CTI BIOPHARMA CORP
Form 10-Q
November 01, 2018

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

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

For the quarterly period ended: September 30, 2018

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 001-12465

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)

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 ý 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 ý 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 ý
Non-accelerated filer	¨	Smaller reporting company ý
		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 ý

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 25, 2018
Common Stock, par value $0.001 per share	57,988,562

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Item 1. Financial Statements

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

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,911	$ 27,218
Restricted cash	—	16,000
Short-term investments	28,005	—
Receivables from Servier	269	1,278
Inventory, net	—	550
Prepaid expenses and other current assets	1,115	1,878
Total current assets	82,300	46,924
Property and equipment, net	1,938	2,365
Other assets	5,391	5,597
Total assets	$ 89,629	$ 54,886
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,078	$ 2,588
Accrued expenses	15,667	13,890
Current portion of deferred revenue	441	912
Current portion of long-term debt	3,923	444
Other current liabilities	888	1,424
Total current liabilities	22,997	19,258
Deferred revenue, less current portion	—	494
Long-term debt, less current portion	10,470	13,575
Other liabilities	4,800	5,469
Total liabilities	38,267	38,796
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share:		
Authorized shares - 33,333		
Series O Preferred Stock, 12,575 and 0 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively (Aggregate liquidation preference of $25,150 and $0 as of September 30, 2018 and December 31, 2017, respectively)	—	—
Series N Preferred Stock, 0 shares and 575 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively (Aggregate liquidation preference of $0 and $1,150 as of September 30, 2018 and December 31, 2017, respectively)	—	—
Common stock, $0.001 par value per share:		
Authorized shares - 101,500,000 and 81,500,000 as of September 30, 2018 and December 31, 2017, respectively.		

Issued and outstanding shares - 57,988,702 and 42,969,494 as of September 30, 2018 and December 31, 2017, respectively	58	43
Additional paid-in capital	2,292,560	2,223,388
Accumulated other comprehensive loss	(9,910)	(6,272)
Accumulated deficit	(2,225,592)	(2,195,346)
Total CTI stockholders' equity	57,116	21,813
Noncontrolling interest	(5,754)	(5,723)
Total stockholders' equity	51,362	16,090
Total liabilities and stockholders' equity	$ 89,629	$ 54,886

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,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$—	$—	$—	$853
License and contract revenue	723	1,705	11,813	23,831
Total revenues	723	1,705	11,813	24,684
Operating costs and expenses:				
Cost of product sold	114	69	792	280
Research and development	9,730	7,601	28,539	25,768
Selling, general and administrative	5,649	5,802	15,923	24,452
Other operating income	—	—	(334)	—
Total operating costs and expenses, net	15,493	13,472	44,920	50,500
Loss from operations	(14,770)	(11,767)	(33,107)	(25,816)
Non-operating income (expense):				
Interest income	436	—	800	—
Interest expense	(308)	(457)	(893)	(1,479)
Amortization of debt discount and issuance costs	(130)	(38)	(394)	(113)
Foreign exchange (loss) gain	(46)	161	(898)	775
Other non-operating income	—	102	4,295	72
Total non-operating (expense) income, net	(48)	(232)	2,910	(745)
Net loss before noncontrolling interest	(14,818)	(11,999)	(30,197)	(26,561)
Noncontrolling interest	9	25	31	157
Net loss	(14,809)	(11,974)	(30,166)	(26,404)
Deemed dividends on preferred stock	—	—	(80)	(4,350)
Net loss attributable to common stockholders	$(14,809)	$(11,974)	$(30,246)	$(30,754)
Basic and diluted net loss per common share	$(0.26)	$(0.28)	$(0.55)	$(0.90)
Shares used in calculation of basic and diluted net loss per common share	57,964	42,878	55,434	34,270

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,	
	2018	2017	2018	2017
Net loss before noncontrolling interest	$(14,818)	$(11,999)	$(30,197)	$(26,561)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	216	(1,029)	(3,276)	(3,474)
Unrealized foreign exchange (loss) gain on intercompany balance	(223)	1,131	(345)	3,795
Net unrealized (loss) gain on available-for-sale securities	(5)	8	(17)	7
Other comprehensive (loss) income	(12)	110	(3,638)	328
Comprehensive loss	(14,830)	(11,889)	(33,835)	(26,233)
Comprehensive loss attributable to noncontrolling interest	9	25	31	157
Comprehensive loss attributable to CTI	$(14,821)	$(11,864)	$(33,804)	$(26,076)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss before noncontrolling interest	$(30,197)	$(26,561)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	4,904	4,303
Depreciation and amortization	448	541
Reserve for excess, obsolete or unsalable inventory	535	—
Gain on dissolution of a foreign entity	(4,288)	—
Noncash interest expense	394	113
Noncash rent benefit	(1,201)	(390)
Unrealized foreign exchange loss	318	—
Other	(36)	(22)
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	996	5,366
Inventory	—	1,047
Prepaid expenses and other current assets	686	998
Other assets	(134)	79
Accounts payable	(493)	(5,264)
Accrued expenses and other	1,858	(9,976)
Deferred revenue	(965)	972
Net cash used in operating activities	(27,175)	(28,794)
Investing activities		
Purchases of property and equipment	(33)	—
Purchases of short-term investments	(29,412)	—
Proceeds from maturities of short-term investments	1,500	—
Proceeds from sale of available-for-sale securities	—	11
Net cash (used in) provided by investing activities	(27,945)	11
Financing activities		
Proceeds from common stock offering, net of issuance costs	64,170	—
Repayment of Hercules debt	—	(4,584)
Proceeds from issuance of preferred stock, net of issuance costs	—	42,669
Other	(67)	(92)
Net cash provided by financing activities	64,103	37,993
Effect of exchange rate changes on cash and cash equivalents	710	(412)
Net increase in cash, cash equivalents and restricted cash	9,693	8,798
Cash, cash equivalents and restricted cash at beginning of period	43,218	44,002
Cash, cash equivalents and restricted cash at end of period	$52,911	$52,800
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$886	$1,523

Supplemental disclosure of noncash financing activities		
Exchange of common stock and preferred stock for preferred stock	$24,080	$—
Conversion of preferred stock to common stock	$—	$41,578

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 covering a spectrum of blood-related cancers that offer a unique benefit to patients and their health care providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are primarily focused on evaluating pacritinib 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, 2018 and 2017 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, 2018 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, 2017 included in our Annual Report on Form 10-K filed with the SEC on March 7, 2018.

The condensed consolidated balance sheet at December 31, 2017 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, 2018, 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.

Reincorporation Merger

In January 2018, we effected a reincorporation merger, or the Reincorporation, following approval by our Board and our shareholders at our Special Meeting of Shareholders held on January 24, 2018, for the sole purpose of changing the state of incorporation from the State of Washington to the State of Delaware. The Reincorporation resulted in reclassification of certain carrying amounts of our preferred stock and common stock to additional paid-in capital since, prior to the Reincorporation, our preferred stock and common stock had no par value. Subsequent to the Reincorporation, our preferred stock and common stock each have a par value of $0.001 per share. The stockholders' equity section of our condensed consolidated balance sheets has been retroactively adjusted as if the Reincorporation had taken place as of January 1, 2017. There was no impact on our assets and liabilities as a result of the Reincorporation.

Liquidity

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

We will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, 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 a net operating loss every year since our formation. As of September 30, 2018, we had an accumulated deficit of $2.2 billion, and we expect to continue to incur net losses for the foreseeable future.

Our available cash, cash equivalents and short-term investments were $80.9 million as of September 30, 2018. We completed the evaluation about our ability to continue as a going concern as required by Accounting Standards Update No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Based on this analysis, we concluded that our present financial resources, together with payments projected to be received under certain contractual agreements and our ability to control costs, will be sufficient to meet our obligations as they come due and to fund our operations into the first quarter of 2020. We may need to acquire additional funds in order to develop our business. 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, 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 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, 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. As of December 31, 2017, our cash and cash equivalents consisted of cash. 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, 2018 and December 31, 2017. 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, 2018				December 31, 2017
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value	Total Estimated Fair Value
Cash	$2,592	$ —	$ —	$ 2,592	$ 43,218
Level 1 securities:					
Money market funds	30,347	—	—	30,347	—
Level 2 securities:					
U.S. government and agency securities	14,969	—	(8)	14,961	—
Corporate debt securities	33,024	—	(8)	33,016	—
	$80,932	$ —	$ (16)	$ 80,916	$ 43,218
Less: restricted cash				—	(16,000)
Total cash, cash equivalents and short-term investments				$ 80,916	$ 27,218

Restricted Cash

The restricted cash balance as of December 31, 2017 represents a legally restricted deposit held as a compensating balance against our secured term loan with Silicon Valley Bank, or SVB. Pursuant to the loan and security agreement entered into with SVB in November 2017, we were required to maintain unrestricted and unencumbered cash in an amount equal to at least $16.0 million at all times prior to the execution of an account control agreement. In January 2018, we obtained a waiver from SVB for such requirement and as a result, we no longer have restrictions placed on the cash balance.

Receivables from Servier

Our receivables from collaborative arrangements relate to amounts payable or reimbursable to us under the terms of collaborative arrangements with our partners. The receivable balance as of September 30, 2018 primarily relates to royalties from our partners Les Laboratoires Servier and Institut de Recherches Internationales Servier, or together Servier. The receivable balance as of December 31, 2017 primarily relates to the sale of PIXUVRI drug product to Servier. If it is deemed probable that an amount is uncollectible, it is written off against the existing allowance. We had no allowance for doubtful accounts from collaborative arrangements as of September 30, 2018 or December 31, 2017.

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 determined that the sales transactions made by us should have been subject to output VAT. Our Italian VAT receivable was approximately $4.5 million and $4.8 million as of September 30, 2018 and December 31, 2017, respectively. Substantially all of our VAT receivable is included in Other assets. As disclosed in Note 7. Legal Proceedings, 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 $4.9 million converted using the currency exchange rate as of September 30, 2018), to the ITA is probable at this time.

Inventory

We carry inventory at the lower of cost or net realizable value. The cost of finished goods and work in process is determined using the standard-cost method, which approximates actual cost based on a first-in, first-out method. Inventory includes the cost of materials, third-party contract manufacturing and overhead costs, quality control costs and shipping costs from the manufacturers to the final distribution warehouse associated with the distribution of PIXUVRI. Production costs for our other product candidates continue to be charged to research and development expense as incurred prior to regulatory approval or until our estimate for regulatory approval becomes probable. We review inventories on a quarterly basis for impairment and reserves are established when necessary. Estimates of excess inventory consider our projected sales of the product and the remaining shelf lives of product. In the event we identify excess, obsolete or unsalable inventory, the value is written down to the net realizable value. The inventory balance

as of September 30, 2018 was fully reserved and had a reserve of $1.0 million and $1.4 million related to excess, obsolete or unsalable inventory as of September 30, 2018 and December 31, 2017, respectively, which was included in Inventory, net.

Revenue Recognition

We adopted Accounting Standards Codification, or ASC, Topic 606 - Revenue from Contracts with Customers, on January 1, 2018, or the adoption date, 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.

Product sales

In April 2017, Servier was granted an exclusive and sublicensable (subject to certain conditions) royalty-bearing license with respect to the development and commercialization of PIXUVRI for use in pharmaceutical products, or Licensed Products, outside of the U.S. (and its territories and possessions). As a result, we no longer have product sales.

Prior to April 2017, PIXUVRI was sold primarily through a limited number of wholesale distributors. Under ASC 606, we would record product sales upon receipt of the product by health care providers and certain distributors, or the Customers, at which time the Customers obtain control of our product. Product sales are recorded net of applicable reserves for variable considerations, including distributor discounts, estimated government-mandated rebates, trade discounts and estimated product returns. Reserves are established for these variable considerations that are subject to constraints under ASC 606 and are included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period.

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 collaboration. 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.

We have determined that our agreement with Servier is within the scope of ASC 606 and that the license and development services separately accounted for under the legacy standard would have remained two distinct performance obligations to Servier under ASC 606. As a result, the deferred revenue balance of $1.4 million as of the adoption date, relating to development services, will continue to be recognized as revenue through approximately the end of 2018 using an input measure. In addition, there were no milestones recognized as a cumulative effect adjustment to the opening accumulated deficit balance because we were not yet able to overcome constraints associated with the remaining milestones as of the adoption date. There was no change to the timing of revenue recognition with respect to royalties. The adoption of ASC 606 did not have a material impact on our condensed consolidated financial statements.

Cost of Product Sold

Cost of product sold includes third-party manufacturing costs, shipping costs, contractual royalties and other costs of PIXUVRI product sold. Cost of product sold also includes allowances, if any, for excess inventory that may expire and become unsalable. Cost of product sold for the three and nine months ended September 30, 2018 related to a provision for excess, obsolete or unsaleable inventory as well as contractual royalties as we no longer have product sales as discussed above.

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 $0.2 million and $0.3 million was recorded in the cumulative foreign currency translation adjustment account for the three and nine months ended September 30, 2018, respectively. As of September 30, 2018, the intercompany balance due from CTILS was €28.3 million (or $32.8 million upon conversion from euros as of September 30, 2018). As of December 31, 2017, the intercompany balance due from CTILS was €26.2 million (or $31.4 million upon conversion from euros as of December 31, 2017).

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 16.7 million shares and 14.8 million shares for the three and nine months ended September 30, 2018, respectively, and common shares underlying stock awards, warrants and convertible preferred stock aggregating 5.0 million and 4.5 million shares for the three and nine months ended September 30, 2017, respectively, were excluded from the calculation of diluted net loss per share because they were anti-dilutive.

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board, or the FASB, issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for interim and annual periods beginning

after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. We adopted the new standard in the first quarter 2018 using the modified retrospective method. The adoption of the standard did not have a material impact on our condensed consolidated financial statements. See "Revenue Recognition" above for further discussion.

In August 2016, the FASB issued an amendment to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows with the objective of reducing diversity in practice regarding eight types of cash flows. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. The adoption of this guidance did not have a material impact on our statement of cash flows.

In March 2018, the FASB issued "Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118," or SAB 118. The guidance adds various SEC paragraphs pursuant to SAB 118 to Accounting Standard Codification 740 “Income Taxes." SAB 118 was issued in December 2017 to provide immediate guidance for accounting implications of U.S. tax reform under the Tax Cuts and Jobs Act, which became effective for us on January 1, 2018. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Recently Issued Accounting Standards

In February 2016, the FASB issued new accounting guidance on accounting for 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. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2018. Early adoption is permitted. We are currently evaluating the impact of this accounting standard on our condensed consolidated financial statements.

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. 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. Inventory

The components of PIXUVRI inventory consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Finished goods	$ —	$ 394
Work-in-process	980	1,523
Inventory, gross	980	1,917
Reserve for excess, obsolete or unsalable inventory	(980)	(1,367)
Inventory, net	$ —	$ 550

3. Leases

The deferred rent balance was $3.3 million as of September 30, 2018, of which $0.9 million was included in other current liabilities and $2.4 million was included in other liabilities. As of December 31, 2017, the deferred rent balance was $4.5 million, of which $1.4 million was included in other current liabilities and $3.1 million was included in other liabilities. Deferred rent includes $0.3 million and $0.4 million in other current liabilities and other liabilities, respectively, as of September 30, 2018, and $0.8 million and $0.6 million in other current liabilities and other

liabilities, respectively, as of December 31, 2017, associated with the sublease of office space entered into in December 2017.

4. Equity Transactions

In February 2018, we offered and sold 23.0 million shares of our common stock, referred to as the Offering. The price to the public in this Offering was $3.00 per share of common stock. The gross proceeds from the Offering were $69.0 million before deducting underwriting commissions and discounts and other offering costs of approximately $4.8 million.

BVF Partners L.P., or BVF, an existing stockholder of the Company, was one of our investors in the Offering. In connection with the Offering, BVF purchased 6.3 million shares of our common stock. In addition, BVF exchanged 8.0 million shares of our common stock owned by BVF and 575 shares of our Series N Preferred Stock owned by BVF for 12,575 shares of our Series O Preferred Stock, pursuant to the exchange agreement executed in February 2018 as well as the letter agreements we entered into with BVF in connection with our Series N-2 Preferred Stock offering in 2015 and our Series N-3 Preferred Stock offering in 2017.

Each share of Series O Preferred Stock is convertible at the option of the holder (subject to certain limitations) into shares of common stock at a conversion price of $3.00 per share of common stock. Each share of Series O Preferred Stock is entitled to a liquidation preference equal to the initial stated value of $2,000 per share, plus any declared and unpaid dividends, and any other payments that may be due on such shares, before any distribution of assets may be made to holders of capital stock ranking junior to the Series O Preferred Stock. The Series O Preferred Stock is not entitled to dividends except to share in any dividends actually paid on common stock or any pari passu or junior securities. The Series O Preferred Stock has no voting rights, except as otherwise expressly provided in the certificate of incorporation of CTI or as otherwise required by law.

For the nine months ended September 30, 2018, we recognized $0.1 million in deemed dividends on preferred stock related to the beneficial conversion feature on Series O Preferred Stock. There were 12,575 shares of Series O Preferred Stock outstanding as of September 30, 2018 which are convertible into 8.4 million shares of common stock.

5. 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,	
	2018	2017	2018	2017
Research and development	$1,231	$229	$1,774	$521
Selling, general and administrative	1,297	1,126	3,130	3,782
Total share-based compensation expense	$2,528	$1,355	$4,904	$4,303

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Restricted stock	$2	$232	$111	$848
Options	2,526	1,123	4,793	3,455
Total share-based compensation expense	$2,528	$1,355	$4,904	$4,303

6. Other Comprehensive Loss

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

	Net Unrealized Loss on Available-For-Sale Securities	Foreign Currency Translation Adjustments (1)	Unrealized Foreign Exchange Loss on Intercompany Balance	Accumulated Other Comprehensive Loss
December 31, 2017	$ 1	$ (6,829)	$ 556	$ (6,272)

Current period other comprehensive loss	(17)	(3,276)	(345)	(3,638)
September 30, 2018	$ (16)	$ (10,105)	$ 211	$ (9,910)

(1) The current period change includes a release of cumulative translation adjustment in the amount of $4.3 million upon dissolution of our foreign branch, which was recognized in other non-operating income in our condensed consolidated statement of operations for the nine months ended September 30, 2018.

7. Legal Proceedings

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 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.

Following is a summary of the status of the legal proceedings surrounding each respective VAT year return at issue:

2003 VAT Assessment. In June 2013, the Regional Tax Court issued decision no. 119/50/13 in regards to the 2003 VAT Assessment, which accepted the October 2012 appeal of the ITA and reversed a previous decision of the Provincial Tax Court. In January 2014, we appealed such decision to the Italian Supreme Court both on procedural grounds and on the merits of the case. In March 2014, we paid a deposit in respect of the 2013 VAT matter of €0.4 million (or $0.6 million upon conversion from euros as of the date of payment), following the ITA's request for such payment.

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

2006 and 2007 VAT Assessments. In November 2013, the ITA appealed to the Italian Supreme Court an April 2013 decision of the Regional Tax Court (57/35/13), that fully rejected the merits of an earlier ITA appeal, declared that no penalties could be imposed against us and found ITA liable to pay us approximately €12,000, as a partial refund of legal expenses we incurred.

No hearing dates have been fixed yet for either the 2003 VAT Assessment or consolidated 2006 and 2007 VAT Assessment cases.

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 $4.9 million converted using the currency exchange rate as of September 30, 2018, including interest and penalties for the period lapsed between the date in which the assessments were issued and the date of effective payment. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us.

SEC Subpoena

We previously disclosed that we had received a subpoena from the SEC in January 2016 in connection with an investigation that related to, among other things, our disclosures concerning the clinical test results of pacritinib. 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.

In addition to the items discussed above, we are from time to time subject to legal proceedings and claims arising in the ordinary course of business.

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," "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 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;
- the design of our clinical trials and anticipated enrollment, and the progress and potential of our other ongoing development programs;
- the timing of and results from clinical trials and pre-clinical development activities, including those related to pacritinib and our other product candidates;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to achieve profitability;
- our ability to receive milestones, royalties and sublicensing fees under our collaborations, and the timing of such payments;
- our expectations regarding federal, state and foreign regulatory requirements;
- the rate and degree of market acceptance and clinical utility of any current or future products;
- the timing of, and our and our collaborators' ability to obtain and maintain, regulatory approvals for 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 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 ending December 31, 2017, 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.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of 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 are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are primarily focused on evaluating pacritinib for the treatment of adult patients with myelofibrosis.

Pacritinib

Our primary development candidate, 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.

Pacritinib was evaluated in two Phase 3 clinical trials, known as the PERSIST program, for patients with myelofibrosis, with one trial in a broad set of patients without limitations on platelet counts, the PERSIST-1 trial, and the other in patients with low platelet counts, the PERSIST-2 trial. In August 2014, pacritinib was granted Fast Track designation by the Food and Drug Administration, or the FDA, for the treatment of intermediate and high risk myelofibrosis including, but not limited to, patients with disease-related thrombocytopenia (low platelet counts); patients experiencing treatment-emergent thrombocytopenia on other JAK2 inhibitor therapy; or patients who are intolerant of or whose symptoms are not well controlled (sub-optimally managed) on other JAK2 therapy.

In May 2015, we announced the final results from PERSIST-1, our Phase 3 trial evaluating the efficacy and safety of pacritinib compared to the Best Available Therapy, or BAT, excluding JAK2 inhibitors, which included a broad range of currently utilized treatments, in 327 patients with myelofibrosis regardless of the patients' platelet counts. The study included patients with severe or life-threatening thrombocytopenia. Patients were randomized to receive 400 mg pacritinib once daily or BAT, excluding JAK2 inhibitors. The trial met its primary endpoint of spleen volume reduction, or SVR, (35 percent or greater from baseline to Week 24 by magnetic resonance imaging, or MRI, or computerized tomography, or CT). The most common treatment-emergent adverse events, or AEs, occurring in 20 percent or more of patients treated with pacritinib within 24 weeks, of any grade, were gastrointestinal (generally

manageable diarrhea and nausea) and anemia.

On February 8, 2016, clinical studies under the investigational new drug, or IND, for pacritinib were placed on a full clinical hold issued by the FDA. A full clinical hold is an order to suspend investigations performed under the IND application. Under the full clinical hold, all patients on pacritinib at the time were required to discontinue pacritinib immediately and no patients could be enrolled or start pacritinib as initial or crossover treatment. In its written notification, the FDA stated that the reasons for the full clinical hold were that it noted interim overall survival results from the PERSIST-2 Phase 3 trial showing a detrimental effect on survival consistent with the results from PERSIST-1, as well as hemorrhagic/cardiac toxicities. The FDA had placed a partial hold on pacritinib on February 4, 2016.

In February 2016, prior to the clinical hold, we completed patient enrollment in the PERSIST-2 Phase 3 clinical trial. Under the full clinical hold, all patients participating in the PERSIST-2 clinical trial discontinued pacritinib treatment.

In August 2016, we announced the top-line results from PERSIST-2, our second Phase 3 trial of pacritinib for the treatment of patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter. Three hundred eleven (311) patients were enrolled in the study, which formed the basis for the safety analysis. Two hundred twenty-one (221) patients reached Week 24 (the primary analysis time point) at the time the clinical hold was imposed and constituted the intent-to-treat analysis population utilized for the evaluation of efficacy. Results demonstrated that the PERSIST-2 trial met one of the co-primary endpoints showing a statistically significant response rate in SVR in patients with myelofibrosis treated with pacritinib compared to BAT, including the approved JAK2 inhibitor ruxolitinib. The co-primary endpoint of reduction of Total Symptom Score, or TSS, was not achieved but trended toward improvement in TSS. There was no significant difference in overall survival across treatment arms, censored at the time of clinical hold. The most common treatment-emergent AEs, occurring in 20 percent or more of patients treated with pacritinib within 24 weeks, of any grade, were gastrointestinal (generally manageable diarrhea, nausea and vomiting) and hematologic (anemia and thrombocytopenia) and were generally less frequent for twice-daily, or BID, versus once-daily, or QD, administration. Details of the trial were presented in a late-breaking oral session at the American Society of Hematology Annual Meeting in December 2016. Subsequently, the results were published in JAMA Oncology in May 2018.

In January 2017, the FDA removed the full clinical hold following review of our complete response submission which included, among other items, final Clinical Study Reports for both the PERSIST-1 and 2 trials and FDA agreement on a proposed study design for a dose-exploration clinical trial. At that time, the PAC203 trial was designed to enroll up to approximately 105 patients with primary myelofibrosis and who had failed prior ruxolitinib therapy across three dose regimens of pacritinib, 100 mg QD, 100 mg BID and 200 mg BID, to evaluate the dose response relationship for safety and efficacy (SVR at 12 and 24 weeks). The 200 mg BID dose was selected as the top dose based upon observations from the completed PERSIST-2 study. Strengthened entry criteria were imposed in PAC203 for patients with a history of cardiac and/or bleeding events and additional dose modification guidelines were implemented for the management of treatment-emergent cardiac and or bleeding events. The first patient in the PAC203 trial was enrolled in July 2017. In April 2018, we amended the protocol to expand the sample size to a maximum of 150 patients (or 50 patients per arm) to collect additional data for the safety and efficacy analyses. In July 2018, we announced that the independent data monitoring committee, or IDMC, for the PAC203 trial completed its planned interim data review of the PAC203 trial and that the IDMC did not identify any drug- or dose-related safety concerns and did not identify any concerns about cardiac or bleeding events. Following meetings with the FDA and EMA and consultation with the IDMC, we eliminated the interim efficacy analysis and focused the second interim data review, and all subsequent data reviews, on an assessment of safety. The protocol was amended to reflect this change and submitted to FDA. In October 2018, we announced the continuation of the PAC203 Phase 2 study without modification, following a planned second interim data review by the IDMC. The IDMC did not identify significant drug- or dose-related safety concerns and specifically did not identify any concerns around hemorrhagic or cardiac toxicity. A complete data set from the full enrollment of 150 patients (including efficacy, safety, pharmacokinetic and pharmacodynamic data) will be used to determine the optimal dose of pacritinib for further clinical development, as requested by the FDA. The PAC203 study is expected to complete enrollment by the end of 2018, with the next planned interim safety review to be conducted in the first quarter of 2019. Top-line data from the study are expected in the second quarter of 2019.

In July 2018, we attended a Type B meeting with the FDA to discuss the proposed regulatory pathway for pacritinib. Based on FDA feedback at that meeting, we plan to conduct a randomized Phase 3 study of pacritinib in patients with myelofibrosis. The dosing for the Phase 3 study will be determined using the results of the PAC203 study. We have scheduled a Type C meeting with the FDA to take place before the end of 2018 to discuss the design of a new registrational Phase 3 trial of pacritinib in myelofibrosis patients with severe thrombocytopenia (platelet counts of less than 50,000 per microliter). Following the identification of the optimal dose from the PAC203 study, we expect to

begin Phase 3 patient recruitment mid-year in 2019.

The original Marketing Authorization Application, or MAA, for pacritinib was submitted to the European Medicines Agency, or EMA, in February 2016 with an indication statement based on the PERSIST-1 trial data. In its initial assessment report, the Committee for Medicinal Products for Human Use, or CHMP, determined that the original application was not approvable at that point in the review cycle because of major objections in the areas of efficacy, safety (hematological and cardiovascular toxicity) and the overall risk-benefit profile of pacritinib. Subsequent to the filing of the original MAA, data from the second Phase 3 trial of pacritinib, PERSIST-2, were reported. These data suggest that pacritinib may show clinical benefit in patients who have failed or are intolerant to ruxolitinib therapy, a population for which there is no approved therapy.

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. Validation confirms that the submission is complete and initiates the centralized review process by the CHMP. The CHMP review period is 210 days, excluding extension, question or opinion response periods, after which the CHMP opinion is reviewed by the European Commission, which usually issues a final decision on E.U. authorization within three months. If authorized, pacritinib would be granted a marketing license valid in all 28 E.U. member states, Norway, Iceland and Liechtenstein.

The Day 120 List of Questions (LoQ) was received by the Company in November 2017 and included Major Objections in areas including efficacy, safety (including hematological, cardiovascular and infectious toxicities) and other concerns including the size of the data set and the pharmacokinetic analyses of the two dosing regimens studied in PERSIST-2. A request for an extension was submitted following a clarification meeting with the rapporteur, co-rapporteur and members of the EMA to provide the EMA with data from PAC203, and on January 25, 2018, we were granted a three-month extension for submitting our response to the Day 120 LoQs. In December 2017 a preapproval GCP inspection of the PERSIST-2 clinical study was conducted by the EMA. In February 2018, the EMA issued its final GCP inspection report, which concluded that the PERSIST-2 clinical trial was generally conducted in compliance with GCP and internationally accepted ethical standards, that the deficient safety reporting procedures identified as inspection findings did not pose a direct risk to data quality and that the results from the PERSIST-2 clinical trial can be used for the evaluation and assessment of the MAA. In July 2018, we received the Day 180 LoQs and were granted a two-month extension to allow us to submit a snapshot of clinical data from the ongoing PAC203 study with our responses to the remaining list of questions. In the third quarter of 2018, we submitted comprehensive responses to the Day 180 LoQs, which included new data from the PAC203 trial. As a result, we expect the CHMP opinion on the MAA by the end of 2018.

PIXUVRI

PIXUVRI is a novel aza-anthracenedione with unique structural and physiochemical properties. In May 2012, the European Commission granted conditional marketing authorization in the European Union, or the E.U. for PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL. As part of our conditional marketing authorization in the E.U., we were required to conduct a post-authorization trial, which we refer to as PIX306, comparing PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL and follicular grade 3 lymphoma. Enrollment for PIX306 was completed in August 2017 and, 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. We continue to carefully evaluate the clinical data for PIXUVRI and we are not currently planning further clinical studies. Servier is evaluating next steps for PIXUVRI in Europe.

Factors Affecting Performance

Exclusive License and Collaboration Agreement with Servier

In April 2017 we amended and restated in its entirety the Exclusive License and Collaboration Agreement, or the Original Agreement, entered into with Servier in September 2014, related to PIXUVRI. Prior to the April 2017 entry into the Restated Agreement with Servier, we sold PIXUVRI primarily through a limited number of wholesale distributors. Gross sales is defined as our contracted reimbursement price in each country. Product sales, net represents gross sales, net of provisions for distributor discounts, estimated government-mandated discounts and rebates, trade discounts and estimated product returns. Following the entry into the Restated Agreement with Servier, we no longer have product sales; Servier is responsible for distribution of PIXUVRI in countries other than the U.S.

Our license and contract revenues include the earned amount of upfront payments and milestone payments under our product collaborations. In connection with the April 2017 execution of the Restated Agreement with Servier, we

allocated and recorded $11.5 million and $1.3 million of the upfront payment received to license revenue and deferred revenue, respectively. The remaining deferred revenue balance as of the date of the Restated Agreement relating to the upfront payment under the Original Agreement was $0.6 million, which, along with the $1.3 million of deferred revenue allocated from the Restated Agreement as mentioned above, is being recognized as revenue using an input measure. Following our July 2018 announcement that PIXUVRI plus rituximab did not show a statistically significant improvement in progression-free survival compared to gemcitabine plus rituximab, the deferred revenue balance of $0.4 million as of September 30, 2018 is expected to be recognized as revenue through approximately the end of 2018.

For additional information on our collaboration with Servier, see Part I, Item 1, “Business - License Agreements and Additional Milestone Activities - Servier” of our Annual Report on Form 10-K for the year ended December 31, 2017.

Research and Development Activities

We will need to commit significant time and resources to develop our current and any future product candidates. Our product candidates, pacritinib and tosedostat, are 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 and tosedostat 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. For example, on February 8, 2016, the FDA placed a full clinical hold on pacritinib. Also, in July 2018, we attended a Type B meeting with the FDA to discuss the proposed regulatory pathway for pacritinib. Based on FDA feedback at the meeting, we intend to conduct a randomized Phase 3 study of pacritinib in patients with myelofibrosis, which Phase 3 study will require significant time and resources to complete. Even if our drugs progress successfully through initial human testing in clinical trials, they may fail in later stages of development. 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 our product candidates 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 these compounds, our product candidates need to be developed to a stage that will enable us to commercialize, sell or license related marketing rights to third parties.

We 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 our product candidates or the ultimate product development cost.

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. We had PIXUVRI sales prior to April 2017 when we entered into the Restated Agreement with Servier. Our license and contract revenues reflect the earned amount of upfront payments and milestone payments under our product collaborations. Total revenues were $0.7 million and $1.7 million for the three months ended September 30, 2018 and 2017, respectively, and $11.8 million and $24.7 million for the nine months ended September 30, 2018 and 2017, respectively. Loss from operations was $14.8 million and $11.8 million for the three months ended September 30, 2018 and 2017, respectively. Loss from operations was $33.1 million and $25.8 million for the nine months ended September 30, 2018 and 2017, 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, 2018, cash, cash equivalents and short-term investments were $80.9 million.

RESULTS OF OPERATIONS

Three and nine months ended September 30, 2018 and 2017

Product sales, net.

Product sales, net from PIXUVRI were $0.9 million for the nine months ended September 30, 2017. We had no product sales for the three months ended September 30, 2017 as well as three and nine months ended September 30, 2018 due to our entry into the Restated Agreement with Servier in April 2017.

License and Contract Revenues

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2018	2017	2018	2017
Servier	Milestone and license revenue	$—	$1,178	$—	$12,665
	Development services revenue	471	355	1,242	822
	Royalty revenue	252	172	571	344
	Total Servier revenue	723	1,705	1,813	13,831
Teva	Milestone revenue	—	—	10,000	10,000
	Total Teva revenue	—	—	10,000	10,000
Total		$723	$1,705	$11,813	$23,831

Servier

Milestone and license revenue for the three months ended September 30, 2017 includes a €1.0 million milestone revenue (or $1.2 million using the currency exchange rate as of the date the milestone was achieved) relating to the attainment of a regulatory milestone in September 2017 under the Restated Agreement. Milestone and license revenue of $12.7 million for the nine months ended September 30, 2017 includes an $11.5 million license revenue allocated from the upfront payment we received in connection with the Restated Agreement in addition to the $1.2 million milestone revenue relating to the attainment of a regulatory milestone in September 2017. There was no such revenue for the same periods in 2018.

License and contract revenue for the three and nine months ended September 30, 2018 includes $0.4 million and $1.0 million, respectively, of development services revenue recognized from the upfront payments we received in connection with the Restated Agreement and the Original Agreement with Servier. Such revenue during the same periods in 2017 was $0.2 million and $0.4 million, respectively. The balance of deferred revenue as of September 30, 2018 was $0.4 million, which is expected to be recognized as revenue through approximately the end of 2018.

In addition, we recorded 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 under the Restated Agreement. We recorded revenue of $0.1 million and $0.3 million for the three and nine months ended September 30, 2017 for the reimbursement of expenses related to commercialization transition under the Restated Agreement.

In February 2016, we entered into an agreement with one of Servier's affiliates whereby we were to conduct a pharmacokinetic sub-study on behalf of Servier in conjunction with our ongoing clinical trial, PIX-306. In relation to this study, we recorded $9,000 and $0.1 million of expense reimbursements as development services revenue for the three and nine months ended September 30, 2017, respectively. There was no such revenue during the three and nine months ended September 30, 2018 as the pharmacokinetic sub-study was completed in September 2017.

Royalty revenue under the terms of the Restated Agreement and the Original Agreement for the three and nine months ended September 30, 2018 was $0.3 million and $0.6 million, respectively, and $0.2 million and $0.3 million for the same periods in 2017.

Teva

During the nine months ended September 30, 2018, we received a $10.0 million milestone payment from Teva related to the achievement of a milestone for FDA approval of TRISENOX for first line treatment of acute promyelocytic leukemia. There was no such revenue during the three months ended September 30, 2018.

During the nine months ended September 30, 2017, we received a $10.0 million milestone payment from Teva upon the achievement of a worldwide net sales milestone of TRISENOX. There was no such revenue during the three months ended September 30, 2017.

Operating costs and expenses

Cost of product sold. Cost of product sold relates to PIXUVRI and includes royalty expenses payable under the agreement with the University of Vermont and the Novartis Termination Agreement. For additional information about these agreements, see Part I, Item1, "Business - License Agreements and Milestone Activities" of our Annual Report on Form 10-K for the year ended December 31, 2017. Cost of product sold for the three and nine months ended September 30, 2018 was $0.1 million and $0.8 million and included royalty expenses of $0.1 million and $0.3 million, respectively. Cost of product sold for the nine months ended September 30, 2018 also included a $0.5 million provision for excess, obsolete or unsaleable inventory. Cost of product sold for the three and nine months ended September 30, 2017 was $0.1 million and $0.3 million, respectively, and included royalty expenses of $0.1 million and $0.2 million for the respective periods. The increase in cost of product sold for the nine months ended September 30, 2018 compared to the same period in 2017 was primarily related to the provision for excess, obsolete or unsalable inventory.

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,	
	2018	2017	2018	2017
Compounds:				
PIXUVRI	$2,384	$1,743	$4,930	$5,765
Pacritinib	3,083	2,511	13,782	10,132
Tosedostat	8	19	105	208
Operating expenses	4,250	3,309	9,696	9,623
Research and preclinical development	5	19	26	40
Total research and development expenses	$9,730	$7,601	$28,539	$25,768

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 as of September 30, 2018 were $132.8 million for PIXUVRI (excluding costs prior to our 2004 merger with Novuspharma S.p.A, formerly a public pharmaceutical company located in Italy), $142.0 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) 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 increased to $9.7 million and $28.5 million for the three and nine months ended September 30, 2018, respectively, compared to $7.6 million and $25.8 million for the same periods in 2017. The

increase between the three-month periods ended September 30, 2018 and 2017 was primarily attributable to a $0.9 million increase in personnel costs, a $0.6 million increase in pacritinib development costs and a $0.6 million increase in PIX306 clinical study close-out costs. The increase between the nine-month periods ended September 30, 2018 and 2017 was primarily attributable to a $6.2 million increase in the pacritinib Phase 2 dosing clinical study which began in the second quarter of 2017 and a $1.4 million increase in other pacritinib development costs, offset by a $2.1 million decrease in expenses for the completion of two pacritinib Phase 3 clinical studies and a $1.9 million decrease in the manufacture of pacritinib, as well as a $0.8 million reduction in expenses related to the PIX306 clinical study between periods.

Selling, general and administrative expenses. Selling, general and administrative expenses were $5.6 million and $15.9 million for the three and nine months ended September 30, 2018 compared to $5.8 million and $24.5 million for the same periods in 2017. The decrease between the three-month periods ended September 30, 2018 and 2017 was primarily attributable

to decreases of $0.7 million in personnel costs and $0.2 million in lease costs, offset by increases of $0.5 million in consulting and professional services and $0.2 million related to litigation settlement. The decrease between the nine-month periods ended September 30, 2018 and 2017 was primarily attributable to decreases of $3.8 million in personnel costs, $2.5 million in legal and patent fees, $2.0 million related to stockholder litigation settlement, $0.6 million in lease costs and $0.3 million in selling costs, offset by an increase of $0.7 million in consulting and professional services.

Other operating income. Other operating income of $0.3 million for the nine months ended September 30, 2018 was primarily related to the sale of PIXUVRI drug product, which had previously been written off, to Servier. There was no such income in the other periods presented.

Non-operating income and expenses

Interest income. Interest income was $0.4 million and $0.8 million for the three and nine months ended September 30, 2018, respectively, primarily related to our short-term investments and cash equivalent securities. There was no such interest income for the same periods in 2017.

Interest expense. Interest expense was $0.3 million and $0.5 million for the three months ended September 30, 2018 and 2017, respectively, and $0.9 million and $1.5 million for the nine months ended September 30, 2018 and 2017, respectively. Interest expense was primarily related to our secured term loans. The decrease between periods primarily relates to a lower average interest rate in 2018 than in 2017 and, to a lesser extent, a lower loan principal balance outstanding in 2018 compared to 2017.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of $0.1 million and $38,000 for the three months ended September 30, 2018 and 2017, respectively, and $0.4 million and $0.1 million for the nine months ended September 30, 2018 and 2017, respectively, related to our secured term loans.

Foreign exchange (loss) gain. Foreign exchange losses for the three and nine months ended September 30, 2018 and foreign exchange gains for the three and nine months ended September 30, 2017 were 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.

Deemed dividends on preferred stock. Deemed dividends on preferred stock of approximately $0.1 million for the nine months ended September 30, 2018 were related to the issuance of Series O Preferred Stock in February 2018. Deemed dividends on preferred stock of $4.4 million for the nine months ended September 30, 2017 were related to the issuance of our Series N-3 Preferred Stock in June 2017. There were no deemed dividends on preferred stock for the three-month periods ended September 30, 2018 and 2017. See Part II, Item 8, "Notes to Consolidated Financial Statements, Note 8, Preferred Stock" of our Annual Report on Form 10-K for the year ended December 31, 2017 for information regarding our Series N-3 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, 2018, we had $80.9 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, the proceeds of which were partially used to repay in full all outstanding indebtedness under our Loan and Security Agreement, dated March 26, 2013, as amended, with Hercules Technology Growth Capital, Inc., or Hercules, (and certain of its affiliates).
As of September 30, 2018, we had an outstanding principal balance under our secured term loan agreement of $16.0 million. We had an option to borrow an additional $2.0 million, which option expired unexercised on July 31, 2018. We are required to

make monthly interest-only payments for at least 12 months after closing, through November 1, 2018, in the approximate amount of $0.1 million per month. After the initial 12-month interest-only period, we are required to pay interest plus principal payments for 36 months, in the approximate amount of $0.5 million per month, with the final principal plus interest payment totaling approximately $0.4 million as well as a back-end fee of $1.4 million on November 1, 2021. These borrowings are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions. In addition, the secured term loan agreement requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required loan payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

Historical Cash Flows

Net cash used in operating activities. Net cash used in operating activities decreased to $27.2 million during the nine months ended September 30, 2018 compared to $28.8 million for the same period in 2017. We received a $13.1 million upfront payment from Servier in connection with the Restated Agreement and collected $7.8 million in 2016 receivables under the arrangement during the nine months ended September 30, 2017 while we had no such receipts during the same period in 2018. After taking these cash receipts in 2017 into account, the overall decrease in net cash used in operating activities was primarily due to decreases in spending for selling, general and administration expenses, as well as the timing of cash payments between the two periods.

Net cash (used in) provided by investing activities. Net cash used in investing activities of $27.9 million during the nine months ended September 30, 2018 was primarily due to purchases of short-term investments. There were no such purchases during the same period in 2017.

Net cash provided by financing activities. Net cash provided by financing activities was $64.1 million and $38.0 million during the nine months ended September 30, 2018 and 2017, respectively. The increase was primarily due to the higher amount of net proceeds from our February 2018 offering of common stock compared to those from our June 2017 offering of Series N-3 preferred stock.

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 or arrangements for additional financing to fund the development and commercial launch of pacritinib, and we may need to seek additional funding. The development and commercialization of a major product candidate like pacritinib without a collaborative partner will require a substantial amount of our time and financial resources, and as a result, we could experience a decrease in our liquidity and a new demand on our capital resources. For additional information relating to the Pacritinib License Agreement, see Part I, Item 1, “Business - License Agreements and Additional Milestone Activities - Baxalta” of our Annual Report on Form 10-K for the year ended December 31, 2017.

Capital Resources

We have prepared our consolidated financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. We believe that our present financial resources, together with payments projected to be received under certain contractual agreements and our ability to control costs, will be sufficient to fund our operations into the first quarter of 2020. However, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for pacritinib. Because of our reacquisition of worldwide rights for pacritinib, we are no longer eligible to receive cost sharing or milestone payments for pacritinib’s development from Baxalta, and losses related to research and development for pacritinib have increased. We have historically funded our operations through

equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of September 30, 2018, our available cash, cash equivalents and short-term investments totaled $80.9 million. We had an outstanding principal balance under our secured term loan agreement of $16.0 million.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, developments in and expenses associated with our clinical trials and the other factors identified under “Capital Requirements” below may consume capital resources earlier than planned. Additionally, it is uncertain whether we will receive significant additional milestone payments or net sales from PIXUVRI following our July 2018 announcement that PIXUVRI plus rituximab did not show a statistically significant improvement in progression-free survival compared to gemcitabine plus rituximab. 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 may need to acquire additional funds in order to develop our business. 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;
- regulatory approval developments;
- our ability to generate sales of any approved product;
- ability to execute appropriate collaborations for development and commercialization activities;
- 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.

As of September 30, 2018, our contractual purchase obligations for which payments are due over the next 12 months, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, decreased by $0.2 million.

LICENSE AGREEMENTS AND MILESTONE ACTIVITIES

For information regarding our license agreements and milestone activities, please see Part I, Item 1, “Business - License Agreements and Additional Milestone Activities” of our Annual Report on Form 10-K for the year ended December 31, 2017.

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 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, 2017. There have been no material changes to our critical accounting policies and estimates discussed therein other than the change to the accounting policy for revenue recognition 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, 2018 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 7, Legal Proceedings" of this report and Part I, Item 3, “Legal Proceedings” of our Annual Report on Form 10-K for the year ended December 31, 2017 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, 2018, we had an accumulated deficit of $2.2 billion, and we expect to continue to incur net losses. As part of our business plan, we will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, is expected to result in operating losses for the foreseeable future. There can be no assurances that we will ever achieve profitability.

Our prospects are dependent on the successful development, regulatory approval and commercialization of pacritinib.

We have resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement in October 2016, and we are no longer eligible to receive cost sharing or milestone payments for pacritinib’s development from Baxalta. Because obtaining regulatory approval requires substantial time, effort and financial resources, the termination of this collaborative partnership could negatively impact our ability to successfully develop and commercialize pacritinib. Even if we are successful in developing and obtaining regulatory approval for pacritinib, it would face intense competition from currently approved compounds and potentially other candidates being developed by our competitors. We currently have no commitments or arrangements for any additional financing to fund the development and commercial launch of pacritinib, and we may need to seek additional funding, which may not be available or may not be available on favorable terms. 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 primary product candidate under development, our prospects are substantially 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 inhibitor, Jakafi® / Jakavi® and may face competition from fedratinib, which Celgene has announced is

being prepared for an NDA submission in myelofibrosis by the end of 2018, and momelotinib, which Sierra Oncology acquired from Gilead and has announced will likely require an additional clinical study to consolidate data across the momelotinib development program.

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 our compounds 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 our compounds 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, the respective 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, inconsistency in yields or variability in product characteristics;

•they may be uneconomical to produce;

•political and legislative changes may make the commercialization of our product candidates 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 our compounds, and we have significant contractual payment obligations. Our available cash, cash equivalents and short-term investments were $80.9 million as of

September 30, 2018. In February 2018, we received approximately $64.2 million in net proceeds from an offering of common stock. In addition, we received a $10.0 million milestone payment from Teva Pharmaceutical Industries Ltd. in January 2018 relating to the achievement of a milestone for FDA approval of TRISENOX for first-line treatment of acute promyelocytic leukemia. While we believe that our present financial resources, together with payments projected to be received under certain of our contractual agreements and our ability to control costs, will be sufficient to fund our operations into the first quarter of 2020, 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 the resumption of primary responsibilities for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement in October 2016, acquisitions of compounds or other assets, 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 may need to acquire additional funds in order to develop our business. 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 do so 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 residual authorized shares, 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; and

•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 these and other reasons, additional funding may not be available on favorable terms or at all. 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.

Our independent registered public accounting firm included an explanatory paragraph in its reports on our consolidated financial statements for each of the years ended December 31, 2007 through December 31, 2011 and for the years ended December 31, 2014 and 2016 regarding their substantial doubt as to our ability to continue as a going concern. Although our independent registered public accounting firm removed this going concern explanatory paragraph in its report on our December 31, 2017 consolidated financial statements, we expect to continue to need to

raise additional financing to fund our operations and satisfy obligations as they become due. The inclusion of a going concern explanatory paragraph in future years may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing, and we cannot guarantee that we will not receive such an explanatory paragraph in the future.

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 substantially 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 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/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.

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 pacritinib 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 compound 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 can be lengthy 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, expose 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 our loan and security agreement with Hercules Technology Growth Capital.

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 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 and eliminate our eligibility to receive additional loans under the agreement.

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.

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.

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. Leadership transitions and management changes can be difficult to manage and may create uncertainty or disruption to our business or increase the likelihood of turnover in our other officers and employees.

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. 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. Pacritinib and tosedostat have both been in-licensed or acquired from third parties. 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.

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 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. The VAT receivable was $4.6 million and $4.8 million as of September 30, 2018 and December 31, 2017, 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 7, Legal Proceedings" 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 $4.9 million converted using the currency exchange rate as of September 30, 2018, 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. As described in Part I, Item 1, "Notes to Condensed Consolidated Financial Statements, Note 7, Legal Proceedings," 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. Litigation is 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 pending litigation. In addition, negative publicity resulting from any allegations of wrong-doing could harm our business, regardless of whether the allegations are valid or whether there is a finding of liability. Furthermore, we may have to incur substantial time and expense in connection with such lawsuits and management’s attention and resources could be diverted from operating our business as we respond to the litigation. Our insurance is subject to high deductibles and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages. In the event of negative publicity resulting from allegations of wrong-doing and/or an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

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

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

- different regulatory requirements for initiating clinical trials and maintaining approval of drugs in foreign countries;
- 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 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 35% 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 impact of which is a $41.3 million reduction in net deferred tax assets to reflect the new statutory rate. 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 subsidiary 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.

Due to the fact that we have a European subsidiary conducting operations, together with the fact that we are party to certain contractual arrangements denoting monetary amounts in foreign currencies, we are subject to risk regarding currency exchange rate fluctuations.

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, in our European subsidiary will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Any expansion of our commercial operations in Europe may increase our exposure to fluctuations in foreign currency exchange rates. In addition, certain of our contractual arrangements, 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.

We may be unable to obtain the raw materials necessary to produce a particular product or product candidate.

We may not be able to purchase the materials necessary to produce a particular product or product candidate in adequate volume and quality. If any raw material required to produce a product or product candidate is insufficient in quantity or quality, if a supplier fails to deliver in a timely fashion or at all or if these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

Because there is a risk of product liability associated with our compounds, 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.

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, 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. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. 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 have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues 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.

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. In addition, we may lose samples or other valuable data. The occurrence of any of the forgoing could have a material adverse effect on our business.

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 original MAA in Europe. While the full clinical hold on pacritinib trials has been removed and a new MAA has been validated by the EMA, our dose-exploration trial for pacritinib and further clinical trials for pacritinib could be subject to further delay or we could be prevented from further studying pacritinib or seeking its commercialization.

In February 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib. A full clinical hold is a suspension of the clinical work conducted under an investigational new drug application. Under the full clinical hold, all patients on pacritinib at the time of the hold order were required to discontinue pacritinib, and we were not permitted to enroll any new patients or start pacritinib as initial or crossover treatment. In January 2017, the full clinical hold was removed. Our complete response submission included, among other items, final Clinical Study Reports for both the PERSIST-1 and 2 trials and FDA agreement on a proposed study design for a dose-exploration clinical trial required by the FDA. In July 2017, we enrolled the first patient in the PAC203 trial, which is evaluating 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 study 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. A complete dataset from the full enrollment of 150 patients (including efficacy, safety, pharmacokinetic and pharmacodynamic data) will be used to determine the optimal dose of pacritinib for further clinical development, as requested by the FDA. Based on FDA feedback received at a July Type B meeting, we plan to conduct a randomized Phase 3 study of pacritinib in patients with myelofibrosis. The dosing for the Phase 3 study will be determined using the results of the PAC203 study. We have scheduled a Type C meeting with the FDA to take place before the end of 2018 to discuss the design of a new registrational Phase 3 trial of pacritinib in myelofibrosis patients with severe thrombocytopenia (platelet counts of less than 50,000 per microliter). We cannot be certain that the proposed new Phase 3 study will be sufficient for regulatory approval or that the full data from the PAC203 study will not raise additional questions from the FDA, and the FDA may again request additional information or require us to pursue new clinical safety trials with changes to, among other things, protocol, study design or sample size.

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. These data suggest that pacritinib may show clinical benefit in patients who have failed or are intolerant to ruxolitinib therapy, a population for which there is no approved therapy. 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. Validation confirms that the submission is complete and initiates the centralized review process by the CHMP. The CHMP review period is 210 days, excluding extension, question or opinion response periods, after which the CHMP opinion is reviewed by the European Commission, which usually issues a final decision on E.U. authorization within three months. If authorized, pacritinib would be granted a marketing license valid in all 28 E.U. member states, Norway, Iceland and

Liechtenstein. 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 address any further recommendations, 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. Delays in the commercialization of pacritinib would prevent us from receiving future milestone or royalty payments, and otherwise significantly harm our business.

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. If we seek and the FDA does not grant accelerated approval or priority review for pacritinib or any of our other product candidates, we would experience a longer time to commercialization, if such product candidates are commercialized at all, our development costs would increase and our competitive position could be materially harmed.

If our development and commercialization collaborations 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.

Our business is dependent on the success of our development and commercialization collaborations. If our existing collaborations fail, or 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 reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, 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:

•delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;

•difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products and obtaining manufacturing approval;

•pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;

•production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products, equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;

•inefficient cost structure of a compound compared to alternative treatments;

•obstacles resulting from proprietary rights held by others with respect to a compound, such as patent rights;

•lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, eligibility criteria for tests and competition with other clinical testing programs;

•preclinical or clinical testing requiring significantly more time than expected, resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;

•failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;

•suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;

•delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, and trial sites; and

•failure of third parties, such as CROs, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials and results.

For example, although PIXUVRI received conditional marketing authorization in the E.U. in May 2012, we were required to conduct a post-authorization trial, referred to as PIX306, comparing PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL and follicular grade 3 lymphoma. 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. We continue to carefully evaluate the clinical data for PIXUVRI and we are not currently planning further clinical studies. Servier is evaluating next steps for PIXUVRI in Europe. In light of the results of the PIX306 trial announced in July 2018, Servier may exercise its right to terminate our collaborative agreement and PIXUVRI may be removed from the E.U. market. If either of these events occurs, our ability to receive future payments and royalties related to PIXUVRI and our collaborative agreement with Servier would cease.

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 our compounds 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 our compounds may be harmed, which could harm our business, financial condition, operating results or prospects.

If we seek and the FDA does not grant accelerated approval or priority review for a drug candidate, we would experience a longer time to commercialization in the U.S., if commercialized at all, our development costs may increase and our competitive position may be harmed.

We may in the future decide to seek an accelerated approval pathway for our compounds. 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 approval will be granted. Even if a product candidate is granted accelerated approval, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials. 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 conduct any required post-approval trial(s) with due diligence.

In the event of priority review, the FDA has a goal to (but is not required to) take action on an application within a total of eight months (rather than a goal of twelve months for a standard review). The FDA grants priority review only if it determines that a product treats a serious condition and, if approved, would provide a significant improvement in safety or

effectiveness when compared to a standard application. 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, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted eight-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 our collaboration partners may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our compounds.

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. Some of our other product candidates are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the E.U., we have not received marketing approval for our compounds. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and preclinical testing 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 any of our products 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 2018, we attended a Type B meeting with the FDA to discuss the proposed regulatory pathway for pacritinib. Based on FDA feedback at the meeting, we intend to conduct a randomized Phase 3 study of pacritinib in patients with myelofibrosis, which Phase 3 study will require significant time and resources to complete and, even if completed, may not be sufficient to support approval. 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.

If our compounds are 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 successfully 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. 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. 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. We continue to carefully evaluate the clinical data for PIXUVRI and we are not currently planning further clinical studies. Servier is evaluating next steps for PIXUVRI in Europe. In light of the results of the PIX306 trial announced in July 2018, Servier may exercise its right to terminate our collaborative agreement and PIXUVRI may be removed from the E.U. market. If either of these events occurs, our ability to receive future payments and royalties related to PIXUVRI and our collaborative agreement with Servier would cease. Additionally, it is uncertain whether we will receive significant additional milestone payments or net sales from PIXUVRI following our July 2018 announcement that PIXUVRI plus rituximab did not show a statistically significant improvement in progression-free survival compared to gemcitabine

plus rituximab.

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. 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 use of our products, except as allowed by the FDA.

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, provide accurate information to the FDA, EMA and other regulators, comply with data privacy and security and healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately 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 comparable laws in non-U.S. jurisdictions, such as the European Union's General Data Privacy Regulations, may impose obligations with respect to safeguarding the privacy, use, security and transmission of individually identifiable health information. 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 studies, 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 PIXUVRI, pacritinib and tosedostat. 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 PIXUVRI, 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: US 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.

Our U.S. and foreign patents for PIXUVRI (pixantrone) expire as follows: US Patent Nos. 5,616,709 and 5,506,232 covering the pixantrone compound (i.e., 6,9-bis[(2-aminoethyl)amino]benzo[g]isoquinoline-5,10-dione), and dimaleate salt thereof, expired in 2014. Other patents relating to PIXUVRI include a US patent expiring in August 2024 (injectable formulation); Foreign patents (except Europe) expiring in May 2023 (injectable formulation); and European patents expiring in March 2020 (salt) and May 2027 (injectable formulation).

Our various tosedostat-directed patents expired in March 2018. Tosedostat has orphan drug designation for acute myeloid leukemia 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 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 or circumvented. 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 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 PIXUVRI, pacritinib or any of the other compounds we are currently developing infringe 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 25, 2018, our stock price ranged from a low of $1.70 to a high of $5.36. 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;

•announcements by us or others of serious adverse events that have occurred during administration of our products to patients;

•announcements by us or others relating to our ongoing development and commercialization activities;

•halting or suspension of trading in our common stock on the Nasdaq;

•announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

•our issuance of debt or equity securities, which we expect to pursue to generate additional funds to operate our business, or any perception from time to time that we will issue such securities;

•our quarterly operating results;

•liquidity, cash position or financing needs;

•developments or disputes concerning patent or other proprietary rights;

•developments in relationships with collaborative partners;

•acquisitions or divestitures;

•our ability to realize the anticipated benefits of our compounds;

•litigation and government proceedings;

•adverse legislation, including changes in governmental regulation;

•third-party reimbursement policies;

•changes in securities analysts' recommendations;

•short selling of our securities;

•changes in health care policies and practices;

•a failure to achieve previously announced goals and objectives as or when projected; and

•general economic and market conditions.

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

stock and consequently may negatively impact the price of our common stock.

We regained compliance in January 2017 with the minimum $1.00 bid price requirement by effecting a 1-for-10 reverse stock split on January 1, 2017, after receiving notice of non-compliance from the Nasdaq in March 2016.

We have in the past and may in the future fail to comply with the Nasdaq requirements. If our common stock ceases to be listed for trading on the Nasdaq for failure to comply with the minimum $1.00 per share closing bid price requirement or for any other reason, it may harm our stock price, increase the volatility of our stock price, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. Our failure to maintain a listing on the Nasdaq may constitute an event of default under our loan and security agreement and any future indebtedness, which would

accelerate the maturity date of such debt or trigger other obligations. In addition, certain institutional investors that are not permitted to own securities of non-listed companies may be required to sell their shares adversely affecting the market price of our common stock. If we are not listed on the Nasdaq or if our public float falls below $75 million, we will be limited in our ability to file new shelf registration statements on Form S-3 and/or to fully use one or more registration statements on Form S-3. 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;
- our Shareholder Rights Agreement, dated December 28, 2009, as amended;
- corporate transactions, such as stock splits or stock dividends; and
- other corporate purposes that have not yet been identified.

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 market value 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, in our shareholder rights agreement, or rights plan, 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 shareholders, 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.

Pursuant to our rights plan, an acquisition of 20% or more of our common stock by a person or group, subject to certain exceptions, could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20% stockholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. The existence of our rights plan could have the effect of delaying, deterring or preventing a third party from making an acquisition proposal for us and may inhibit a change in control that some, or a majority, of our stockholders might believe to be in their best interest or that could give our stockholders the opportunity to realize a premium over the then-prevailing market prices for their shares.

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. 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, 2018, options to purchase 9,222,961 shares of our common stock with a weighted-average exercise price of $5.18 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

On October 31, 2018, following approval by the compensation committee of our board of directors, we and Dr. Adam R. Craig, our president and chief executive officer, entered into an amendment to Dr. Craig's employment agreement, or the Amendment.
Pursuant to the Amendment, if Dr. Craig's employment terminates before the end of a fiscal year, Dr. Craig is eligible for a prorated portion of his annual incentive bonus corresponding to such fiscal year. Such incentive bonus, if any, will be paid at such time we pay bonuses to other executives.
In addition, pursuant to the Amendment, we no longer have the option of waiving Dr. Craig's non-competition and customer non-solicitation covenants in exchange for our ability not to pay severance to Dr. Craig upon our choice not to renew Dr. Craig's employment agreement at the end of its initial five-year term. Pursuant to the Amendment, any

non-renewal of the employment agreement by us will be treated as a termination without Cause (as defined in the employment agreement), thus triggering severance, and under such circumstances all of Dr. Craig's restrictive covenants will remain intact.

Except for the revisions noted above and other immaterial revisions, the terms of Dr. Craig's existing employment agreement will remain in full force and effect. The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment. A copy of the Amendment is filed herewith as Exhibits 10.2.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Location
10.1	Separation Agreement and Release dated September 4, 2018, by and between Jack W. Singer and the Company.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 6, 2018.
10.2+	Amendment to Employment Agreement, dated October 31, 2018, by and between Adam R. Craig and the Company.	Filed herewith.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101. INS	XBRL Instance	Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101. CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101. DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101. LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101. PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

+ Indicates a management contract or compensatory plan.

SIGNATURES

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

CTI BIOPHARMA CORP.
(Registrant)

Dated: November 1, 2018 By: /s/ Adam R. Craig
Adam R. Craig
President, Chief Executive Officer and Interim Chief Medical Officer

Dated: November 1, 2018 By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer