting, we may not be able to accurately report our financial results, which could adversely affect our investors' confidence, our business and the trading prices of our securities.

If we fail to maintain the adequacy of our internal controls, we may be unable to provide financial information in a timely and reliable manner within the time periods required for our financial reporting under SEC rules and regulations. Internal controls over financial reporting may not prevent or detect misstatements or omissions in our financial statements because of their inherent limitations, including the possibility of human error, the circumvention or overriding of controls or fraud. We have recently implemented a reduction in force, which may result in changes to our internal controls over financial reporting. The changes could relate to different employees performing internal control activities than those who have previously performed those activities or revisions to our actual control activities as we evaluate the appropriate internal control structure after our workforce reduction. A changing internal control environment increases the risk that our system of internal controls is not designed effectively or that internal control activities will not occur as designed. The occurrence of or failure to remediate a significant deficiency material weakness may adversely affect our reputation and business and the market price of shares of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could cause you to incur dilution and could cause the market price of our common stock to fall.

As of March 31, 2020, options to purchase 10,884,118 shares of our common stock with a weighted-average exercise price of $2.54 per share were outstanding. The exercise of any of these options would result in dilution to current stockholders. Further, because we will need to raise additional capital to fund our operations and clinical development programs, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, directors and consultants. Future option grants and issuances of common stock under our share-based compensation plans may have an adverse effect on the market price of our common stock.

These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares of common stock issued in connection with acquisitions, if any, may result in further dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price of our common stock and the trading volume of our common stock could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts cover our company, the market price of our common stock would likely be negatively impacted. If securities and industry analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, the market price of our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause the market price of our common stock and the trading volume of our common stock to decline.

Our management team has broad discretion as to the use of the net proceeds from public or private equity or debt financings and the investment of these proceeds may not yield a favorable return. We may invest the proceeds in ways with which our stockholders disagree.

We have broad discretion in the application of the net proceeds to us from our "at the market" equity offering program and the 2020 rights offering. You may not agree with our decisions, and our use of the proceeds and our existing cash and cash equivalents and marketable securities may not improve our results of operation or enhance the value of our common stock. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that you do not agree with or that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the market price of our common stock to decline. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

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
3.1	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock.	8-K	000-28386	3.1	February 14, 2020
10.1	Investment Agreement, dated as of January 31, 2020, by and among the Registrant, on the one hand, and the purchasers identified on the signature pages thereto, on the other hand.	8-K	000-28386	10.1	February 3, 2020
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith.
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Furnished herewith.
101. INS	XBRL Instance				Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema				Filed herewith.
101. CAL	XBRL Taxonomy Extension Calculation				Filed herewith.
101. DEF	XBRL Taxonomy Extension Definition				Filed herewith.

101. LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101. PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

* Indicates a management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized:

CTI BIOPHARMA CORP.
(Registrant)

Dated: May 14, 2020

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

Dated: May 14, 2020

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

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: May 14, 2020

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: May 14, 2020

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 March 31, 2020 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: May 14, 2020

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 March 31, 2020 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: May 14, 2020

By: /s/ David H. Kirske

David H. Kirske

Chief Financial Officer