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: September 30, 2019

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 October 24, 2019
Common Stock, par value $0.001 per share	57,978,725

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)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,917	$ 36,439
Short-term investments	11,815	30,599
Receivables from license and development services arrangements	137	13,679
Prepaid expenses and other current assets	2,798	1,775
Total current assets	49,667	82,492
Property and equipment, net	1,381	1,793
Other assets	7,534	5,547
Total assets	$ 58,582	$ 89,832
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,965	$ 4,498
Accrued expenses	11,036	12,852
Current portion of long-term debt	10,470	4,812
Other current liabilities	3,448	893
Total current liabilities	27,919	23,055
Long-term debt, less current portion	—	9,267
Other liabilities	4,472	4,571
Total liabilities	32,391	36,893
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share:		
Authorized shares - 33,333 as of September 30, 2019 and December 31, 2018		
Series O Preferred Stock, 12,575 shares issued and outstanding as of September 30, 2019 and December 31, 2018 (Aggregate liquidation preference of $25,150 as of September 30, 2019 and December 31, 2018)	—	—
Common stock, $0.001 par value per share:		
Authorized shares - 131,500,000 and 101,500,000 as of September 30, 2019 and December 31, 2018, respectively		
Issued and outstanding shares - 57,978,725 and 57,986,075 as of September 30, 2019 and December 31, 2018, respectively	58	58
Additional paid-in capital	2,297,931	2,294,025
Accumulated other comprehensive loss	(10,663)	(10,643)
Accumulated deficit	(2,255,375)	(2,224,746)
Total CTI stockholders' equity	31,951	58,694
Noncontrolling interest	(5,760)	(5,755)
Total stockholders' equity	26,191	52,939
Total liabilities and stockholders' equity	$ 58,582	$ 89,832

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
License and contract revenues	$ 2,289	$ 723	$ 3,345	$ 12,182
Operating costs and expenses:				
Research and development	7,598	9,730	19,126	28,539
Selling, general and administrative	4,403	5,763	14,662	16,750
Restructuring expenses	—	—	794	—
Total operating costs and expenses	12,001	15,493	34,582	45,289
Loss from operations	(9,712)	(14,770)	(31,237)	(33,107)
Non-operating income (expense):				
Interest income	276	436	1,003	800
Interest expense	(240)	(308)	(803)	(893)
Amortization of debt discount and issuance costs	(131)	(130)	(391)	(394)
Foreign exchange loss	(240)	(46)	(409)	(898)
Other non-operating income	—	—	—	4,295
Total non-operating (expense) income, net	(335)	(48)	(600)	2,910
Net loss before noncontrolling interest	(10,047)	(14,818)	(31,837)	(30,197)
Noncontrolling interest	—	9	5	31
Net loss	(10,047)	(14,809)	(31,832)	(30,166)
Deemed dividends on preferred stock	—	—	—	(80)
Net loss attributable to common stockholders	$ (10,047)	$ (14,809)	$ (31,832)	$ (30,246)
Basic and diluted net loss per common share	$ (0.17)	$ (0.26)	$ (0.55)	$ (0.55)
Shares used in calculation of basic and diluted net loss per common share	57,974	57,964	57,973	55,434

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss before noncontrolling interest	$ (10,047)	$ (14,818)	$ (31,837)	$ (30,197)
Other comprehensive income (loss):				
Foreign currency translation adjustments	1,332	216	1,570	(3,276)
Unrealized foreign exchange loss on intercompany balance	(1,359)	(223)	(1,610)	(345)
Net unrealized (loss) gain on available-for-sale securities	(14)	(5)	20	(17)
Other comprehensive loss	(41)	(12)	(20)	(3,638)
Comprehensive loss	(10,088)	(14,830)	(31,857)	(33,835)
Comprehensive loss attributable to noncontrolling interest	—	9	5	31
Comprehensive loss attributable to CTI	$ (10,088)	$ (14,821)	$ (31,852)	$ (33,804)

See accompanying notes.

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

	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 December 31, 2018	13	$ —	57,986	$ 58	$ 2,294,025	$ (10,643)	$ (2,224,746)	$ (5,755)	$ 52,939
Cumulative effect adjustments	—	—	—	—	(7)	—	1,203	—	1,196
Balance at January 1, 2019	13	$ —	57,986	$ 58	$ 2,294,018	$ (10,643)	$ (2,223,543)	$ (5,755)	$ 54,135
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
Equity-based compensation	—	—	—	—	1,361	—	—	—	1,361
Other	—	—	—	—	1	—	—	—	1
Noncontrolling interest	—	—	—	—	—	—	—	(5)	(5)
Net loss	—	—	—	—	—	—	(10,971)	—	(10,971)
Other comprehensive income	—	—	—	—	—	12	—	—	12
Balance at June 30, 2019	13	$ —	57,979	$ 58	$ 2,296,637	$ (10,622)	$ (2,245,328)	$ (5,760)	$ 34,985
Equity-based compensation	—	—	—	—	1,294	—	—	—	1,294
Net loss	—	—	—	—	—	—	(10,047)	—	(10,047)
Other comprehensive loss	—	—	—	—	—	(41)	—	—	(41)
Balance at September 30, 2019	13	$ —	57,979	$ 58	$ 2,297,931	$ (10,663)	$ (2,255,375)	$ (5,760)	$ 26,191

	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, 2018	1	$ —	42,969	$ 43	$ 2,223,388	$ (6,272)	$ (2,195,346)	$ (5,723)	$ 16,090
Issuance of common stock, net of issuance costs	—	—	23,012	23	64,166	—	—	—	64,189
Exchange of common stock for preferred stock	12	—	(8,000)	(8)	8	—	—	—	—
Value of beneficial conversion features related to preferred stock	—	—	—	—	80	—	(80)	—	—
Equity-based compensation	—	—	—	—	1,336	—	—	—	1,336
Other	—	—	—	—	(1)	—	—	—	(1)
Noncontrolling interest	—	—	—	—	—	—	—	(14)	(14)
Net loss	—	—	—	—	—	—	(4,021)	—	(4,021)
Other comprehensive loss	—	—	—	—	—	(532)	—	—	(532)
Balance at March 31, 2018	13	$ —	57,981	$ 58	$ 2,288,977	$ (6,804)	$ (2,199,447)	$ (5,737)	$ 77,047
Issuance costs related to common stock issuance	—	—	—	—	(19)	—	—	—	(19)
Equity-based compensation	—	—	—	—	1,040	—	—	—	1,040
Other	—	—	4	—	19	—	—	—	19
Noncontrolling interest	—	—	—	—	—	—	—	(9)	(9)
Net loss	—	—	—	—	—	—	(11,336)	—	(11,336)
Other comprehensive loss	—	—	—	—	—	(3,094)	—	—	(3,094)
Balance at June 30, 2018	13	$ —	57,985	$ 58	$ 2,290,017	$ (9,898)	$ (2,210,783)	$ (5,746)	$ 63,648
Equity-based compensation	—	—	—	—	2,528	—	—	—	2,528
Other	—	—	4	—	15	—	—	—	15
Noncontrolling interest	—	—	—	—	—	—	—	(8)	(8)
Net loss	—	—	—	—	—	—	(14,809)	—	(14,809)
Other comprehensive loss	—	—	—	—	—	(12)	—	—	(12)
Balance at September 30, 2018	13	$ —	57,989	$ 58	$ 2,292,560	$ (9,910)	$ (2,225,592)	$ (5,754)	$ 51,362

See accompanying notes.

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

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss before noncontrolling interest	$ (31,837)	$ (30,197)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	3,911	4,904
Depreciation and amortization	412	448
Write-off of deferred financing costs	213	—
Reserve for excess, obsolete or unsalable inventory	—	535
Gain on dissolution of a foreign entity	—	(4,288)
Noncash interest expense	391	394
Noncash rent benefit	(484)	(1,201)
Other	57	282
Changes in operating assets and liabilities:		
Receivables from license and development services arrangements	13,534	996
Prepaid expenses and other current assets	252	686
Other assets	1,683	(134)
Accounts payable	(1,532)	(493)
Accrued expenses	(1,809)	1,858
Deferred revenue	—	(965)
Other liabilities	(1,127)	—
Net cash used in operating activities	(16,336)	(27,175)
Investing activities		
Purchases of property and equipment	—	(33)
Purchases of short-term investments	(8,507)	(29,412)
Proceeds from maturities of short-term investments	27,400	1,500
Net cash provided by (used in) investing activities	18,893	(27,945)
Financing activities		
Proceeds from common stock offering, net of issuance costs	—	64,170
Repayment of debt	(4,000)	—
Payment of tax withholding obligations related to stock compensation	—	(20)
Proceeds from stock option exercises	—	47
Proceeds from sales of common stock under employee stock purchase plan	1	6
Cash paid for issuance costs	(45)	(100)
Net cash (used in) provided by financing activities	(4,044)	64,103
Effect of exchange rate changes on cash and cash equivalents	(35)	710
Net (decrease) increase in cash and cash equivalents	(1,522)	9,693
Cash and cash equivalents at beginning of period	36,439	43,218
Cash and cash equivalents at end of period	$ 34,917	$ 52,911
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 834	$ 886
Supplemental disclosure of noncash activities		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 4,208	$ —
Exchange of common stock and preferred stock for preferred stock	$ —	$ 24,080

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 wholly-owned 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 U.S., the European Medicines Agency, or the EMA, in the European Union, or the E.U., 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 and nine months ended September 30, 2019 and 2018 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 and nine months ended September 30, 2019 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, 2018 included in our Annual Report on Form 10-K filed with the SEC on March 13, 2019.

The condensed consolidated balance sheet at December 31, 2018 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. As of September 30, 2019, 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.

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 pacritinib 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. In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of a 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 net operating losses every year since our formation. As of September 30, 2019, 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 $46.7 million as of September 30, 2019, and we expect that our present financial resources will only be sufficient to meet our obligations as they come due and to fund our operations into the third quarter of 2020. Based on our evaluation completed pursuant to Accounting Standards Update No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* these factors raise substantial doubt about our ability to continue as a going concern.

Accordingly, we will need to acquire additional funds in order to develop our business and continue the development 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 selling, general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, refrain from making our contractually required payments when due (including debt payments) and/or 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 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. 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. See *Long-term Debt* below for further discussion. 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 September 30, 2019 and December 31, 2018, 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 September 30, 2019 and December 31, 2018. 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):

	September 30, 2019				December 31, 2018
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value	Total Estimated Fair Value
Cash	$ 801	$ —	$ —	$ 801	$ 919
Level 1 securities:					
Money market funds	31,624	—	—	31,624	20,525
Level 2 securities:					
U.S. government and agency securities	8,786	2	—	8,788	15,213
Corporate debt securities	5,516	3	—	5,519	30,381
Total cash, cash equivalents and short-term investments	$ 46,727	$ 5	$ —	$ 46,732	$ 67,038

Receivables from License and Development Services Arrangements

Our receivables relate to amounts payable or reimbursable to us under the terms of license and development services arrangements with our partners. The receivable balance as of September 30, 2019 primarily related to royalties from our partners Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier. The receivable balance as of December 31, 2018 primarily related to a milestone receivable from Servier for the attainment of a regulatory milestone in November 2018 as well as a milestone receivable from Teva for the attainment of a worldwide net sales milestone of TRISENOX in December 2018. Receivables are reviewed for collectability whenever circumstances indicate that the carrying amount of the receivable may not be recoverable. We had no allowance for doubtful accounts from license and development services arrangements as of September 30, 2019 or December 31, 2018.

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 $4.3 million and $4.5 million as of September 30, 2019 and December 31, 2018, respectively. Substantially all of our VAT receivable is included in *Other assets.* As disclosed in Note 9. 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 €4.2 million (or approximately $4.6 million converted using the currency exchange rate as of September 30, 2019) to the ITA is probable at this time.

Leases

As discussed in *Recently Adopted Accounting Standards* below, we adopted Accounting Standards Codification, or ASC, Topic 842 - *Leases,* on January 1, 2019. Under ASC 842, 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 *Selling, general and administrative* expenses in our condensed consolidated statements of operations. The current portion of right-of-use assets and the non-current portion of right-of-use assets are included in *Prepaid expenses and other current assets* and *Other assets*, respectively, 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.

Long-term Debt

All amounts due under the loan and security agreement with SVB have been classified as a current liability as of September 30, 2019 due to the considerations discussed in *Liquidity* above and the assessment that the material adverse change clause under the loan and security agreement is not within our control. We have not been notified of an event of default by SVB as of the date of the filing of this Quarterly Report on Form 10-Q.

Revenue Recognition

We adopted ASC 606 - *Revenue from Contracts with Customers*, on January 1, 2018, using a modified retrospective method. This standard applies to all contracts with customers, except for contracts that are within the scope of other authoritative literature. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) we satisfy a performance obligation. We apply the five-step model to arrangements that meet the definition of a contract under ASC 606 including when it is probable that we will collect the consideration we are entitled to in exchange for goods or services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. We recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation as the performance obligation is satisfied.

License and Development Services Arrangements

We recognize license and contract revenue under license and development services arrangements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. We evaluate these agreements under ASC 606 to determine distinct performance obligations. Prior to recognizing revenue, we make estimates of the transaction price, including any variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that there will not be a significant reversal in the amount of cumulative revenue recognized and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the arrangement. If there are multiple, distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on its relative standalone selling price. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure in accordance with ASC-340-40, *Other Assets and Deferred Costs: Contracts with Customers*.

Foreign Currency Translation and Transaction Gains and Losses

We record foreign currency translation adjustments and transaction gains and losses in accordance with ASC 830 - *Foreign Currency Matters.* For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss, but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of stockholders' equity, except for intercompany transactions that are of a short-term nature with entities that are consolidated, combined or accounted for by the equity method in our condensed consolidated financial statements. We and our subsidiary also have transactions in foreign currencies other than the functional currency. We record transaction gains and losses in our condensed consolidated statements of operations related to the recurring measurement and settlement of such transactions.

The intercompany balance due from CTILS is considered to be of a long-term nature. An unrealized foreign exchange loss of $1.4 million and $1.6 million for the three and nine months ended September 30, 2019, respectively, and an unrealized foreign exchange loss of $0.2 million and $0.3 million for the same periods in 2018 were recorded in the cumulative foreign currency

translation adjustment account. As of September 30, 2019 and December 31, 2018, the intercompany balance due from CTILS was €29.8 million (or $32.5 million upon conversion from euros as of September 30, 2019) and €28.7 million (or $32.8 million upon conversion from euros as of December 31, 2018), respectively. As discussed in Note 8. Other Comprehensive Loss, we anticipate the dissolution of CTILS in the fourth quarter of 2019, and the intercompany balance due from CTILS is expected to be treated as capital contribution in connection with the dissolution. See Note 8. Other Comprehensive Loss for further discussion.

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 19.8 million shares and 18.5 million shares for the three and nine months ended September 30, 2019, respectively, and 16.7 million shares and 14.8 million shares for the same periods in 2018, respectively, were excluded from the calculation of diluted net loss per share because they were anti-dilutive.

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASC 842 -*Leases*, which requires lessees to recognize virtually all of their leases (other than leases that meet the definition of a short-term lease) on the balance sheet. On January 1, 2019, we adopted ASC 842 using the modified retrospective approach with a cumulative-effect adjustment as of January 1, 2019 in accordance with ASU No. 2018-11, *Leases* (Topic 842) - *Targeted Improvements*. Prior period amounts are not adjusted and continue to be reported under previous lease guidance, ASC 840 - *Leases*.

We have performed an evaluation of our contracts with customers and suppliers in accordance with ASC 842 and have determined that the agreements for our office space, parking and office equipment contained a lease. All identified leases are classified as operating leases. We had no finance or capital leases as of September 30, 2019 and December 31, 2018 and for the three and nine months ended September 30, 2019 and 2018. We also elected a package of practical expedients permitted under the transition guidance within the new standard.

The impact of the adoption of ASC 842 on our condensed consolidated balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments due to adoption of ASC 842	January 1, 2019
Right-of-use assets, current	$ —	$ 1,034	$ 1,034
Right-of-use assets, non-current	$ —	$ 3,174	$ 3,174
Lease liabilities, current	$ —	$ 1,687	$ 1,687
Lease liabilities, non-current	$ —	$ 4,946	$ 4,946
Deferred rent, current	$ 893	$ (893)	$ —
Deferred rent, non-current	$ 2,157	$ (2,157)	$ —
Accumulated deficit	$ (2,224,746)	$ 1,196	$ (2,223,550)

The adoption of the standard did not materially impact our condensed consolidated statements of operations or condensed consolidated statements of cash flows. See Note 4. Leases for further details about our leases.

In June 2018, the FASB issued new accounting guidance which simplifies the accounting for share-based payments granted to nonemployees for goods and services by aligning it with the accounting for share-based payments to employees, with certain exceptions. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We adopted this guidance on January 1, 2019. 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, 2019, 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.

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. Early adoption is permitted for either the entire standard or any eliminated or modified disclosures. 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.

Reclassifications

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

2. Other Assets

Other assets consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Right-of-use assets, non-current	$ 2,259	$ —
Italian VAT receivables	4,265	4,480
Italian VAT deposit	469	493
Rent deposit	194	194
Other	347	380
Other assets	$ 7,534	$ 5,547

On January 1, 2019, we adopted ASC 842 -*Leases* and recorded right-of-use assets for our operating leases. See Note1. Description of Business and Summary of Significant Accounting Policies - *Recently Adopted Accounting Standards* and Note 4. Leases for further details.

For details regarding our Italian VAT receivables and Italian VAT deposit, see Note1. Description of Business and Summary of Significant Accounting Policies - *Italian Value Added Tax Receivable*and Note 9. Contingencies.

3. Other Liabilities

Other liabilities consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Lease liabilities, non-current	$ 3,498	$ —
Deferred rent, non-current	—	2,157
Other long-term obligations	974	2,414
Total other liabilities	$ 4,472	$ 4,571

On January 1, 2019, we adopted ASC 842 -*Leases* and recorded lease liabilities and corresponding right-of-use assets for our operating leases. Deferred rent, less current portion as of December 31, 2018 included amounts related to lease

incentives associated with our operating lease for office space. Under ASC 842, such lease incentives are accounted for as a reduction to the right-of-use asset balance. See Note 1. Description of Business and Summary of Significant Accounting Policies - *Recently Adopted Accounting Standards* and Note 4. Leases for further details.

Other long-term obligations as of December 31, 2018 included a fee in the amount of $1.4 million payable to Silicon Valley Bank. 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, 2018 for additional information. As of September 30, 2019, this balance has been reclassified to *Other current liabilities.* See Note 1. Description of Business and Summary of Significant Accounting Policies- *Long-term Debt* for further details regarding reclassification.

4. Leases

In January 2012, we entered into an agreement with Selig Holdings Company LLC, or Selig, to lease approximately 66,000 square feet of office space in Seattle, Washington for a term of 10 years, commencing May 2012. We have two five-year options to extend the term of the lease at a market rate determined according to the lease. We also had an option to early terminate the lease after the fifth anniversary from the commencement date. We were provided with a total of $3.9 million for certain tenant improvements and other lease incentives. The options to extend or terminate the lease were not considered in the determination of the right-of-use asset and the lease liability as we did not consider it reasonably certain that we would exercise such options. We also lease parking space and certain office equipment. We have elected not to separate a non-lease component from a lease component for these leases.

In December 2017, we entered into an agreement to sublease approximately 44,000 square feet of our office space. No payments were due through May 2018, after which monthly rent is due through the sublease termination date in April 2022.

The operating lease for our office space includes common area maintenance services provided by Selig, which are considered a non-lease component. Since the payments for these services are based on the actual costs incurred by Selig in providing the services, we consider these payments as variable lease expenses.

The components of lease expense, which were included in our condensed consolidated statements of operations, were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating lease expense	$ 421	$ 342	$ 1,274	$ 1,043
Variable lease expense	45	50	132	145
Sublease income	(311)	(311)	(935)	(935)
Total lease expense, net	$ 155	$ 81	$ 471	$ 253

The balance sheet classification of operating lease right-of-use assets and operating lease liabilities were as follows (in thousands):

	September 30, 2019
Right-of-use assets, current (included in *Prepaid expenses and other current assets*)	$ 1,193
Right-of-use assets, non-current (included in *Other assets*)	2,259
Total right-of-use assets	$ 3,452
Lease liabilities, current (included in *Other current liabilities*)	$ 1,894
Lease liabilities, non-current (included in *Other liabilities*)	3,498
Total lease liabilities	$ 5,392

As September 30, 2019, the maturities of operating lease liabilities were as follows (in thousands):

	Operating Leases
2019	$ 604
2020	2,443
2021	2,437
2022	820
Total lease payments	6,304
Less imputed interest	(912)
Total lease liabilities	$ 5,392

The schedule above does not contemplate any sublease income from subleasing of our office space. As of September 30, 2019, the total remaining scheduled sublease payments were $3.7 million.

Supplemental information relating to our operating leases is as follows (in thousands):

	September 30, 2019
Supplemental cash flow information	
Cash paid for amounts included in the measurement of lease liabilities	$ 1,788
Right-of-use assets obtained in exchange for operating lease liabilities	$ 4,208
Weighted-average remaining lease term of operating leases (years)	2.56
Weighted-average discount rate of operating leases	12.4%

5. Termination of Servier Agreement

In February 2019, we entered into a Termination and Transfer Agreement, or the Termination Agreement, among, on the one hand, the Company and its subsidiary, CTILS, and, on the other hand, Servier. The Termination Agreement terminates the Amended and Restated Exclusive License and Collaboration Agreement, dated as of April 21, 2017 by and among the Company, CTILS and Servier, or the Restated Agreement.

Under the Termination Agreement, we were responsible for non-U.S. pharmacovigilance for PIXUVRI (pixantrone), the submission of a marketing authorization application for PIXUVRI and wind down of the PIX306 clinical trial during a transition period.

Servier agreed to reimburse us €620,000 (of which, €65,000 was reimbursed and recognized as license and contract revenue in 2018) for costs to be incurred in connection with transition period activities on or before May 31, 2019 and to provide additional reimbursement to us for transition period activities occurring after May 31, 2019, not to exceed €50,000 per month or €200,000 in the aggregate. For the nine months ended September 30, 2019, we recognized $0.6 million of license and contract revenue related to the transition period activities, which does not include the aforementioned additional reimbursement. There was no such license and contract revenue during the three months ended September 30, 2019.

In April 2019, Servier announced that the EMA's Committee for Medicinal Products for Human Use, or CHMP, issued a positive opinion for PIXUVRI to convert its conditional approval into a standard marketing authorization as a single agent for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma, and in June 2019, the European Commission adopted the decision to grant non-conditional marketing authorization for PIXUVRI. Pursuant to the Termination Agreement, we agreed to transfer and assign all of our rights and responsibilities for PIXUVRI globally to Servier pursuant to an asset purchase agreement.

In August 2019, we entered into the asset purchase agreement, which was amended and restated in September 2019, or the Asset Purchase Agreement. The Asset Purchase Agreement required, among other things, Servier to pay us €2.0 million and assume responsibility for all of the obligations related to PIXUVRI, including the Company’s remaining royalty payments to Novartis International Pharmaceutical Ltd. and the University of Vermont. For the three and nine months ended September 30,

2019, we recognized $2.2 million of license and contract revenue related to the Asset Purchase Agreement, and all of our rights and responsibilities for PIXUVRI were transferred and assigned globally to Servier pursuant to the Asset Purchase Agreement.

6. Restructuring Activities

In December 2018, we announced a restructuring plan to improve efficiencies and reduce costs within the Company, which impacted a total of 21 positions. The restructuring activities were substantially completed as of March 31, 2019, and we have incurred total restructuring expenses of approximately $1.5 million to date, of which $0.8 million was incurred during the nine months ended September 30, 2019.

The following table summarizes the accrual balance and utilization for the nine months ended September 30, 2019 (in thousands):

	Employee Separation Costs
Restructuring accruals - December 31, 2018	$ 660
Restructuring expenses	794
Cash payments	(1,325)
Restructuring accruals - September 30, 2019	$ 129

7. Share-based Compensation Expense

The following table summarizes share-based compensation expense, which was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 56	$ 1,231	$ 308	$ 1,774
Selling, general and administrative	1,238	1,297	3,603	3,130
Total share-based compensation expense	$ 1,294	$ 2,528	$ 3,911	$ 4,904

We incurred share-based compensation expense (reversals) due to the following types of awards (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Restricted stock	$ 1	$ 2	$ (14)	$ 111
Options	1,293	2,526	3,925	4,793
Total share-based compensation expense	$ 1,294	$ 2,528	$ 3,911	$ 4,904

8. Other Comprehensive Loss

Total accumulated other comprehensive loss consisted of the following (in thousands):

	Net Unrealized (Loss) Gain on Available-For-Sale Securities	Foreign Currency Translation Adjustments	Unrealized Foreign Exchange Loss on Intercompany Balance	Accumulated Other Comprehensive Loss
December 31, 2018	$ (14)	$ (9,672)	$ (957)	$ (10,643)
Current period other comprehensive income (loss)	20	1,570	(1,610)	(20)
September 30, 2019	$ 6	$ (8,102)	$ (2,567)	$ (10,663)

We anticipate the dissolution of CTILS, our wholly-owned subsidiary in the U.K., in the fourth quarter of 2019. Upon dissolution, we expect to recognize a loss on dissolution in *Other non-operating (expense) income* in the consolidated statement of operations, primarily attributable to a release of cumulative translation adjustment relating to an unrealized foreign exchange loss on intercompany balance in the table above. As of September 30, 2019, such balance was $2.6 million.

9. 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, €2.7 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, 2018. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 18. Commitments and Contingencies" of our Annual Report on Form 10-K for the year ended December 31, 2018 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 €4.2 million, or approximately $4.6 million converted using the currency exchange rate as of September 30, 2019, 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, in addition to historical information, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on Form 10-Q, terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of those terms or other comparable terms are intended to identify such forward-looking statements.

These forward-looking statements include, but are not limited to:

- *our expectations regarding sufficiency of cash resources, cash expenditures, sources of cash flows and other projections, product manufacturing and sales, research and development expenses, selling, general and administrative expenses and additional losses;*
- *our ability to obtain funding for our operations;*
- *the 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 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 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;*
- *the timing of, and our and our collaborators' ability to obtain and maintain, regulatory approvals for any of our product candidates;*
- *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;*
- *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; and*
- *developments relating to our competitors and our industry, including the success of competing therapies that are or become available.*

These statements are based on assumptions about many important factors and information currently available to us to the extent that we have thus far had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. Additionally, these statements are subject to known and unknown risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, particularly in "Factors Affecting Our Business, Financial Condition, Operating Results and Prospects," that could cause actual results, levels of activity, performance or achievements to differ significantly from those projected. Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments, except as required by law. Readers are cautioned not to place undue reliance on these forward-looking statements.

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 Quarterly Report on Form 10-Q, and although 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 a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

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 May 2019, our independent data monitoring committee, or IDMC, for the dose-exploration clinical trial of pacritinib, which we refer to as the PAC203 Phase 2 trial, completed its planned fourth and final interim safety review and recommended that the trial continue without modification. We intend to report final results from the Phase 2 trial to the IDMC by providing them with the final study report. We also expect to report safety and efficacy data from the PAC203 Phase 2 trial at a scientific conference before the end of 2019. In July 2019, we met with the FDA for a Type B, End-of-Phase 2a meeting regarding the continued development of pacritinib and, 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 (platelet counts of less than 50,000 per microliter) who are treatment-naïve or intolerant to ruxolitinib. The current PACIFICA Phase 3 protocol provides for the evaluation of 180 adult patients. Based on a trial of the size provided for in the current PACIFICA Phase 3 trial protocol, we would anticipate topline data from the PACIFICA Phase 3 trial in mid-2021. We previously submitted to the FDA a proposed protocol amendment, which allowed a rapid transition to the PACIFICA Phase 3 trial. Additionally, in July 2019 we announced our decision to undertake an expanded access program, or EAP, for pacritinib for patients in the PAC203 Phase 2 trial. As a result, we extended the PAC203 Phase 2 trial to enable the patients to continue receiving pacritinib through the launch of the EAP. We expect the PACIFICA Phase 3 trial to be conducted at more than 100 sites worldwide with patients randomized in a ratio of 2:1 between pacritinib and physician's choice. Under the current protocol for the PACIFICA Phase 3 trial, the primary endpoint is the percentage of patients who achieve at least 35% reduction in spleen volume at week 24 and secondary endpoints include the efficacy of pacritinib versus physician's choice therapy as assessed by the proportion of patients achieving at least a 50% reduction in total symptom score between baseline and week 24, the overall survival of patients treated with pacritinib versus physician's choice therapy and the percentage of patients treated with pacritinib who self-assess improvement compared to other patients treated with physician's choice therapy.

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. Such a change to the trial protocol would 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. We continue to analyze our regulatory options with regards to the assessment of TSS in the trial.

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. If investors view negatively FDA's suggested change or other potential changes to the PACIFICA Phase 3 trial protocol that would increase the cost of the study and prolong the study, or if we are unable to expedite the regulatory approval process, we may be required to pursue strategic alternatives for the development of pacritinib and/or our company.

In April 2019, Les Laboratoires Servier and Institut de Recherches Internationales Servier, or together, Servier, announced that CHMP issued a positive opinion for PIXUVRI (pixantrone) to convert its conditional approval into a standard marketing authorization as a single agent for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma, and in June 2019, the European Commission adopted the decision to grant non-conditional marketing authorization for PIXUVRI. Pursuant to the Termination and Transfer Agreement between us and Servier, which we refer to as the Termination Agreement, in September 2019, we transferred and assigned all of our rights and responsibilities for PIXUVRI globally to Servier pursuant to an amended and restated asset purchase agreement. For more information on the Termination Agreement, see our Current Report on Form 8-K filed with the SEC on February 27, 2019.

We have incurred significant operating losses to date and expect that our operating losses will increase significantly as we advance pacritinib, through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. Our net losses were $10.0 million and $14.8 million for the three-month periods ended September 30, 2019 and 2018, respectively, and $31.8 million and $30.2 million for the nine-month periods ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $2.3 billion and cash, cash equivalents and short-term investments of $46.7 million. We believe that our cash, cash equivalents and short-term investments will only be sufficient to fund our projected operations into the third quarter of 2020. This raises substantial doubt about our ability to continue as a going concern. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information on our assessment.

Our ability to generate product revenue will depend on the successful development and eventual commercialization of pacritinib, and we must raise additional financing to fund the PACIFICA Phase 3 trial to completion. 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. Until such time as we can generate significant revenue from sales of pacritinib, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of pacritinib.

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 product candidate, pacritinib, is currently in clinical development. 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. 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 revenues are generated from license and development services agreements. Our license and contract revenues primarily reflect milestone and royalty payments under such agreements. We had PIXUVRI sales prior to April 2017 when we entered into the Restated Agreement with Servier, which was terminated in February 2019. All of our rights and responsibilities for PIXUVRI were transferred and assigned globally to Servier in September 2019. Total revenues were $2.3 million and $0.7 million for the three months ended September 30, 2019 and 2018, respectively, and $3.3 million and $12.2 million for the nine months ended September 30, 2019 and 2018, respectively. Loss from operations was $9.7 million and $14.8 million for the three months ended September 30, 2019 and 2018, respectively, and $31.2 million and $33.1 million for the nine months ended September 30, 2019 and 2018, 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 September 30, 2019, cash, cash equivalents and short-term investments were $46.7 million.

RESULTS OF OPERATIONS

Three and nine months ended September 30, 2019 and 2018

License and contract revenues

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2019	2018	2019	2018
Servier	Development services revenue	$ —	$ 471	$ 99	$ 1,242
	Royalty revenue	104	252	446	571
	Other revenue	2,185	—	2,800	369
	Total Servier revenue	2,289	723	3,345	2,182
Teva	Milestone revenue	—	—	—	10,000
	Total Teva revenue	—	—	—	10,000
Total		$ 2,289	$ 723	$ 3,345	$ 12,182

Servier. License and contract revenue for the nine months ended September 30, 2019 included$0.1 million of development services revenue relating to the reimbursement of certain regulatory agency costs. There was no such revenue for the three months ended September 30, 2019. Other revenue for the three and nine months ended September 30, 2019 included $2.2 million of revenue recognized in connection with the Asset Purchase Agreement with Servier. In addition, other revenue for the nine months ended September 30, 2019 included $0.6 million of revenue related to transition period activities pursuant to the terms of the Termination Agreement with Servier. There was no such revenue relating to transition period activities for the three months ended September 30, 2019. See Part I, Item 1, Note 5. Termination of Servier Agreement of this Quarterly Report on Form 10-Q for further details.

License and contract revenue for the three and nine months ended September 30, 2018 included $0.4 million and $1.0 million, respectively, of development services revenue recognized from the upfront payments we received in connection with our license and collaboration agreement with Servier. In addition, we recorded development services revenue of $0.1 million and $0.2 million during the three and nine months ended September 30, 2018, respectively, for the reimbursement of pharmacovigilance expenses by Servier. Other revenue of $0.4 million for the nine months ended September 30, 2018 was related to the sale of PIXUVRI drug product to Servier, which had previously been written off. There was no such revenue for the three months ended September 30, 2018.

Teva. During the nine months ended September 30, 2018, we recognized $10.0 million in milestone revenue from Teva related to the achievement of a milestone for FDA approval of TRISENOX for first line treatment of acute promyelocytic leukemia. There were no such revenues for the comparable period in 2019 and during the three-month periods ended September 30, 2019 and 2018.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Compounds:				
Pacritinib	$ 5,912	$ 3,083	$ 13,330	$ 13,782
PIXUVRI	288	2,384	1,227	4,930
Tosedostat	6	8	29	105
Operating expenses	1,392	4,250	4,536	9,696
Research and preclinical development	—	5	4	26
Total research and development expenses	$ 7,598	$ 9,730	$ 19,126	$ 28,539

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 U.S. and Europe, as well as upfront license fees for acquired technology. Subsequent to receiving a positive opinion for conditional approval of PIXUVRI in the E.U. from the EMA's CHMP, costs associated with commercial batch production, quality control, stability testing, and certain other manufacturing costs of PIXUVRI were capitalized as inventory. 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 through September 30, 2019 were $159.6 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), $135.1 million for PIXUVRI (excluding costs prior to our 2004 merger with Novuspharma S.p.A, formerly a public pharmaceutical company located in Italy) and $14.0 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma Therapeutics Limited, or Chroma, in 2011 and $21.9 million of in-process research and development expenses associated with the acquisition of certain assets from Chroma).

Research and development expenses decreased to $7.6 million and $19.1 million for the three and nine months endedSeptember 30, 2019, respectively, compared to $9.7 million and $28.5 million for the same periods in2018. The decrease

between the three-month periods ended September 30, 2019 and 2018 was primarily attributable to a $2.7 million decrease in personnel costs due to the reduction of our workforce in the fourth quarter of 2018, a $2.1 million decrease in PIX306 clinical trial close-out costs and a $0.1 million decrease in other operating expenses. These decreases were partially offset by a $2.8 million increase in pacritinib development costs primarily related to the commencement of the PACIFICA Phase 3 trial. The decrease between the nine-month periods ended September 30, 2019 and 2018 was primarily attributable to a $5.0 million decrease in personnel costs due to the reduction of our workforce in the fourth quarter of 2018, a $3.7 million decrease in PIX306 clinical trial close-out costs, a $0.2 million decrease in other operating expenses as well as a $0.5 million net decrease in pacritinib development costs, which was primarily related to the PAC203 Phase 2 dosing clinical trial, partially offset by an increase due to the commencement of the PACIFICA Phase 3 trial.

Selling, general and administrative expenses. Selling, general and administrative expenses were $4.4 million and $14.7 million for the three and nine months ended September 30, 2019, respectively, compared to $5.8 million and $16.8 million for the same periods in 2018. The decrease between the three-month periods ended September 30, 2019 and 2018 was primarily attributable to a $0.7 million decrease in professional and consulting services, a $0.5 million decrease in personnel costs due to the reduction of our workforce in the fourth quarter of 2018, and a $0.2 million decrease in travel and other expenses. The decrease between the nine-month periods ended September 30, 2019 and 2018 was primarily attributable to a $0.9 million decrease in professional and consulting services, a $0.8 million decrease in personnel costs due to the reduction of our workforce in the fourth quarter of 2018, a $0.5 million provision for excess, obsolete or unsalable inventory in 2018, and a $0.3 million decrease in travel and other expenses, offset by a $0.4 million increase in tax 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 nine months ended September 30, 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 2018 and for the three months ended September 30, 2019 and 2018. The restructuring activities were substantially completed as of March 31, 2019 and as such, we do not anticipate additional employee separation costs. See Part I, Item 1, Note 6. Restructuring Activities of this Quarterly Report on Form 10-Q for further details.

Non-operating income and expenses

Interest income. Interest income was $0.3 million and $1.0 million for the three and nine months ended September 30, 2019, respectively, and $0.4 million and $0.8 million for the same periods in 2018. Interest income was primarily related to our short-term investments and cash equivalent securities.

Interest expense. Interest expense was $0.2 million and $0.8 million for the three and nine-month periods ended September 30, 2019, respectively, and $0.3 million and $0.9 million for the same periods in 2018. Interest expense was primarily related to our secured term loan. Interest expense decreased slightly between periods primarily due to a decrease in the average loan principal balance outstanding.

Amortization of debt discount and issuance costs Amortization of debt discount and issuance costs of $0.1 million and $0.4 million for the three and nine months ended September 30, 2019, respectively, and $0.1 million and $0.4 million for the same periods in 2018 related to our secured term loan.

Foreign exchange loss. Foreign exchange loss for the three and nine months ended September 30, 2019 and 2018 was due to fluctuations in foreign currency exchange rates, primarily related to operations in our European subsidiary as well as assets and liabilities denominated in foreign currencies.

Other non-operating income. Other non-operating income for the nine months ended September 30, 2018 includes a $4.3 million gain on the dissolution of our foreign branch, primarily relating to the release of cumulative translation adjustment. There was no such income for the three and nine months ended September 30, 2019 or for the three months ended September 30, 2018.

Deemed dividends on preferred stock. Deemed dividends on preferred stock of $0.1 million for the nine months ended September 30, 2018 were related to the issuance of Series O Preferred Stock in February 2018. There were no deemed dividends on preferred stock for the three and nine months ended September 30, 2019 or for the three months ended September 30, 2018. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 8. Equity Transactions" of our Annual Report on Form 10-K for the year ended December 31, 2018 for information regarding our Series O Preferred Stock.

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 September 30, 2019, we had $46.7 million in cash, cash equivalents and short-term investments.

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 a prior loan and security agreement. As of September 30, 2019, we had an outstanding principal balance under our secured term loan agreement of $11.6 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. Among other events, a failure to make a required loan payment, an uncured covenant breach or a material adverse change in our business, operations or condition (financial or otherwise) 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 decreased to $16.3 million during the nine months ended September 30, 2019 compared to $27.2 million for the same period in 2018. During the nine months ended September 30, 2019, we received €2.0 million pursuant to the Asset Purchase Agreement with Servier (or $2.2 million using the currency exchange rate as of the date of cash receipt). During this period, we also collected €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 $10.0 million from Teva relating to the December 2018 achievement of a worldwide net sales milestone of TRISENOX. During the nine months ended September 30, 2018, we collected $10.0 million from Teva for the achievement of the milestone related to FDA approval of TRISENOX for first line treatment of acute promyelocytic leukemia. After taking these cash receipts into account, the remaining decrease in net cash used in operating activities was primarily due to a decrease in research and development activities as well as the timing of cash payments between the two periods.

Net cash provided by (used in) investing activities. Net cash provided by investing activities was $18.9 million during the nine months ended September 30, 2019, and net cash used in investing activities was $27.9 million during the same period in 2018. The change was primarily attributable to a decrease in purchases of short-term investments as well as an increase in proceeds from maturities of short-term investments during the nine-month period in 2019.

Net cash (used in) provided by financing activities. Net cash used in financing activities was $4.0 million during the nine months ended September 30, 2019, and net cash provided by financing activities was $64.1 million during the same period in 2018. The change was primarily due to the net proceeds from our February 2018 offering of common stock as well as repayment of debt in 2019.

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 will 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, 2018.

Capital Resources

We have prepared our condensed consolidated financial statements assuming we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, we believe that our present financial resources will only be sufficient to fund our operations into the third quarter of 2020. This raises substantial doubt about our ability to continue as a going concern and we will need to raise substantial additional capital in the near term in order to fund our operations through and beyond the third quarter of 2020 and to continue as a going concern thereafter. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information on our assessment. Further, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for pacritinib. Because of our reacquisition of worldwide rights for pacritinib, we are no longer eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta, and losses related to research and development for pacritinib have increased. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of September 30, 2019, our available cash, cash equivalents and short-term investments totaled$46.7 million. We had an outstanding principal balance under our secured term loan agreement of $11.6 million as of September 30, 2019.

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, other than amounts we are entitled to or may become entitled to pursuant to our termination agreement, we do not anticipate additional revenues or payments from Servier relating to PIXUVRI. Although we received a $10.0 million milestone payment from Teva Pharmaceutical Industries Ltd. in February 2019 relating to the achievement of a worldwide net sales milestone of TRISENOX, 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 selling, general and administrative expenses, be unable to attract and retain highly qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, refrain from making our contractually required payments when due (including debt payments) and/or be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Our future capital requirements will depend on many factors, including:

- 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.

Off-Balance Sheet Arrangements

We do not presently have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for another contractually narrow or limited purpose.

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, 2018.

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, 2018. There have been no material changes to our critical accounting policies and estimates discussed therein other than the accounting policy for leases as discussed in Part I, Item 1, Note 1. Description of Business and Summary of Significant Accounting Policies of this Quarterly Report on Form 10-Q.

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

There have been no changes to our internal control over financial reporting that occurred during the third fiscal quarter ended September 30, 2019 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 9. 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, 2018 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 September 30, 2019, we had an accumulated deficit of $2.3 billion, and we expect to continue to incur additional 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.

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, 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.

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 U.S. 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, pacritinib will 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 has announced the design of a Phase 3 clinical trial planned for launch in the fourth quarter of 2019.

In addition to the specific competitive factors discussed above, new anti-cancer drugs 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. 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;
- 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, 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 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.

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. Our available cash, cash equivalents and short-term investments were $46.7 million as of

September 30, 2019. We received a $10.0 million milestone payment from Teva Pharmaceutical Industries Ltd. in February 2019 relating to the achievement of a worldwide net sales milestone of TRISENOX in December 2018. However, we believe that our present financial resources will only be sufficient to fund our operations into the third quarter of 2020. This raises substantial doubt about our ability to continue as a going concern and we will need to raise substantial additional capital in the near term in order to fund our operations through and beyond the third quarter of 2020 and to continue as a going concern thereafter. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information on our assessment. Uncertainty regarding our ability to continue as a going concern could also have a material and adverse impact on the price of our common stock, which could negatively impact our ability to raise sufficient funds to continue development of pacritinib and continue as a going concern. In addition, 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 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 selling, 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 the 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 materially 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. In February 2017, we announced the appointment of Adam Craig, M.D., Ph.D., as

President and Chief Executive Officer effective March 2017, and also in September 2017, we announced the appointment of Bruce J. Seeley as Executive Vice President, Chief Operating Officer and David H. Kirske as Chief Financial Officer. In December 2018, we announced a restructuring plan to improve efficiencies and reduce costs within the organization, which resulted in workforce reductions impacting approximately half of the total number of our employees immediately prior to the restructuring. These leadership transitions, management changes and the recent reduction in force can be difficult to manage and may create uncertainty or disruption to our business, increase the likelihood of turnover in our other officers and employees and negatively impact our ability to recruit.

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.

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. Our Italian VAT receivable was $4.3 million and $4.5 million as of September 30, 2019 and December 31, 2018, respectively.

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, €2.7 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 9. 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 €4.2 million, or approximately $4.6 million converted using the currency exchange rate as of September 30, 2019, 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. For more information, see Part I, Item 1, "Notes to Condensed Consolidated Financial Statements, Note 9. Contingencies" 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 policies are subject to high deductibles or self-insured retention amounts 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;
- 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 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. 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. For example, the United States signed into law, on December 22, 2017, tax reform legislation commonly referred to as the U.S. Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act. The 2017 Tax Act significantly revises the U.S. corporate income tax by, among other things, lowering the statutory corporate tax rate from 34% to 21%, eliminating certain deductions, imposing a mandatory one-time tax on accumulated earnings of foreign subsidiaries, introducing new tax regimes, and changing how foreign earnings are subject to U.S. tax. The 2017 Tax Act also enhances and extends through 2026 the option to claim accelerated depreciation deductions on qualified property. We have completed our determination of the accounting implications of the 2017 Tax Act. The rate adjustment to deferred tax assets, a discrete item for the quarter, is fully offset by a decrease in the valuation allowance: there is therefore no rate impact to us. In addition, there is no impact to current or deferred taxes related to the one-time deemed repatriation, as our foreign subsidiaries do not have cumulative positive earnings and profits. We are continuing to evaluate the impact of the 2017 Tax Act as further guidance is released. The foregoing items could have a material adverse effect on our business, cash flow, financial condition or results of operations.

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.

Our international operations subject us to potential adverse tax consequences.

We generally conduct our international operations through wholly owned subsidiaries and report our taxable income in various jurisdictions worldwide based upon our business operations in those jurisdictions. Our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. We believe that our financial statements reflect adequate reserves to cover such a contingency, but there can be no assurances in that regard.

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 rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks 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 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. Our contract manufacturers 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 E.U. General Data Protection Regulation and other regulations, the breach of which could result in significant penalties.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from serious disaster.

Our headquarters are located in Seattle, Washington. We are vulnerable to natural disasters such as earthquakes that could disrupt our operations. If a natural disaster, power outage, fire 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 earthquake, 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 implemented a restructuring plan in December 2018, which we cannot guarantee will achieve its intended benefits

In December 2018, we announced a restructuring plan to improve our efficiencies and reduce costs. We have incurred significant costs to implement this restructuring plan, and the implementation of the restructuring plan may subject us to litigation risks and expenses. Moreover, while we currently expect to realize cost savings of approximately $20 million primarily associated with reduced employee costs over the three years from December 2018 as a result of our restructuring plan, there can be no assurance that the restructuring plan will achieve its intended benefits. In addition, our restructuring plan may have other consequences, such as attrition beyond our planned reduction in workforce, a negative effect on employee morale and productivity or our ability to attract highly skilled employees. As a result, our restructuring plan and its implementation could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

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 clinical trials for pacritinib could be subject to further delay or we could be prevented from further studying pacritinib or seeking its commercialization.

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib clinical trials. A full clinical hold is a suspension of the clinical work requested under an IND application. Under the full clinical hold, all patients on pacritinib at the time of the hold order were required to discontinue pacritinib immediately, and no new patients could be enrolled or start pacritinib as initial or crossover treatment. In January 2017, the full clinical hold was removed following review of our complete response submission which included, among other items, final Clinical Study Reports for both PERSIST-1 and 2 trials and FDA agreement on a proposed study design for a dose-exploration clinical trial. In July 2017, we enrolled the first patient in the PAC203 Phase 2 trial, which evaluated the safety and efficacy of three dosing schedules over 24 weeks in patients with myelofibrosis previously treated with ruxolitinib. In October 2018, we announced the continuation of the PAC203 Phase 2 trial without modification, following a planned second interim data review by the independent data monitoring committee, or IDMC. Following meetings with the FDA and EMA and in consultation with the IDMC, we eliminated the interim efficacy analysis and focused the second IDMC review, and all subsequent data reviews, on an assessment of safety. We completed a Type C meeting with the FDA in December 2018 and received input on key elements of the design of the PACIFICA Phase 3 trial in adult patients with myelofibrosis (primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis) and who have severe thrombocytopenia (platelet counts of less than 50,000 per microliter). In July 2019, we met with the FDA for a Type B, End-of-Phase 2a meeting regarding the continued development of pacritinib, and 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 180 adult patients. Although the 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% 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% reduction in total symptom score between baseline and 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 PAC203 Phase 2 trial and 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. For example, 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. Such a change to the trial protocol would 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. We continue to analyze our regulatory options with regards to the assessment of TSS in the trial. If investors view negatively the FDA's suggested change or other potential changes to the PACIFICA Phase 3 trial protocol that would increase the cost of the study and prolong the study, we will be significantly hindered in our ability to obtain sufficient financing to complete the PACIFICA Phase 3 trial.

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 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview."

The submission of new marketing applications, complying with any additional requests for information from the FDA or EMA or making any changes to protocol, 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.

We previously sought accelerated approval and requested priority review of our NDA for pacritinib. However, following the full clinical hold placed on pacritinib in February 2016, we subsequently withdrew our NDA. 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. Such a change to the trial protocol would 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. We continue to analyze our regulatory options with regards to the assessment of TSS in the trial. If investors view negatively FDA's suggested change or other potential changes to the PACIFICA Phase 3 trial protocol that would increase the cost of the study and prolong the study, or if we are unable to expedite the regulatory approval process, we may be required to pursue strategic alternatives for the development of pacritinib and/or our company. Our ability to expedite the regulatory approval process is highly uncertain and we may be unsuccessful.

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.

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.

If we are unable to expedite the regulatory approval process for pacritinib, we may be required to pursue strategic alternatives for the development of pacritinib and/or our company.

We have previously pursued an accelerated approval pathway for pacritinib and are currently seeking ways to potentially expedite the regulatory approval process for pacritinib. Our ability to expedite the regulatory approval process is highly uncertain and we may be unsuccessful. If investors view negatively FDA's suggested change to the PACIFICA Phase 3 trial protocol to include change in TSS as a co-primary endpoint or other potential changes to the PACIFICA Phase 3 trial protocol that would increase the cost of the study and prolong the study, or if we are unable to expedite the regulatory approval process, we may be required to pursue strategic alternatives for the development of pacritinib and/or our company.

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. 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 twelve 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. Also, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted six-month cycle or thereafter.

A failure to obtain accelerated approval or priority review would result in a longer time to commercialization of the applicable compound in the U.S., if commercialized at all, could increase the cost of development and could harm our competitive position in the marketplace.

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.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the EMA in the E.U. Pacritinib is currently in clinical development. Pacritinib may not be marketed in the U.S. 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. For instance, in February 2016, the FDA placed pacritinib on full clinical hold and the clinical hold was not removed until January 2017. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the compound, the disease or condition that the compound is designed to address and the regulations applicable to any particular compound. For example, in July 2019, we met with the FDA for a Type B, End-of-Phase 2a meeting regarding the continued development of pacritinib and, 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 180 adult patients. Under the current protocol for the PACIFICA Phase 3 trial, the primary endpoint is the percentage of patients who achieve at least 35% 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% reduction in total symptom score between baseline and week 24. However, we cannot be certain that the anticipated PACIFICA Phase 3 trial will be sufficient for regulatory approval. 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. 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 current good manufacturing practices, or 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.

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 U.S. to continue. In the U.S., 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.

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, good clinical practices, or 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. In addition, regulatory agencies may impose post-approval/post-authorization clinical trials, such as the PIX306 trial of PIXUVRI required by the EMA. In July 2018, we and Servier announced that PIXUVRI plus rituximab did not show a statistically significant improvement in progression-free survival compared to gemcitabine plus rituximab; in February 2019, we and Servier mutually agreed to terminate our collaborative agreement; and in September 2019, we transferred and assigned all of our rights and responsibilities for PIXUVRI globally to Servier pursuant to an amended and restated asset purchase agreement, which eliminates our ability to receive future payments and royalties related to PIXUVRI. For more information on the termination of our agreement with Servier, see Part I, Item 1, “Business - License Agreements - Servier” of our Annual Report on Form 10-K for the year ended December 31, 2018.

Any other failure to comply with applicable regulations could result in warning or untitled letters, 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 U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses, or uses not approved by the FDA. This means that in the U.S., 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 U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, 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.

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 U.S. and abroad, reporting inaccurate financial information or clinical data or 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. Additionally, laws regarding data privacy and security, including the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, as well as applicable laws in non-U.S. jurisdictions, such as the European Union's General Data Privacy Regulation and Clinical Trials Regulation, the latter of which will replace the E.U. Clinical Trials Directive and which is expected to take effect beginning in late 2019 or in 2020, 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. 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 E.U. which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new E.U. Clinical Trials Regulation, EMA disclosure initiatives, and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. 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. 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. Additionally, we rely on the use of standard contractual clauses approved by the European Commission in order to transfer personal data from the E.U. to the U.S. These standard contractual clauses are subject to legal challenge in the E.U., 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 E.U. to the U.S., which we may be unable to do in a commercially reasonable manner or at all. In the U.S., in addition to possible civil and criminal penalties for 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.

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.

Risks Related to Intellectual Property

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

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

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 may allow our competitors to copy the inventions that are currently protected.

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the U.S. 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. Patents have been issued on many of these applications. We have pending patent applications or issued patents in the U.S. and foreign countries directed to pacritinib and other product candidates. However, the lives of these patents are limited. 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. Pacritinib has orphan drug designation for myelofibrosis in the U.S. and the E.U.

Each patent 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 U.S., 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.

In the absence of a patent, we would, to the extent possible, need to rely on unpatented technology, know-how and confidential information. Ultimately, the lack or expiration at any given time of a patent to protect our compounds may allow our competitors to copy the underlying inventions and better 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. Our success depends in part on our ability to:

- obtain and maintain patent protection for our products or processes both in the U.S. and other countries;
- protect trade secrets; and
- prevent others from infringing on our proprietary 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 has not established a consistent policy regarding the breadth of claims that it will allow in pharmaceutical and biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the U.S. and the risk of infringement litigation may increase. If it 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 technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated, circumvented or found unenforceable. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us.

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

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

Costly litigation might be necessary 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 products and product candidates in an effort to guide the design and development of our products to avoid infringement, but may not have conducted 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 nor do we believe that they are materially infringed upon by third parties; however, there can be no assurance that our technology 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, lawsuits take significant time, may, even if resolved in our favor, be expensive and divert management attention from other business concerns. Uncertainties resulting from the initiation and continuation of any litigation 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 these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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, litigation could result in substantial costs and be a distraction to management.

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 October 24, 2019, our stock price ranged from a low of $0.60 to a high of $1.89. 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.

On June 3, 2019, we received written notice from Nasdaq indicating that we are not in compliance with the $1.00 minimum bid price requirement for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until December 2, 2019, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this 180-day period. If we do not regain compliance with the minimum bid price requirement by December 2, 2019, Nasdaq may grant us a second period of 180 calendar days to regain compliance. To qualify for this additional compliance period, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq, other than the minimum bid price requirement. In addition, we would also be required to notify Nasdaq of our intent to cure the minimum bid price deficiency, which may include, if necessary, implementing a reverse stock split. If we meet these requirements, the Nasdaq may inform us that we have been granted a second period of 180 calendar days to regain compliance. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not otherwise eligible, the Nasdaq will notify us that our securities will be subject to delisting. If we do not regain compliance within the allotted

compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement by December 2, 2019, and we cannot guarantee that we will be able to meet the criteria required to qualify for an additional compliance period or that Nasdaq will grant us such additional compliance period. Further, if we pursue a reverse stock split to regain compliance with Nasdaq listing requirements, the announcement of the reverse stock split could adversely affect the trading price per share even if we ultimately regain compliance.

If our common stock ceases to be listed for trading on the Nasdaq, 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. 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 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% 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% 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 September 30, 2019, options to purchase 10,985,026 shares of our common stock with a weighted-average exercise price of $2.58 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 November 2017 debt financing and February 2018 public equity offering of our common stock. 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
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.

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: November 4, 2019

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

Dated: November 4, 2019

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: November 4, 2019

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: November 4, 2019

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 September 30, 2019 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: November 4, 2019

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 September 30, 2019 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: November 4, 2019

By: /s/ David H. Kirske

David H. Kirske

Chief Financial Officer