CTI BIOPHARMA CORP
Form 10-Q
August 04, 2017

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: June 30, 2017

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)

Washington	91-1533912
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3101 Western Avenue, Suite 600	
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ý No ¨

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

Large accelerated filer ¨	Accelerated filer ý
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No 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 July 27, 2017
Common Stock, no par value	42,982,568

CTI BIOPHARMA CORP.
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PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

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

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,740	$ 44,002
Accounts receivable	480	378
Receivables from collaborative arrangements	259	7,778
Inventory, net	1,507	1,525
Prepaid expenses and other current assets	1,377	2,141
Total current assets	78,363	55,824
Property and equipment, net	2,642	3,023
Other assets	5,327	4,996
Total assets	$ 86,332	$ 63,843
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,013	$ 7,227
Accrued expenses	22,076	24,765
Current portion of deferred revenue	1,321	103
Current portion of long-term debt	8,419	7,949
Other current liabilities	634	602
Total current liabilities	36,463	40,646
Deferred revenue, less current portion	611	514
Long-term debt, less current portion	7,007	11,311
Other liabilities	3,331	3,615
Total liabilities	47,412	56,086
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value:		
Authorized shares - 33,333		
Series N-3 Preferred Stock, $2,000 stated value per share, 22,500 shares designated, 575 and 0 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	1,090	—
Common stock, no par value:		
Authorized shares - 81,500,000 and 41,500,000 at June 30, 2017 and December 31, 2016, respectively		
Issued and outstanding shares - 42,994,481 and 28,228,602 at June 30, 2017 and December 31, 2016, respectively	2,219,067	2,170,300
Accumulated other comprehensive loss	(6,437)	(6,655)
Accumulated deficit	(2,169,106)	(2,150,326)
Total CTI shareholders' equity	44,614	13,319
Noncontrolling interest	(5,694)	(5,562)

Total shareholders' equity	38,920	7,757
Total liabilities and shareholders' equity	$ 86,332	$ 63,843

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	$339	$1,051	$1,025	$2,274
License and contract revenue	21,886	6,310	21,954	41,562
Total revenues	22,225	7,361	22,979	43,836
Operating costs and expenses:				
Cost of product sold	78	160	211	350
Research and development	8,914	16,697	18,167	37,543
Selling, general and administrative	7,962	9,571	18,650	20,883
Total operating costs and expenses	16,954	26,428	37,028	58,776
Income (loss) from operations	5,271	(19,067)	(14,049)	(14,940)
Non-operating income (expense):				
Interest expense	(488)	(677)	(1,022)	(1,391)
Amortization of debt discount and issuance costs	(37)	(38)	(75)	(139)
Foreign exchange gain (loss)	657	(236)	614	(38)
Other non-operating expense	(30)	(4)	(30)	(523)
Total non-operating income (expense), net	102	(955)	(513)	(2,091)
Net income (loss) before noncontrolling interest	5,373	(20,022)	(14,562)	(17,031)
Noncontrolling interest	25	256	132	577
Net income (loss)	5,398	(19,766)	(14,430)	(16,454)
Deemed dividends on preferred stock	(4,350)	—	(4,350)	—
Net income (loss) attributable to common shareholders	$1,048	$(19,766)	$(18,780)	$(16,454)
Net income (loss) per common share:				
Basic	$0.03	$(0.71)	$(0.63)	$(0.59)
Diluted	$0.03	$(0.71)	$(0.63)	$(0.59)
Shares used in calculation of income (loss) per common share:				
Basic	31,725	27,960	29,895	27,877
Diluted	31,901	27,960	29,895	27,877

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net income (loss) before noncontrolling interest	$5,373	$(20,022)	$(14,562)	$(17,031)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(1,944)	813	(2,445)	(550)
Unrealized foreign exchange gain (loss) on intercompany balance	2,118	(930)	2,664	540
Other-than-temporary impairment on available-for-sale securities	—	—	—	519
Net unrealized loss on available-for-sale securities	—	(9)	(1)	(8)
Other comprehensive income (loss)	174	(126)	218	501
Comprehensive income (loss)	5,547	(20,148)	(14,344)	(16,530)
Comprehensive loss attributable to noncontrolling interest	25	256	132	577
Comprehensive income (loss) attributable to CTI	$5,572	$(19,892)	$(14,212)	$(15,953)

See accompanying notes.

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

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net loss before noncontrolling interest	$(14,562)	$(17,031)
Adjustments to reconcile net loss to net cash used in operating activities:		
Baxalta milestone revenue	—	(32,000)
Share-based compensation expense	2,948	6,157
Depreciation and amortization	382	442
Provision for bad debt	—	345
Other-than-temporary impairment on available-for-sale securities	—	519
Noncash interest expense	75	139
Noncash rent benefit	(253)	(222)
Other	(32)	—
Changes in operating assets and liabilities:		
Accounts receivable	(66)	(622)
Receivables from collaborative arrangements	7,534	(6,568)
Inventory	140	269
Prepaid expenses and other current assets	802	1,336
Other assets	69	285
Accounts payable	(3,284)	3,726
Accrued expenses	(3,110)	(5,224)
Deferred revenue	1,315	(437)
Total adjustments	6,520	(31,855)
Net cash used in operating activities	(8,042)	(48,886)
Investing activities		
Purchases of property and equipment	—	(108)
Other	11	—
Net cash provided by (used in) investing activities	11	(108)
Financing activities		
Repayment of Hercules debt	(3,909)	(1,764)
Payment of tax withholding obligations related to stock compensation	(49)	(304)
Proceeds from issuance of preferred stock, net of issuance costs	43,031	(314)
Other	(30)	20
Net cash provided by (used in) financing activities	39,043	(2,362)
Effect of exchange rate changes on cash and cash equivalents	(274)	(119)
Net increase (decrease) in cash and cash equivalents	30,738	(51,475)
Cash and cash equivalents at beginning of period	44,002	128,182
Cash and cash equivalents at end of period	$74,740	$76,707
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$1,060	$3,174
Cash paid during the period for taxes	$—	$—

Supplemental disclosure of noncash financing activities		
Conversion of preferred stock to common stock	$41,549	$—
Preferred stock issuance costs included in accounts payable and accrued expenses	$393	$—
Baxalta milestone advance - earned in lieu of repayment	$—	$32,000

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 subsidiaries, 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 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 and the further development of PIXUVRI worldwide, for which our partners Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively Servier, have commercialization rights outside the United States, or the U.S.

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 six months ended June 30, 2017 and 2016 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 six months ended June 30, 2017 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, 2016 included in our Annual Report on Form 10-K filed with the SEC on March 2, 2017.

The condensed consolidated balance sheet at December 31, 2016 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 subsidiaries, which include Systems Medicine LLC and CTI Life Sciences Limited, or CTILS. We also retain ownership of our branch, CTI BioPharma Corp.– Sede Secondaria, or CTI (Europe); however, we ceased operations related to this branch in September 2009.

As of June 30, 2017, 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.

Reverse Stock Split

On January 1, 2017, we effected a one-for-ten reverse stock split, or the Stock Split. All impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the Stock Split. Unless

otherwise noted, impacted amounts include shares of common stock authorized and outstanding, share issuances and cancellations, shares underlying warrants and stock options, shares reserved, conversion prices of convertible securities, exercise prices of warrants and options, and income (loss) per share. Additionally, the Stock Split impacted preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the Stock Split).

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. In accordance with Financial Accounting Standards Board, or the FASB, Accounting Standards Update No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40), 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. Additionally, 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 will no longer be eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta Incorporated and its affiliates, or Baxalta, which is now part of Shire plc. We have incurred a net operating loss every year since our formation. As of June 30, 2017, 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 and cash equivalents were $74.7 million as of June 30, 2017. 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 only be sufficient to fund our operations into the third quarter of 2018. This raises substantial doubt about our ability to continue as a going concern.

Accordingly, we will need to raise additional funds to operate 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 shareholders 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.

Accounts Receivable

Our accounts receivable balance includes trade receivables related to PIXUVRI sales. We estimate an allowance for doubtful accounts based upon the age of outstanding receivables and our historical experience of collections, which includes adjustments for risk of loss for specific customer accounts. We periodically review the estimation process and make changes to our assumptions as necessary. When it is deemed probable that a customer account is uncollectible, the account balance is written off against the existing allowance. We also consider the customer's

country of origin to determine if an allowance is required. We continue to monitor economic conditions, including the volatility associated with international economies and the sovereign debt crisis in certain European countries, and associated impacts on the financial markets and our business.

As of June 30, 2017 and December 31, 2016, our accounts receivable did not include any material balance from a customer in a country that has exhibited financial stress. We recorded no allowance for doubtful accounts as of June 30, 2017 and December 31, 2016.

Receivables from Collaborative Arrangements

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 December 31, 2016 primarily relates to a milestone receivable from Servier for the attainment of a certain enrollment event in December 2016 in connection with our PIX306 study. When 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 June 30, 2017 or December 31, 2016.

Value Added Tax Receivable

Our European operations are subject to a value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was approximately $4.6 million and $4.4 million as of June 30, 2017 and December 31, 2016, respectively, of which $4.5 million and $4.1 million, respectively, was included in other assets and $0.1 million and $0.3 million, respectively, was included in prepaid expenses and other current assets. The collection period of VAT receivable for our European operations ranges from approximately three months to five years. For our Italian VAT receivable, the collection period is approximately three to five years. As of June 30, 2017, the VAT receivable related to operations in Italy was approximately $4.6 million. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate that the carrying amount might not be recoverable.

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. We had a reserve of $1.6 million and $1.5 million related to excess, obsolete or unsalable inventory as of June 30, 2017 and December 31, 2016, respectively, which was included in Inventory, net.

Revenue Recognition

We currently have conditional marketing authorization for PIXUVRI in the E.U. Revenue is recognized when there is persuasive evidence of the existence of an agreement, delivery has occurred, prices are fixed or determinable, and collectability is assured. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria under the provision are met.

Product sales

We sell PIXUVRI primarily through a limited number of wholesale distributors. We generally record product sales upon receipt of the product by the health care providers and certain distributors at which time title and risk of loss pass. Product sales are recorded net of distributor discounts, estimated government-mandated rebates, trade discounts, and estimated product returns. Reserves are established for these deductions and actual amounts incurred are offset against the applicable reserves. We reflect these reserves as either a reduction in the related account receivable or as an accrued liability, depending on the nature of the sales deduction. These estimates are periodically reviewed and adjusted as necessary.

Collaboration Agreements

Milestone payments under collaboration agreements are generally aggregated into three categories for reporting purposes: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the FDA, or with the regulatory authorities of other countries, or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to

achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable development and regulatory milestones that are expected to be achieved as a result of our efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met.

We follow Accounting Standard Codification, or ASC, 605-25, Revenue Recognition – Multiple-Element Arrangements, and ASC 808, Collaborative Arrangements, if applicable, to determine the accounting of reimbursement arrangements under collaborative research and development and commercialization agreements.

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.

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 shareholders' (deficit) 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 subsidiaries 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 gain of $2.1 million and an unrealized foreign exchange loss of $0.9 million was recorded in the cumulative foreign currency translation adjustment account for the three months ended June 30, 2017 and 2016, respectively. An unrealized foreign exchange gain of $2.7 million and $0.5 million was recorded in the cumulative foreign currency translation adjustment account for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, the intercompany balance due from CTILS was €27.2 million (or $31.0 million upon conversion from euros as of June 30, 2017). As of December 31, 2016, the intercompany balance due from CTILS was €29.7 million (or $31.2 million upon conversion from euros as of December 31, 2016).

Net Income (Loss) Per Share

Basic net income (loss) per share, or EPS, is calculated based on the net income (loss) attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding dilutive effects, if any, of options, warrants, unvested share awards and convertible securities. Diluted EPS assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock, using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and restricted stock, using the treasury stock method.

Recently Adopted Accounting Standards

In July 2015, the FASB issued new accounting guidance on simplifying the measurement of inventory which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Prior to the issuance of the standard, inventory was measured at the lower of cost or market (where market was defined as replacement cost, with a ceiling of net realizable value and floor of net realizable value less a normal profit margin). The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2016. The adoption of this standard in the first quarter of 2017 did not have a material impact on our condensed consolidated financial statements.

In August 2014, the FASB issued a new accounting standard which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern for each annual and interim reporting period and to

provide related footnote disclosures in certain circumstances. The accounting standard is effective for annual reporting periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. The adoption of this standard in the fourth quarter of 2016 did not have a material impact on our condensed consolidated financial statements.

In March 2016, the FASB issued new accounting guidance for employee share-based payments accounting. The accounting standard primarily affects the accounting for forfeitures, minimum statutory tax withholding requirements, and income tax effects related to share-based payments at settlement (or expiration). The accounting guidance is effective for annual reporting periods beginning after December 15, 2016 (including interim periods within those periods). We have historically maintained a full valuation allowance against deferred tax assets. The adoption of this standard in the first quarter of 2017 did not have a material impact on our condensed consolidated financial statements, and we will continue to estimate expected forfeitures.

Recently Issued Accounting Standards

In May 2014, the FASB issued a new financial accounting standard which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and which supersedes current revenue recognition guidance. In March 2016, the FASB issued an amendment to clarify the implementation guidance around considerations of whether an entity is a principal or an agent, impacting whether an entity reports revenue on a gross or net basis. In April 2016, the FASB issued an amendment to clarify guidance on identifying performance obligations and the implementation guidance on licensing. In May 2016, the FASB issued amendments to certain aspects of the new revenue guidance (including transition, collectability, noncash consideration and the presentation of sales and other similar taxes) and provided certain practical expedients. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017. Early adoption is permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the impact of this accounting standard on our consolidated financial statements.

In January 2016, the FASB issued a new accounting standard on recognition and measurement of financial assets and financial liabilities. The accounting standard primarily affects the accounting for equity investments and financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. Early adoption is permitted for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

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 consolidated financial statements.

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. Early adoption is permitted. We do not expect the adoption of this standard to have a material impact on our statements of cash flows.

In May 2017, the FASB issued an amendment to the scope of modification accounting for share-based payment arrangements which provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The accounting guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. We do

not expect the adoption of this standard to have a material impact on our 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):

	June 30, 2017	December 31, 2016
Finished goods	$1,571	$ 477
Work-in-process	1,524	2,558
Inventory, gross	3,095	3,035
Reserve for excess, obsolete or unsalable inventory	(1,588)	(1,510)
Inventory, net	$1,507	$ 1,525

3. Leases

Our deferred rent balance was $3.3 million as of June 30, 2017, of which $0.6 million was included in other current liabilities and $2.7 million was included in other liabilities. As of December 31, 2016, our deferred rent balance was $3.5 million, of which $0.5 million was included in other current liabilities and $3.0 million was included in other liabilities.

4. Preferred Stock

In June 2017, in an underwritten public offering, we issued 22,500 shares of Series N-3 Preferred Stock, for gross proceeds of $45.0 million before deducting underwriting commissions and discounts and other offering costs of approximately $2.4 million.

Each share of Series N-3 Preferred Stock is convertible at the option of the holder (subject to a limited exception) and 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 N-3 Preferred Stock. The Series N-3 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 N-3 Preferred Stock has no voting rights, except as otherwise expressly provided in the amended articles or as otherwise required by law.

In June 2017, 21,925 shares of Series N-3 Preferred Stock were converted into 14.6 million shares of common stock at a conversion price of $3.00 per share. For the three and six months ended June 30, 2017, we recognized $4.4 million in deemed dividends on preferred stock related to the beneficial conversion feature on our Series N-3 Preferred Stock. There were 575 shares of Series N-3 Preferred Stock outstanding as of June 30, 2017.

5. Collaborative Arrangement

In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement (the “Restated Agreement”) with Servier, pursuant to which the Exclusive License and Collaboration Agreement (the “Original Agreement”), entered into in September 2014 with Servier, was amended and restated in its entirety.

Under the Restated Agreement, we granted Servier 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).

In May 2017, we received a non-refundable, non-creditable cash upfront payment of €12.0 million. This amount included a €2.0 million payment for a milestone relating to EMA approval of an additional third-party manufacturer of

PIXUVRI, which was not included in the Original Agreement and was deemed achieved at the time of the Restated Agreement. Subject to the achievement of certain conditions, we are eligible to receive additional payments of up to €76.0 million upon the achievement of certain milestones, which are comprised of the following: up to €36.0 million in potential regulatory milestone payments, and up to €40.0 million in potential sales-based milestone payments. We have determined that all the regulatory milestones, other than the €2.0 million milestone mentioned above, are substantive due to significant uncertainty involved in each milestone and will be recognized as revenue upon achievement of the respective milestones, assuming all other revenue recognition criteria are met. We have also determined that the sales-based milestone payments are contingent consideration and will be recognized as revenue in the period in which the respective revenue recognition criteria are met.

We are eligible to receive tiered royalty payments on net sales of products containing PIXUVRI, ranging from a low-double-digit percentage up to a percentage in the low twenties, subject to certain reductions of up to mid-double-digit percentages under certain circumstances. Royalties are subject to expiration upon certain events, including upon expiration of exclusivity rights to products containing PIXUVRI in the respective country. We owe royalties on net sales of PIXUVRI products as well as other payments to certain third parties.

Under the Restated Agreement, with the exception of the conclusion of the PIX306 trial and certain other services, Servier will be responsible for development, commercialization and manufacturing activities within its territory. We have agreed to enter into a commercialization transition plan whereby we will transfer to Servier medical affairs and commercialization activities relating to the Licensed Products in Israel, Turkey, Germany, Austria, the United Kingdom, Denmark, Finland, Norway and Sweden, or collectively, the Transition Territory. Upon the implementation of the commercialization transition plan, we will terminate or assign certain distributor and wholesaler contracts to Servier in the Transition Territory. Each party will be responsible for the manufacture and supply of drug products and substances in their respective territories. We record reimbursements received from Servier as revenue and the full amount of costs as operating expenses in the statements of operations.

The Restated Agreement will expire on a country-by-country basis upon the expiration of the royalty terms in the countries in the Servier territory, at which time all licenses granted to Servier would become perpetual and royalty-free. Each party may terminate the Restated Agreement in the event of an uncured repudiatory breach of the other party's obligations. Subject to applicable notification periods, Servier may terminate the Restated Agreement on a country-by-country basis upon 30 days' written notice in the event of (i) certain safety or public health issues relating to the Licensed Product, (ii) suspension or withdrawal of marketing authorizations and (iii) without cause. In the event of a termination prior to the expiration date, rights granted to Servier will terminate, subject to certain exceptions.

Pursuant to accounting guidance under ASC 605-25 Revenue Recognition - Multiple-Element Arrangements, we identified the following non-contingent deliverables with standalone value at the inception of the Restated Agreement:

- a license with respect to the development and commercialization of PIXUVRI
- development services
- joint committee obligations
- regulatory responsibilities
- commercialization responsibilities
- manufacturing and supply responsibilities

The license deliverable has standalone value because it is sublicensable and can be used for its intended purpose without the receipt of the remaining deliverables. The service deliverables have standalone value because these services are not proprietary in nature, and other vendors could provide the same services in order to derive value from the license. Further, there is no general right of return associated with these deliverables. As such, the deliverables meet the criteria for separation and qualify as separate units of accounting.

We determined that the value of the joint committee obligations and the regulatory, commercial, and manufacturing and supply responsibilities were insignificant. These deliverables have been combined with the development services and included as "Other services" in the table below.

We allocated the arrangement consideration of $12.8 million (€12.0 million converted into U.S. dollars using the currency exchange rate as of the date of the Restated Agreement) based on the percentage of the relative selling price of each unit of accounting as follows (in thousands):

License	$11,487

Other services	1,348
Total upfront payment	$12,835

We estimated the selling price of the license using the income approach that values the license by discounting direct cash flow expected to be generated over the remaining life of the license, net of cash flow adjustments related to working capital. The estimates and assumptions include, but are not limited to, estimated market opportunity, expected market share, and contractual royalty rates. We estimated the selling price of the development services deliverable, which includes personnel costs as well as third-party costs for applicable services and supplies, by discounting estimated expenditures for services to the

date of the Restated Agreement. We concluded that a change in the key assumptions used to determine the best estimate of the selling price for the license deliverable would not have a significant effect on the allocation of the arrangement consideration.

During the three and six months ended June 30, 2017, we recognized $11.5 million of consideration allocated to the license as revenue upon delivery of the license and the satisfaction of the remaining revenue recognition criteria. The $1.3 million consideration allocated to other services was recorded as deferred revenue. This amount, along with the unamortized deferred revenue balance from the Original Agreement of $0.6 million, is expected to be recognized as revenue through approximately 2019 based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred. During the three and six months ended June 30, 2017, $0.1 million and $0.2 million, respectively, of other services consideration was recognized as revenue; the remaining $1.8 million is included in deferred revenue in the condensed consolidated balance sheet as of June 30, 2017.

6. Share-based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$260	$635	$292	$1,421
Selling, general and administrative	889	1,696	2,656	4,736
Total share-based compensation expense	$1,149	$2,331	$2,948	$6,157

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Performance rights	$—	$209	$—	$569
Restricted stock	296	1,119	616	3,190
Options	853	1,003	2,332	2,398
Total share-based compensation expense	$1,149	$2,331	$2,948	$6,157

7. Earnings (Loss) Per Share

The numerator for both basic and diluted earnings (loss) per share, or EPS, is net income (loss). The denominator for basic EPS (referred to as basic shares) is the weighted average number of common shares outstanding during the period, whereas the denominator for diluted EPS (referred to as diluted shares) also takes into account the dilutive effect of outstanding stock options and restricted stock awards using the treasury stock method. Basic and diluted shares were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Basic shares	31,725	27,960	29,895	27,877
Effect of dilutive securities	176	—	—	—
Diluted shares	31,901	27,960	29,895	27,877

The effect of dilutive securities for the three months ended June 30, 2017 included equity awards and convertible preferred stock. Equity awards, warrants and convertible preferred stock aggregating 4.3 million shares and equity awards and warrants aggregating 4.3 million shares for the three and six months ended June 30, 2017, respectively, were excluded from the calculation of diluted EPS because they were anti-dilutive. Equity awards and warrants aggregating 2.8 million shares and 2.6 million shares for the three and six months ended June 30, 2016, respectively, were excluded from the calculation of diluted EPS because they were anti-dilutive.

8. 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	Unrealized Foreign Exchange Gain (Loss) on Intercompany Balance	Accumulated Other Comprehensive Loss
December 31, 2016	$ (6)	$ (2,902)	$ (3,747)	$ (6,655)
Current period other comprehensive income (loss)	(1)	(2,445)	2,664	218
June 30, 2017	$ (7)	$ (5,347)	$ (1,083)	$ (6,437)

The value of available-for-sale securities of $2,500 and $13,500 as of June 30, 2017 and December 31, 2016, respectively, was included in Prepaid expenses and other current assets.

9. Legal Proceedings

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or 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, 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). We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case 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. In June 2013, the Regional Tax Court issued decision no. 119/50/13 in regards to the 2003 VAT assessment, which accepted the appeal of the ITA and reversed the 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, 2006 and 2007. The ITA has appealed to the Italian Supreme Court the decisions of the respective appellate court which were favorable to CTI with respect to each of the 2005, 2006 and 2007 VAT returns.

The Italian Supreme Court has scheduled the first hearing for the 2005 VAT case for September 26, 2017. No hearing has been fixed yet for 2003 and consolidated 2006/2007 VAT 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 €9.4 million, or approximately $10.7 million converted using the currency exchange rate as of June 30, 2017, plus collection fees, notification expenses and additional interest 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.

Securities and Exchange Commission Subpoena

We previously disclosed that we received a subpoena from the SEC in January 2016. The SEC's subpoena requested, among other things; internal and external communications related to pacritinib Phase 3 trials, including communications with the independent data monitoring committee, or IDMC, for pacritinib's Phase 3 trials, our steering committee, our board of directors, our audit committee, representatives of Baxter and Baxalta, and the FDA,

and other documents related to pacritinib.

We believe that the SEC is seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib. The SEC Staff's letter sent with the subpoena stated that the investigation is a fact-finding inquiry, and the investigation and subpoena do not mean that the SEC has concluded that we or anyone else has violated any law. We are cooperating with this investigation, which is ongoing.

In re CTI BioPharma Corp. Securities Litigation

On February 10, 2016 and February 12, 2016, class action lawsuits entitled Ahrens v. CTI BioPharma Corp. et al., Case No. 1:16-cv-01044 and McGlothlin v. CTI BioPharma Corp. et al., Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib. On May 2, 2016, the Company filed a motion to transfer the Ahrens case to the United States District Court for the Western District of Washington. The motion was unopposed and granted by the court on May 19, 2016. On June 3, 2016, the parties filed a joint motion to consolidate the McGlothlin case with the Ahrens case in order to proceed as a single consolidated proceeding. On June 13, 2016, the court granted the motion to consolidate with the action being captioned In re CTI BioPharma Corp. Securities Litigation, Master File No. 2:16-cv-00216-RSL. On September 2, 2016, the court appointed Lead Plaintiffs and Lead Counsel. On September 28, 2016, the court entered a scheduling order, as revised by order entered December 8, 2016, setting November 8, 2016 as the deadline to file a consolidated class action complaint and deadlines for briefing defendants' motion to dismiss. Briefing concluded on February 22, 2017. A hearing on the defendants' motion to dismiss has not been set. The consolidated class action complaint asserts claims similar to those asserted in the initial complaints, although it no longer asserts claims relating to the September 24, 2015 public offering, but adds claims relating to the Company's October 27, 2015 and December 4, 2015 public offerings. On July 26, 2017, we received a written offer for the global resolution and settlement of the consolidated action in exchange for cash payment of $20 million. The Company has insurance coverage related to this matter and such insurance is expected to cover $18 million of the claim. We have agreed in principle to the terms of the settlement offer and are currently negotiating the terms of a memorandum of understanding with respect to the terms of the settlement offer with the lead plaintiff's representatives. The terms of any final agreement for the settlement of the litigation will be subject to court approval, amongst other customary terms and conditions.

Wei v. James A. Bianco, et al.; England v. James A Bianco, et al; Nahar v. James A. Bianco, et al.; Hill v. James A. Bianco, et al.

On March 14, 2016, a Company shareholder filed the first of four similar derivative lawsuits on behalf of the Company seeking damages for alleged harm to the Company caused by certain current and former officers and directors. The first suit, Wei v. James A. Bianco, et al., 16-2-05818-3, was filed in King County Superior Court, Washington. A second suit, England v. James A. Bianco, et al., 16-2-14422-5, was filed in King County Superior Court, Washington, on June 16, 2016. Two additional derivative suits, Nahar v. James A. Bianco, et al., 2:16-cv-0756, and Hill v. James A. Bianco, et al., 2:16-cv-1250, were filed in the United States District Court for the Western District of Washington on May 24, 2016 and August 9, 2016, respectively. The four suits raise similar allegations and seek similar relief against certain current and former officers and directors, including James A. Bianco, Louis A. Bianco, Jack W. Singer, Bruce J. Seeley, John H. Bauer, Phillip M. Nudelman, Reed V. Tuckson, Karen Ignagni, Richard L. Love, Mary O. Mundinger and Frederick W. Telling. Consistent with the requirements of a derivative action, the Company is named in each suit as a nominal defendant against which no monetary relief is sought. The complaints generally allege claims of: (1) breach of fiduciary duty; (2) abuse of control; (3) gross mismanagement; (4) waste of corporate assets and (5) unjust enrichment (receiving compensation that was unjust in light of the alleged conduct). Each is based on the assertion that the Company made materially false and misleading statements and

omitted material information from its disclosures about pacritinib and its safety. Plaintiffs in none of the suits made a pre-suit demand on the current Board to investigate whether to pursue claims against officers or directors, instead claiming demand is excused because the named defendants lack independence, are not disinterested because they lack impartiality, received and want to continue to receive their compensation, have longstanding personal and business relationships, and cannot evaluate a demand since they are facing personal liability. Each of plaintiffs' suits requested the court to award the Company the damages allegedly sustained as a result of the conduct and to direct the Company and the individual defendants to reform and improve the Company's corporate governance to avoid future damages. On March 29, 2017 during mediation, the parties to the derivative suits reached an agreement in principle to settle all four suits subject to Board and court approvals. As part of the settlement, CTI has agreed to adopt certain corporate governance reforms and agreed not to object to an attorneys' fee application by plaintiffs' counsel of up to $0.8 million collectively. There is no admission of liability or any wrongdoing by any of the individual defendants or CTI.

In connection with the securities litigation and four derivative lawsuits described above, after taking into account our existing insurance coverage, we recorded $2.0 million and $2.2 million of settlement expense in Selling, general and administrative expenses in our condensed consolidated statement of operations for the three and six months ended June 30, 2017, respectively.

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.

10. Related Party Transactions

Aequus

We have a majority ownership interest in Aequus. In May 2007, we entered into a license agreement with Aequus whereby Aequus gained rights to our Genetic Polymer™ technology. We also entered into an agreement to fund Aequus in exchange for a convertible promissory note.

In March 2017, we and Aequus entered into a License and Promissory Note Termination Agreement and a Note Cancellation Agreement, pursuant to which, (i) all of the then-outstanding principal, plus all accrued and unpaid interest, approximately $13.7 million in total, were cancelled and terminated, (ii) our license agreement with Aequus was terminated, (iii) all obligations to Aequus were terminated with the exception of providing additional funding of up to $347,500 to Aequus, and (iv) Aequus agreed to pay us a) 20% of milestone and similar payments, up to a maximum amount of $20.0 million, and b) royalties, on a product-by-product and county-by country basis, of 5% of net sales of certain ACTH Products being developed by Aequus. Payments from Aequus are due the later of (i) expiration of the last to expire valid patent claim that claims the ACTH Product, or (ii) ten years from the first commercial sale of the applicable ACTH Product. We have the right to terminate the License and Promissory Note Termination Agreement and require Aequus to assign all ACTH Product related assets to us if Aequus does not file an Investigational New Drug Application for an ACTH Product with the FDA by September 6, 2019.

BVF Partners, L.P.

In June 2017, as discussed in Note 4. Preferred Stock, we completed an underwritten public offering of 22,500 shares of our Series N-3 Preferred Stock, no par value per share. BVF Partners L.P., or BVF, an existing shareholder of the Company, purchased 6,750 shares of our Series N-3 Preferred Stock, of which 6,175 shares were converted into approximately 4.1 million shares of our common stock. As a result of this transaction, BVF beneficially owned approximately 19.99% of our outstanding common stock as of June 30, 2017. BVF beneficially owned 15.87% of our outstanding common stock as of December 31, 2016. In connection with the Series N-3 Preferred Stock offering, we entered into a letter agreement with BVF, pursuant to which, we agreed to, upon BVF’s election and subject to any board and committee approvals, exchange shares of common stock purchased by BVF directly from us or underlying convertible preferred stock purchased by BVF directly from us, including the shares of common stock underlying the Series N-3 Preferred Stock, into shares of a convertible non-voting preferred stock with substantially similar terms as the Series N-3 Preferred Stock, including a conversion “blocker” initially set at 9.99% of our common stock. Such right would terminate if at any time BVF’s beneficial ownership of our common stock falls below 5%. We will take commercially reasonable efforts to cooperate to effectuate such exchange, provided that it does not adversely affect us and complies with applicable federal and state securities laws.

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 should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on Form 10-Q, terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negat terms or other comparable terms are intended to identify such forward-looking statements. Such statements include statements concerning sufficiency of cash resources and other projections, product manufacturing and sales, research and development expenses, selling, general and administrative expenses, financings and additional losses. 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, 2016, or the 2016 Form 10-K, 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. We will not update any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q.

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 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 and the further development of PIXUVRI worldwide, for which our partner, Servier, has commercialization rights outside the U.S.

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 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. PIXUVRI is the first approved treatment in the E.U. for patients with multiply relapsed or refractory aggressive B-cell NHL who have failed two or three prior lines of therapy. As a part of the conditional marketing authorization, we are 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. In August 2017, we announced the completion of enrollment in the trial. If positive, the results from this trial could support broader indications. Top-line results are event-driven and are expected in the first half of 2018. Although we do not have and are not currently pursuing regulatory approval of PIXUVRI in the U.S., we may reevaluate a possible submission strategy in the U.S. based on the data generated from the PIX306 study. Pursuant to our conditional marketing authorization in the E.U., and an extension granted in September 2016, we are required to submit the requisite clinical study report for PIX306 by December 2018.

In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement, or the Restated Agreement, with Servier. Under the Restated Agreement, Servier will have rights to PIXUVRI in all markets except in the U.S. where we will retain the commercialization rights. Previously, Servier had rights to commercialize the drug globally except in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the United Kingdom, or the U.K., and the U.S. Servier paid us €12.0 million in May 2017 and purchased PIXUVRI drug product for an additional €0.9 million in July 2017. We are eligible to receive up to €76.0 million in additional sales and regulatory milestone payments as well as royalties on net product sales.

For additional information on our collaboration with Servier, please see the discussion in Part I, Item 2, “License Agreements and Milestone Activities - Servier.”

Pacritinib

Our lead 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 BAT (Best Available Therapy), 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 (SVR) (35 percent or greater from baseline to Week 24 by magnetic resonance imaging (MRI) or computerized tomography (CT)). The most common treatment-emergent adverse events (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.

In February 2016, clinical studies under the investigational new drug (IND) for pacritinib were subject to a full clinical hold issued by the FDA. A full clinical hold is a suspension of the clinical work requested under the IND application. Under the full clinical hold, all patients currently on pacritinib 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 cited 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.

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 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 had a chance to reach 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 (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 (BID) versus once-daily (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.

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 PERSIST-1 and 2 trials and a dose-exploration clinical trial protocol that the FDA requested. At that time, we announced that we intend to conduct a new trial, PAC203, that plans to enroll up to approximately 105 patients with primary myelofibrosis who have failed prior ruxolitinib therapy to evaluate the dose response relationship for safety and efficacy (SVR at 12 and 24 weeks) of three dose regimens: 100 mg QD, 100 mg BID and 200 mg BID. The 200 mg BID dose regimen was used in PERSIST-2. In July 2017, the first patient was enrolled in this trial.

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 (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 myelofibrosis patients with thrombocytopenia.

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 question or opinion response periods, after which the CHMP opinion is reviewed by the European Commission, which usually issues a final decision on EU authorization within three months. If authorized, pacritinib would be granted a marketing license valid in all 28 EU member states, Norway, Iceland and Liechtenstein.

Other Pipeline Candidates

Our earlier stage product candidate, tosedostat, is a novel oral, once-daily aminopeptidase inhibitor that has demonstrated significant responses in patients with AML. It is currently being evaluated in several Phase 2 cooperative group-sponsored trials and investigator-sponsored trials. These trials are evaluating tosedostat in combination with hypomethylating agents in AML and MDS, which are cancers of the blood and bone marrow. We anticipate data from these signal-finding trials may be used to determine an appropriate design for a Phase 3 trial.

Board of Directors

In July 2017, we announced that Laurent Fischer, M.D., was appointed to the Board of Directors. Dr. Fischer was appointed Senior Vice President, Head of the Liver Therapeutic Area at Allergan following the acquisition of Tobira Therapeutics. Dr. Fischer currently serves as a Senior Advisor on the Frazier Healthcare Partners' Life Sciences team since March 2017. He was previously chairman and CEO of Jennerex, Inc., a company with a first-in-class oncolytic immunotherapy for Liver Cancer acquired for $150 million by Sillajen. He was co-founder, president and CEO of Ocera Therapeutics and held senior positions at DuPont-Merck, DuPont Pharmaceuticals, and Hoffmann-La Roche in liver disease, virology and oncology. Dr. Fischer received his undergraduate degree from the University of Geneva and his medical degree from the Geneva Medical School, Switzerland.

In June 2017, we announced that David R. Parkinson, M.D., was appointed to the Board of Directors. Dr. Parkinson has served as President and Chief Executive Officer of Essa Pharmaceuticals, Inc. since 2016. Dr. Parkinson has served as a venture partner at New Enterprise Associates (NEA), Inc. since 2012 and in 2016 moved to the role of venture advisor to NEA. From 2007 until 2012, Dr. Parkinson served as President and CEO of Nodality, a biotechnology company focused on the biological characterization of signaling pathways in patients with malignancy to enable more effective therapeutics development and clinical decision-making. Dr. Parkinson has previously led oncology clinical development activities at Novartis (1997-2003), Amgen (2003-2006) and Biogen Idec (2006-2007). He worked at the National Cancer Institute from 1990 to 1997, serving as Chief of the Investigational Drug Branch, and then as Acting Associate Director of the Cancer Therapy Evaluation Program (CTEP). Dr. Parkinson is a past Chairman of the Food & Drug Administration (FDA) Biologics Advisory Committee, has also served on the FDA's Science Board, and is a recipient of the FDA's Cody Medal. He has held academic positions both at Tufts and at the University of Texas MD Anderson Cancer Center, and has authored over 100 peer-reviewed

publications.

In June 2017, we announced that Phillip M. Nudelman, Ph.D., resigned as a member of the Board of Directors due to health reasons. Richard L. Love, a current director, is acting as Interim Chairman of the Board until the Board selects a permanent successor. Jack W. Singer, M.D., also resigned as a member of the Board. Dr. Singer will remain an employee of the Company in his role as Executive Vice President, Chief Scientific Officer, Interim Chief Medical Officer and Global Head of Translational Medicine.

Financial Summary

Our revenues are generated from a combination of PIXUVRI sales and collaboration and license agreements. Collaboration revenues reflect the earned amount of upfront payments and milestone payments under our product collaborations. Total revenues were $22.2 million and $7.4 million for the three months ended June 30, 2017 and 2016, respectively, and $23.0 million and $43.8 million for the six months ended June 30, 2017 and 2016, respectively. Income from operations was $5.3 million for the three months ended June 30, 2017 and loss from operations was $19.1 million for the three months ended June 30, 2016. Loss from operations was $14.0 million and $14.9 million for the six months ended June 30, 2017 and 2016, respectively. Results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

As of June 30, 2017, cash and cash equivalents were $74.7 million.

RESULTS OF OPERATIONS
Three and six months ended June 30, 2017 and 2016

Product sales, net. We sell PIXUVRI primarily through a limited number of wholesale distributors. Servier is responsible for distribution of PIXUVRI in countries other than the U.S. (and its territories and possessions.) We generally record product sales upon receipt of the product by the health care provider or distributor at which time title and risk of loss pass.

Gross sales is defined as our contracted reimbursement price in each country. Gross sales from PIXUVRI were $0.2 million and $1.0 million for the three months ended June 30, 2017 and 2016, respectively, and $0.9 million and $2.2 million for the six months ended June 30, 2017 and 2016, respectively. Product sales, net represents gross sales and royalty revenue as well as provisions for distributor discounts, estimated government-mandated discounts and rebates, trade discounts and estimated product returns. Product sales, net from PIXUVRI were $0.3 million and $1.1 million for the three months ended June 30, 2017 and 2016, respectively, and $1.0 million and $2.3 million for the six months ended June 30, 2017 and 2016, respectively. Royalty revenue of $128,000 and $76,000 for the three months ended June 30, 2017 and 2016, respectively, and $188,000 and $76,000 for the six months ended June 30, 2017 and 2016, respectively, were included in product sales, net.

The provision for product returns relates to a limited right of return or replacement that we offer to certain customers. Distributor discounts, returns and rebates were $0.1 million during the six months ended June 30, 2017 while no material amounts were recorded for the three months ended June 30, 2017 or for the three and six months ended June 30, 2016. During the periods presented, there were no other material payments and credits applied towards provision for discounts, rebates and other for current or prior period sales.

The decrease in product sales, net for the three and six months ended June 30, 2017 from the respective periods in 2016 was primarily related to the Restated Agreement we entered into with Servier in April 2017 under which Servier assumed commercialization rights to PIXUVRI in all markets except in the U.S.

License and Contract Revenues

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

		Three Months Ended June 30,		Six Months Ended June 30,	
		2017	2016	2017	2016
Baxalta	Milestone and license revenue	$—	$—	$—	$32,000
	Development services revenue	—	6,165	—	9,041
	Total Baxalta revenue	—	6,165	—	41,041
Servier	Milestone and license revenue	11,487	—	11,487	—
	Development services revenue	399	145	467	521
	Total Servier revenue	11,886	145	11,954	521
Teva	Milestone revenue	10,000	—	10,000	—
	Total Teva revenue	10,000	—	10,000	—
		$21,886	$6,310	$21,954	$41,562

Baxalta

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 with Baxalta Incorporated and its affiliates, or Baxalta, which is now part of Shire plc. As such, we will no longer be eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta.

During the six months ended June 30, 2016, we recorded milestone revenue of $32.0 million. We received the cash advance for these milestone payments in the second quarter of 2015; it was accounted for as long-term debt until the achievement of the associated milestones in the first quarter of 2016. No such milestone payments were received during the six months ended June 30, 2017 due to the termination of the Pacritinib License Agreement as discussed above.

During the three and six months ended June 30, 2016, we recorded $6.2 million and $9.0 million, respectively, of development services revenue, of which $6.0 million and $8.6 million, respectively, was related to the reimbursable development costs from Baxalta under the terms of the Pacritinib License Agreement and $0.2 million and $0.4 million, respectively, was related to the upfront payment we received in connection with the execution of the Pacritinib License Agreement in 2013. No such revenue was recorded during the same periods in 2017 due to the termination of the Pacritinib License Agreement as discussed above.

For additional information relating to the Pacritinib License Agreement, see Part I, Item 2, "License Agreements and Milestone Activities - Baxalta".

Servier

In April 2017, in connection with the 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. We expect to recognize this deferred revenue based on a proportional performance method through approximately 2019.

The Restated Agreement with Servier amended and restated in its entirety the Exclusive License and Collaboration Agreement (the "Original Agreement") entered into in September 2014. 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 was allocated to the Restated Agreement and will be recognized as revenue based upon a proportional performance method as noted above.

We recognized deferred revenue related to development services allocated from the upfront payments we received in connection with the Original Agreement, as well as the Restated Agreement, of $0.1 million and $26,000 during the three months ended June 30, 2017 and 2016, respectively, and $0.2 million and $51,000 during the six months ended June 30, 2017 and 2016, respectively. We recorded revenue of $0.2 million during the three and six months ended June 30, 2017 for the reimbursement of expenses related to commercialization transition under the Restated Agreement. The balance of deferred

revenue related to the Restated Agreement (including the remaining portion of $0.6 million allocated from the Original Agreement) as of June 30, 2017 was $1.8 million.

In February 2016, we entered into an agreement with one of Servier's affiliates whereby we are 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 $64,000 and $0.1 million of expense reimbursements as development services revenue during the three months ended June 30, 2017 and 2016, respectively, and $0.1 million and $0.5 million during the six months ended June 30, 2017 and 2016, respectively. Deferred revenue as of June 30, 2017 included a $0.1 million prepayment related to the pharmacokinetic sub-study. There was no such prepayment as of December 31, 2016.

For additional information on our collaboration with Servier, see Part I, Item 2, “License Agreements and Milestone Activities - Servier”.

Teva

During the three and six months ended June 30, 2017, we received a $10.0 million milestone payment from Teva upon the achievement of a worldwide net sales milestone of TRISENOX. There were no such revenues for the comparative periods in 2016.

Operating costs and expenses

Cost of product sold. Cost of product sold is related to sales of PIXUVRI. Cost of product sold was $0.1 million and $0.2 million for the three months ended June 30, 2017 and 2016, respectively, and $0.2 million and $0.4 million for the six months ended June 30, 2017 and 2016, respectively. The decrease for both periods presented was primarily as a result of the Restated Agreement we entered into with Servier in April 2017 whereby Servier takes responsibility for the manufacture and supply of drug products and substances in their respective territories. For additional information, see Part I, Item 2, License Agreements and Milestone Activities - Servier.

We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional marketing authorization by the EMA's CHMP. While we tracked the quantities of individual PIXUVRI product lots, we did not track manufacturing costs prior to capitalization and, therefore, the manufacturing cost of PIXUVRI produced prior to capitalization is not reasonably determinable. We expect approximately half of this reduced-cost inventory will be available for us to use commercially and to fulfill expected demand under the Restated Agreement with Servier. Accordingly, we reserved $1.6 million and 1.5 million of existing inventory expected to be unsalable as of June 30, 2017 and December 31, 2016, respectively. The timing of the sales of such reduced-cost inventory and its impact on gross margin is dependent on the level of PIXUVRI sales as well as our ability to utilize this inventory prior to its expiration date. We expect that our cost of product sold as a percentage of product sales may increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold; however, such future costs will ultimately depend on several factors in the near term, including, but not limited to, the consumption rate and availability of reduced cost inventory, the effect of expiring inventory and applicable manufacturing pricing structures (which will depend, in part, on the particular drug substance manufacturers we select).

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016

Compounds:				
PIXUVRI	$1,957	$3,068	$4,022	$6,571
Pacritinib	3,516	7,492	7,621	19,117
Opaxio	13	39	16	65
Tosedostat	83	827	189	1,204
Operating expenses	3,345	5,056	6,298	10,044
Research and preclinical development	—	215	21	542
Total research and development expenses	$8,914	$16,697	$18,167	$37,543

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 and an allocation of occupancy, depreciation and amortization expenses associated with developing these compounds. Research and preclinical development costs primarily include costs associated with external laboratory services associated with the compound under development by Aequus Biopharma, Inc. 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 June 30, 2017 were $124.4 million for PIXUVRI (excluding costs prior to our 2004 merger with Novuspharma S.p.A, formerly a public pharmaceutical company located in Italy), $122.7 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S*BIO, in May 2012 and $29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S*BIO), $228.0 million for Opaxio and $14.1 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma Therapeutics Limited, or Chroma, in 2011 and $21.9 million of in-process research and development expenses associated with the acquisition of certain assets from Chroma).

Research and development expenses decreased to $8.9 million and $18.2 million for the three and six months ended June 30, 2017 compared to $16.7 million and $37.5 million for the respective periods in 2016. The decrease was primarily attributed to a decrease in pacritinib development costs as a result of the completion of the Phase 3 clinical studies in 2017, a decrease in expenses for the manufacture of pacritinib, a decrease in operating expenses primarily attributed to personnel costs associated with a reduction in average headcount between periods, and a reduction in expenses related to the PIX306 trial between periods.

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 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, and our product PIXUVRI, which is currently being commercialized in parts of Europe, is undergoing a post-authorization trial. 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, and to complete the post-authorization PIX306 trial of PIXUVRI, 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. 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. 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 generate material net cash inflows from PIXUVRI or be able to begin commercializing pacritinib or tosedostat 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 Quarterly Report on Form 10-Q.

Selling, general and administrative expenses. Selling, general and administrative expenses were $8.0 million and $18.7 million for the three and six months ended June 30, 2017 compared to $9.6 million and $20.9 million for the respective periods

in 2016. The decrease between the three-month periods ended June 30, 2017 and 2016 was primarily attributable to decreases of $1.8 million in personnel costs, $0.9 million in legal fees, $0.3 million in fees for commercial services associated with PIXUVRI, $0.3 million in travel costs, and $0.3 million in other expense, offset by an increase of $2.0 million in settlement expense. The decrease between the six-month periods ended June 30, 2017 and 2016 was primarily attributable to decreases of $2.3 million in personnel costs, $0.6 million in travel costs, $0.3 million in bad debt expense, $0.2 million in professional fees for marketing initiatives related to our drug candidate, pacritinib, $0.4 million in pacritinib promotional costs previously shared with our collaboration partner, Baxalta, $0.2 million in tax expense, $0.1 million in other professional services associated with PIXUVRI, $0.1 million in board fees, $0.1 million in reporting and investor relation costs, and $0.4 million in other expenses. Offsetting these decreases were increases of $0.2 million in legal fees, $2.0 million in settlement expense, $0.2 million in audit and tax related fees, and $0.1 million in consulting fees.

Non-operating income and expenses

Interest expense. Interest expense was $0.5 million and $0.7 million for the three months ended June 30, 2017 and 2016 respectively, and $1.0 million and $1.4 million for the six months ended June 30, 2017 and 2016, respectively. Interest expense was primarily related to our senior secured term loan.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of $37,000 and $38,000 for the three months ended June 30, 2017 and 2016, respectively, related to our senior secured term loan. Amortization of $0.1 million for the both of the six months ended June 30, 2017 and 2016 related to our senior secured term loan in 2017 and to our senior secured term loan and the Baxalta milestone advances in 2016.

Foreign exchange gain (loss). Foreign exchange gains for the three and six months ended June 30, 2017 and foreign exchange losses for the three and six months ended June 30, 2016 were due to fluctuations in foreign currency exchange rates, primarily related to operations in our European branches and subsidiaries denominated in foreign currencies.

Other non-operating expense. Other non-operating expense of $0.5 million for the six months ended June 30, 2016 primarily represents the other-than-temporary impairment recognized on our investment in equity securities.

Deemed dividends on preferred stock. Deemed dividends on preferred stock of $4.4 million for the three and six months ended June 30, 2017 related to the issuance of our Series N-3 Preferred Stock. (See Part I, Item 1, Note 4, Preferred Stock in this Quarterly Report on Form 10-Q, which note is incorporated herein by reference.) There were no deemed dividends on preferred stock for the comparative periods in 2016.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Cash and cash equivalents. As of June 30, 2017, we had $74.7 million in cash and cash equivalents.

Net cash used in operating activities. Net cash used in operating activities decreased to $8.0 million during the six months ended June 30, 2017 compared to $48.9 million for the same period in 2016. This decrease was primarily due to receipt of a $13.1 million upfront payment from Servier in connection with the Restated Agreement in 2017, receipt of a $10.0 million sales milestone payment from Teva in 2017, and the collection of $7.8 million in receivables under the collaborative arrangement with Servier in 2017 as well as decreases in spending for research and development and selling, general and administration expenses during the six months ended June 30, 2017 compared to the same period

in 2016.

Net cash provided by (used in) investing activities. Net cash used in investing activities of $0.1 million for the six months ended June 30, 2016 was due to purchases of property and equipment. There was no such purchase for the same period in 2017.

Net cash provided by (used in) financing activities. Net cash provided by financing activities was $39.0 million for the six months ended June 30, 2017 and net cash used in financing activities was $2.4 million for the six months ended June 30, 2016. The increase was primarily due to net proceeds from the Series N-3 preferred stock offering in June 2017.

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 will need to seek additional funding.

The development and commercialization of a major product candidate like pacritinib without a collaborative partner will require a substantial amount of our time and financial resources, and as a result, we will 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 2, “License Agreements and Milestone Activities - Baxalta.”

Capital Resources

We have prepared our condensed consolidated financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, we believe that our present financial resources, together with payments projected to be received under certain contractual agreements and our ability to control costs, will only be sufficient to fund our operations into the third quarter of 2018. This raises substantial doubt about our ability to continue as a going concern. Further, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for PIXUVRI, pacritinib, and tosedostat. Because of our reacquisition of worldwide rights for pacritinib, we will no longer be eligible to receive cost sharing or milestone payments for pacritinib’s development from Baxalta, and losses related to research and development for pacritinib will increase. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of June 30, 2017, our available cash and cash equivalents totaled $74.7 million. We had an outstanding principal balance under our senior secured term loan agreement of $15.6 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, we may not receive the anticipated milestone payments or achieve projected net sales from PIXUVRI. Due to these and other factors, the foregoing forecast for the period for which we will have sufficient resources to fund our operations may fail.

Capital Requirements

We will need to raise additional funds to operate 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 shareholders 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.

Our future capital requirements will depend on many factors, including:

•developments in and expenses associated with our research and development activities;

•acquisitions of compounds or other assets;

•changes in manufacturing;

•ability to generate sales of PIXUVRI in the U.S.;

•regulatory approval developments;

•ability to execute appropriate collaborations for development and commercialization activities;

•ability to reach milestones triggering payments under certain of our contractual arrangements;

•litigation and other disputes;

•competitive market developments; and

•other unplanned business developments.

As of June 30, 2017, 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, 2016, decreased by approximately $2.4 million.

LICENSE AGREEMENTS AND MILESTONE ACTIVITIES

Servier

In September 2014, we entered into the Original Agreement, pursuant to which we granted Servier 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 outside of Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S.

We received an upfront payment in October 2014 of €14.0 million (or $17.8 million using the currency exchange rate as of the date we received the funds). In addition, subject to the achievement of certain conditions, the Original Agreement provided for us to potentially receive milestone payments thereunder in the aggregate amount of up to €89.0 million, which was comprised of the following: up to €49.0 million in potential clinical and regulatory milestone payments (of which €9.5 million was payable upon occurrence of certain enrollment events in connection with the PIX306 study for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. As of June 30, 2017, of these potential milestone payments, we have received a €1.5 million (or $1.7 million upon conversion from euros as of the date we received the funds) milestone payment relating to the attainment of reimbursement approval for PIXUVRI in Spain and a €7.5 million (or $8.0 million upon conversion from euros as of the date we achieved the milestone in December 2016) milestone payment relating to the occurrence of a certain enrollment event in the PIX306 study.

In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement (the “Restated Agreement”) with Servier (together with the Company, the “Parties”) pursuant to which the Parties amended and restated the Original Agreement regarding the development and commercialization of PIXUVRI (to the extent incorporated in a pharmaceutical product, the “Licensed Product(s)”). The Restated Agreement replaces the Original Agreement in its entirety.

We have obtained conditional marketing authorization in the E.U. to market PIXUVRI for the treatment of adult patients with relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. Under the Restated Agreement, we will transfer our European marketing authorization to Servier upon positive, statistically significant results in an ongoing post-authorization Phase III clinical trial, PIX306, unless Servier elects to terminate the Restatement Agreement within thirty (30) days after the positive results.

Under the Restated Agreement, we have granted to Servier an exclusive, sublicensable (subject to certain exceptions) license to manufacture the Licensed Products worldwide, and an exclusive, sublicenseable (subject to certain exceptions) license to develop and commercialize the Licensed Products worldwide, excluding the U.S. (the “Company Territory”). The Parties have agreed to a commercialization transition plan whereby we will transfer to Servier medical affairs and commercialization activities relating to the Licensed Products in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey and the U.K. (collectively, the "Transition Territory"). We are in the process of terminating or assigning certain distributor and wholesaler contracts to Servier in the Transition Territory, and expect the last contract to be terminated in 2018. Each party will be responsible for the manufacture and supply of drug products and substances in their respective territories.

We received payments of €12.0 million from Servier, which included €2.0 million for a new milestone previously achieved, and Servier purchased a certain amount of PIXUVRI drug product for an additional €0.9 million in July 2017. Subject to the achievement of certain conditions, we are eligible to receive additional milestone payments from Servier in the aggregate amount of up to €76.0 million, which is comprised of the following: up to €36.0 million in potential regulatory milestone payments and up to €40.0 million in potential sales milestone payments. We are eligible to receive tiered royalty payments ranging from a low-double digit percentage up to a percentage in the low-twenties based on net sales of the Licensed Product, subject to certain reductions of up to mid-double digit percentages under certain circumstances. The Parties will no longer use a joint marketing plan, and marketing costs will no longer be shared equally between the Parties; instead Servier will be solely responsible for marketing costs within Europe. Mutually agreed upon development costs other than PIX306 will continue to be shared equally between the Parties, which represents no change to the development cost sharing.

The Restated Agreement also requires the Parties to amend the trademark license agreement entered into between the Parties on June 8, 2015 to provide for Servier’s right to use of our trademark PIXUVRI in connection with Licensed Products worldwide, excluding the Company Territory.

Baxalta

In November 2013, we entered into a Development, Commercialization and License Agreement, dated as of November 14, 2013, with Baxter International Inc., or Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas, or the Original Pacritinib License Agreement. The Original Pacritinib License Agreement, the rights and obligations to which Baxter had assigned to Baxalta, was amended by the License Amendment, effective June 8, 2015. The Original Pacritinib License Agreement, as amended by the License Amendment, is referred to herein as the "Pacritinib License Agreement." Under the Pacritinib License Agreement, Baxalta had an exclusive, worldwide (subject to co-promotion rights discussed below), royalty-bearing, non-transferable license (which was sub-licensable under certain circumstances) relating to pacritinib. Licensed products under the Pacritinib License Agreement consisted of products in which pacritinib is an ingredient.

We received an upfront payment of $60.0 million under the Pacritinib License Agreement, which included a $30.0 million investment in our equity. The Pacritinib License Agreement also provided for us to receive potential additional payments of up to $302.0 million upon the successful achievement of certain development and commercialization milestones, comprised of $112.0 million of potential clinical, regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to $190.0 million. We have received milestone payments of $52.0 million pursuant to the Pacritinib License Agreement.

In June 2015, we entered into the License Amendment. Pursuant to the License Amendment, two potential milestone payments in the aggregate amount of $32.0 million from Baxalta to us were accelerated from the schedule contemplated by the original Pacritinib License Agreement relating to the PERSIST-2 Milestone and the MAA Milestone. In the first quarter of 2016, we recorded $32.0 million in license and contract revenue upon attainment of the milestones.

In October 2016, we regained worldwide rights for the development and commercialization of pacritinib following termination of the Pacritinib License Agreement with Baxalta. Pursuant to the termination, Baxalta paid us a one-time cash payment in the amount of approximately $10.3 million as reimbursement for certain expenses incurred or to be incurred. In exchange, we have agreed to provide a one-time payment to Baxalta, upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib, in the amount of approximately $10.3 million which represents certain amounts paid by Baxalta for the benefit of the pacritinib program manufacturing efforts. We have also agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of pacritinib unless the transferee/licensee/sublicensee agrees to be bound by the terms of the Asset Return and Termination Agreement with Baxalta.

University of Vermont

We entered into an agreement with the University of Vermont, or UVM, in March 1995, as amended, or the UVM Agreement, which grants us an exclusive sublicensable license for the rights to PIXUVRI. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use PIXUVRI, and we are obligated to make royalty payments to UVM ranging from low single digits to mid-single digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of PIXUVRI, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the

first sale of PIXUVRI in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement in the event of an uncured material breach of the UVM Agreement by the other party or in the event of bankruptcy of the other party.

S*BIO

We acquired the compounds SB1518 (which is referred to as “pacritinib”) and SB1578, which inhibit JAK2 and FLT3, from S*BIO in May 2012. Under our agreement with S*BIO, we are required to make milestone payments to S*BIO up to an aggregate amount of $132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any compound that we acquired from S*BIO for use for specific diseases, infections or other conditions. At our election, we may pay up to 50% of any milestone payments to S*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible

into our common stock. In addition, S*BIO will also be entitled to receive royalty payments from us at incremental rates in the low single-digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis.

Vernalis

We entered into an amended and restated exclusive license agreement with Vernalis (R&D) Limited, or Vernalis, in October 2014, or the Vernalis License Agreement, for the exclusive worldwide right to use certain patents and other intellectual property rights to develop, market and commercialize tosedostat and certain other compounds. Under the Vernalis License Agreement, we have agreed to make tiered royalty payments of no more than a high single-digit percentage of net sales of products containing licensed compounds, with such obligation to continue on a country-by-country basis for the longer of ten years following commercial launch or the expiry of relevant patent claims.

The Vernalis License Agreement will terminate when the royalty obligations expire, although the parties have early termination rights under certain circumstances, including the following: (i) we have the right to terminate, with three months' notice, upon the belief that the continued development of tosedostat or any of the other licensed compounds is not commercially viable; (ii) Vernalis has the right to terminate in the event of our uncured failure to pay sums due; and (iii) either party has the right to terminate in the event of the other party's uncured material breach or insolvency.

Gynecologic Oncology Group

We entered into an agreement with the Gynecologic Oncology Group, now part of NRG Oncology, in March 2004, as amended, related to the GOG-0212 trial of Opaxio it is conducting in patients with ovarian cancer. Pursuant to the terms of such agreement, we paid an aggregate of $1.2 million in milestone payments during 2014 based on certain enrollment milestones achieved. In addition, a milestone of $0.5 million was paid during the three and six months ended June 30, 2017. We may be required to pay an additional $0.5 million upon the attainment of a certain milestone. No further development of Opaxio is planned.

PG-TXL

In November 1998, we entered into an agreement with PG-TXL, as amended in February 2006, or the PG-TXL Agreement, which granted us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL's polymer technology. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we were obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to $14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement was based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we were required to make royalty payments to PG-TXL based on net sales. Our royalty obligations ranged from low to mid-single digits as a percentage of net sales. In February 2017, we terminated our agreement with PG-TXL and the exclusive worldwide license for rights to Opaxio and certain polymer technology under our agreement with PG-TXL.

Novartis

In January 2014, we entered into a Termination Agreement, or the Novartis Termination Agreement, with Novartis, to reacquire the rights to PIXUVRI previously granted to Novartis under our agreement entered into in September 2006, as amended, or the Original Novartis Agreement. Pursuant to the Novartis Termination Agreement, the Original Novartis Agreement was terminated in its entirety, except for certain customary provisions, including those pertaining

to confidentiality and indemnification, which survive termination.

Under the Novartis Termination Agreement, we agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of PIXUVRI and Opaxio unless the recipient thereof agrees to be bound by the terms of the Novartis Termination Agreement. We also agreed to provide potential payments to Novartis, including a percentage ranging from the low double-digits to the mid-teens, of any consideration received by us or our affiliates in connection with any transfer, license, sublicense or other grant of rights with respect to intellectual property of PIXUVRI or Opaxio; provided that such payments will not exceed certain prescribed ceilings in the low single-digit millions. Novartis is entitled to receive potential payments of up to $16.6 million upon the successful achievement of certain sales milestones of PIXUVRI and Opaxio. We are also obligated to pay to Novartis tiered low single-digit percentage royalty payments for the first several hundred million dollars in annual net sales, and 10% royalty payments thereafter based on annual net sales of each of PIXUVRI and Opaxio, subject to reduction in the event generic drugs are introduced and sold by a third party, causing the sale of

PIXUVRI to fall by a percentage in the high double digits. Royalty payments for PIXUVRI are subject to certain minimum floor percentages in the low single digits.

Teva Pharmaceutical Industries Ltd.

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon, pursuant to which we divested the compound, TRISENOX. Cephalon was subsequently acquired by Teva Pharmaceutical Industries Ltd., or Teva. Under this agreement, we have the right to receive up to $100 million in payments upon achievement by Teva of specified sales and development milestones related to TRISENOX. To date, we have received $40.0 million of such potential milestone payments as a result of having achieved certain sales milestones.

Other Agreements

We have several agreements with CROs, third-party manufacturers and distributors that have durations of greater than one year for the development and distribution of certain of our compounds.

CRITICAL ACCOUNTING ESTIMATES

We make certain judgments and use certain estimates and assumptions when applying accounting principles generally accepted in the U.S. in the preparation of our condensed consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary materially from what we anticipate and different assumptions or estimates about the future could change our reported results. 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 2016 Form 10-K. There have been no material changes to our critical accounting estimates discussed therein.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Foreign Exchange Market Risk

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 held in our European branches and subsidiaries will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. In addition, certain of our contractual arrangements, such as the Restated Agreement with Servier, 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. Changes in the value of the U.S. dollar as compared to applicable foreign currencies (in particular, the euro) might have an adverse effect on our reported results of operations and financial condition. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. As of June 30, 2017, we had a net asset balance, excluding intercompany payables and receivables, in our European branches and subsidiaries denominated in euros. If the euro were to weaken 20 percent against the dollar, our net asset balance would decrease by approximately $1.4 million as of this date.

Interest Rate Risk

Our senior secured term loan bears interest at variable rates. Based on the outstanding principal balance of $15.6 million under such loan as of June 30, 2017, a hypothetical increase of 1.0% in interest rates would result in additional interest expense of $0.1 million over the next twelve months. For a detailed discussion of our senior secured term loan, including a discussion of the applicable interest rate, refer to Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" in our 2016 Form 10-K.

Item 4. Controls and Procedures

(a) 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 Principal Finance and Accounting 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 Principal Finance and Accounting 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.

Our management is conducting an internal investigation regarding certain expense reimbursements. We are currently seeking to recover certain amounts that we determined were not reimbursable to an executive under the policy applicable to the executive management team. We are in the process of completing our investigation, and may seek reimbursement of additional amounts. The outcome of the investigation could result in the identification of significant deficiencies or material weaknesses in the design or operation of our internal controls over financial reporting or the identification of deficiencies in our expense reimbursement procedures.

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, regardless of how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met. These inherent limitations include the following:

- Judgments in decision-making can be faulty, and control and process breakdowns can occur because of simple errors or mistakes.
- Controls can be circumvented by individuals, acting alone or in collusion with each other, or by management override.
- The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.
- Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the second fiscal quarter ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Other Financial Information

With respect to our unaudited condensed consolidated financial statements as of June 30, 2017 and for the three and six-month periods ended June 30, 2017 and 2016 included herein, Marcum LLP, or Marcum, reported that they have applied limited procedures in accordance with professional standards for a review of such information. However, their report dated August 3, 2017 appearing herein, states that they did not audit and they do not express an opinion on that unaudited financial information. Accordingly, the degree of reliance on their report on such information should be restricted in light of the limited nature of the review procedures applied. Marcum is not subject to the liability provisions of Section 11 of the Securities Act of 1933, as amended.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the Board of Directors
and Shareholders of CTI BioPharma Corp.

We have reviewed the accompanying condensed consolidated balance sheet of CTI BioPharma Corp. as of June 30, 2017, and the related condensed consolidated statements of operations and comprehensive loss for the three and six-month periods ended June 30, 2017 and 2016, and the condensed consolidated statements of cash flows for the six-month periods ended June 30, 2017 and 2016, and the related notes to the financial statements. These financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the condensed consolidated financial information taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the accompanying condensed consolidated interim financial information for it to be in accordance with accounting principles generally accepted in the United States of America.

Note 1 to the Company's audited financial statements as of December 31, 2016, and for the year then ended disclosed that the Company did not expect that their existing cash and cash equivalents would be sufficient to fund their operations beyond the third quarter of 2017. Our auditors' report on those financial statements included an explanatory paragraph referring to the matters in Note 1 of those financial statements indicating that these matters raised substantial doubt about the Company's ability to continue as a going concern. As indicated in Note 1 to the Company's June 30, 2017 unaudited interim financial statements, the Company believes its present financial resources are only sufficient to fund its operations into the third quarter of 2018. The accompanying interim financial information does not include any adjustments that might result from the outcome of this uncertainty

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board, the consolidated balance sheet of CTI BioPharma Corp. as of December 31, 2016, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated March 2, 2017, we expressed an unqualified opinion on those financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2016 is fairly stated, in all material respects, in relation to the balance sheet from which it has been derived.

/s/ Marcum LLP
Marcum LLP
San Francisco, California
August 3, 2017

PART II – OTHER INFORMATION

Item 1. 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. 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, 2005, 2006 and 2007 are €0.5 million, €5.5 million, €2.5 million and €0.8 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 are defending ourselves against the assessments both on procedural grounds and on the merits of the case, although we can make no assurances regarding the ultimate outcome of these 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 €9.4 million, or approximately $10.7 million converted using the currency exchange rate as of June 30, 2017, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment.

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

- 2003 VAT. In September 2011, the Provincial Tax Court issued decision no. 229/3/2011, which (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found the ITA liable to pay us €10,000, as partial refund of the legal expenses we incurred for our appeal. In October 2012, the ITA appealed this decision. In June 2013, the Regional Tax Court issued decision no. 119/50/13, which accepted the appeal of the ITA and reversed the previous decision of the Provincial Tax Court. We believe that such decision has not carefully taken into account our arguments and the documentation we filed, and therefore appealed such decision in front of the Supreme Court both on procedural grounds and on the merits of the case in January 2014. In January 2014 the Company was provided a notice of payment with which the ITA requested the advance payment of €0.4 million of VAT, interest and penalties. We paid such amount in March 2014.

- 2005 VAT. In January 2011, the Provincial Tax Court issued decision No. 4/2010 which (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the ITA to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. Both the ITA and the Company appealed to the higher court against the decision. In October 2012, the Regional Tax Court issued decision no. 127/31/2012, which (i) fully accepted the merits of our appeal and (ii) confirmed that no penalties can be imposed against us. In April 2013, the ITA appealed the decision to the Italian Supreme Court.

- 2006 VAT. In October 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2007 VAT case) in which it (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found that for the 2006 and 2007 VAT cases the ITA was liable to pay us €10,000 as partial refund of the legal expenses incurred for the appeal. In December 2011, the ITA appealed this decision to the Regional Tax Court. On April 16, 2013, the Regional Tax Court issued decision no. 57/35/13 (jointly with the 2007 VAT case) in which it fully rejected the merits of the ITA's appeal, declared that no penalties can be imposed against us, and found the ITA liable to pay us €12,000, as partial refund of the legal expenses we incurred for this appeal. In November 2013, the ITA appealed the decision to the Supreme Court.

- 2007 VAT. In October 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2006 VAT case described above) in which the Provincial Tax Court (i) fully accepted the merits of our appeal, (ii) declared that

no penalties can be imposed against us, and (iii) found that for the 2006 and 2007 VAT cases the ITA was liable to pay us €10,000 as partial refund of the legal expenses incurred for the appeal. In December 2011, the ITA appealed this decision to the Regional Tax Court. On April 16, 2013, the Regional Tax Court issued decision no. 57/35/13 (jointly with the 2006 VAT case) in which it fully rejected the merits of the ITA's appeal, declared that no penalties can be imposed against us, and found the ITA liable to pay us €12,000, as partial refund of the legal expenses we incurred for this appeal. In November 2013, the ITA appealed the decision to the Supreme Court.

The Italian Supreme Court has scheduled the first hearing for the 2005 VAT case for September 26, 2017. No hearing has been fixed yet for 2003 and consolidated 2006/2007 VAT cases.

Securities and Exchange Commission Subpoena

We previously disclosed that we had received a subpoena from the SEC in January 2016. We believe that the SEC is seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib. The SEC Staff's letter sent with the subpoena stated that the investigation is a fact-finding inquiry, and the investigation and subpoena do not mean that the SEC has concluded that we or anyone else has violated any law. We are cooperating with this investigation, which is ongoing.

In re CTI BioPharma Corp. Securities Litigation

On February 10, 2016 and February 12, 2016, class action lawsuits entitled Ahrens v. CTI BioPharma Corp. et al., Case No. 1:16-cv-01044 and McGlothlin v. CTI BioPharma Corp. et al., Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib. On May 2, 2016, the Company filed a motion to transfer the Ahrens case to the United States District Court for the Western District of Washington. The motion was unopposed and granted by the court on May 19, 2016. On June 3, 2016, the parties filed a joint motion to consolidate the McGlothlin case with the Ahrens case in order to proceed as a single consolidated proceeding. On June 13, 2016, the court granted the motion to consolidate with the action being captioned In re CTI BioPharma Corp. Securities Litigation, Master File No. 2:16-cv-00216-RSL. On September 2, 2016, the court appointed Lead Plaintiffs and Lead Counsel. On September 28, 2016, the court entered a scheduling order, as revised by order entered December 8, 2016, setting November 8, 2016 as the deadline to file a consolidated class action complaint and deadlines for briefing defendants' motion to dismiss. Briefing concluded on February 22, 2017. A hearing on the defendants' motion to dismiss has not been set. The consolidated class action complaint asserts claims similar to those asserted in the initial complaints, although it no longer asserts claims relating to the September 24, 2015 public offering, but adds claims relating to the Company's October 27, 2015 and December 4, 2015 public offerings. On July 26, 2017, we received a written offer for the global resolution and settlement of the consolidated action in exchange for cash payment of $20 million. The Company has insurance coverage related to this matter and such insurance is expected to cover $18 million of the claim. We have agreed in principle to the terms of the settlement offer and are currently negotiating the terms of a memorandum of understanding with respect to the terms of the settlement offer with the lead plaintiff's representatives. The terms of any final agreement for the settlement of the litigation will be subject to court approval, amongst other customary terms and conditions.

Wei v. James A. Bianco, et al.; England v. James A Bianco, et al; Nahar v. James A. Bianco, et al.; Hill v. James A. Bianco, et al.

On March 14, 2016, a Company shareholder filed the first of four similar derivative lawsuits on behalf of the Company seeking damages for alleged harm to the Company caused by certain current and former officers and directors. The first suit, Wei v. James A. Bianco, et al., 16-2-05818-3, was filed in King County Superior Court, Washington. A second suit, England v. James A. Bianco, et al., 16-2-14422-5, was filed in King County Superior

Court, Washington, on June 16, 2016. Two additional derivative suits, Nahar v. James A. Bianco, et al., 2:16-cv-0756, and Hill v. James A. Bianco, et al., 2:16-cv-1250, were filed in the United States District Court for the Western District of Washington on May 24, 2016 and August 9, 2016, respectively. The four suits raise similar allegations and seek similar relief against certain current and former officers and directors, including James A. Bianco, Louis A. Bianco, Jack W. Singer, Bruce J. Seeley, John H. Bauer, Phillip M. Nudelman, Reed V. Tuckson, Karen Ignagni, Richard L. Love, Mary O. Mundinger and Frederick W. Telling. Consistent with the requirements of a derivative action, the Company is named in each suit as a nominal defendant against which no monetary relief is sought. The complaints generally allege claims of: (1) breach of fiduciary duty; (2) abuse of control; (3) gross mismanagement; and (4) waste of corporate assets and (5) unjust enrichment (receiving compensation that was unjust in light of the alleged conduct). Each is based on the assertion that the Company made materially false and misleading statements and omitted material information from its disclosures about pacritinib and its safety. Plaintiffs in none of the suits made a pre-suit demand on the current Board to investigate whether to pursue claims against officers or directors, instead claiming demand is excused because the named defendants lack independence, are not disinterested because they lack impartiality, received and

want to continue to receive their compensation, have longstanding personal and business relationships, and cannot evaluate a demand since they are facing personal liability. Each of plaintiffs' suits requested the court to award the Company the damages allegedly sustained as a result of the conduct and to direct the Company and the individual defendants to reform and improve the Company's corporate governance to avoid future damages. On March 29, 2017 during mediation, the parties to the derivative suits reached an agreement in principle to settle all four suits subject to Board and court approvals. As part of the settlement, CTI has agreed to adopt certain corporate governance reforms and agreed not to object to an attorneys' fee application by plaintiffs' counsel of up to $0.8 million collectively. There is no admission of liability or any wrongdoing by any of the individual defendants or CTI.

In connection with the securities litigation and four derivative lawsuits described above, after taking into account our existing insurance coverage, we recorded $2.0 million and $2.2 million of settlement expense in Selling, general and administrative expenses in our condensed consolidated statement of operations for the three and six months ended June 30, 2017, respectively.

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 1A. Risk Factors

This Quarterly Report on Form 10-Q 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.

Factors Affecting Our Business, Financial Condition, Operating Results and Prospects

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 the commercialization of PIXUVRI, and we have significant contractual payment obligations. Our available cash and cash equivalents were $74.7 million as of June 30, 2017. 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 only be sufficient to fund our operations into the third quarter of 2018. 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, our ability to generate projected sales of PIXUVRI, any expansion of our sales and marketing organization for PIXUVRI, 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.

As of June 30, 2017, we had an outstanding principal balance under our senior secured term loan agreement of $15.6 million. We were required to make monthly interest-only payments in respect thereof in the approximate amount of $0.2 million until March 31, 2016. We are required to make monthly interest plus principal payments through December 1, 2018 in the approximate amount of $0.8 million, with the final principal payment of approximately $3.3 million on December 1, 2018. 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 senior 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.

We will need to raise additional funds to operate 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 shareholder approval to increase authorized shares and the restrictive covenants under our senior secured term loan agreement;
- issuance of equity-based securities will dilute the proportionate ownership of existing shareholders;
- our ability to obtain further funds from any potential loan arrangements is limited by our existing senior secured term loan 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 audit report for the year ended December 31, 2016 contains an explanatory paragraph on our consolidated financial statements, and we may in the future, receive additional such reports.

Our independent registered public accounting firm included an explanatory paragraph in its reports on our consolidated financial statements for the year ended December 31, 2016 regarding their substantial doubt as to our ability to continue as a
going concern. 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 only be sufficient to fund our operations into the third quarter of 2018, which does raise substantial doubt about our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in our audit report for the year ended December 31, 2016 and for 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 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 June 30, 2017, 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.

In order to develop and commercialize pacritinib, we will need to raise additional financing or seek a new collaboration partner for 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 pacrtinib. We currently have no commitments or arrangements for any additional

financing to fund the development and commercial launch of pacritinib, and we will need to seek additional funding, which may not be available or may not be available on favorable terms. 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 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 heavily dependent on the success of our development and commercialization collaborations. In particular, under the Restated Agreement with Servier, we rely heavily on Servier to collaborate with us to develop and commercialize PIXUVRI. As a result of our dependence on our relationship with Servier, the success or commercial viability of PIXUVRI is, to a certain extent, beyond our control. We are subject to a number of specific risks associated with our dependence on our collaborative relationship with Servier, including the following: possible disagreements as to the timing, nature and extent of development plans for the respective compound, including clinical trials or regulatory approval strategy; changes in their respective personnel who are key to the collaboration efforts; any changes in their respective business strategies adverse to our interests, whether in connection with a change of control or otherwise; possible disagreements regarding ownership of proprietary rights; the ability to meet our financial and other contractual obligations under the respective agreements; and the possibility that Servier could elect to terminate their agreement with us pursuant to “at-will” termination clauses or breach their agreement with us. Furthermore, the contingent financial returns under our collaboration with Servier depends in large part on the achievement of development and commercialization milestones and the ability to generate applicable product sales to trigger royalty payments. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large part on the performance of Servier. 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.

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.

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib until we determine next steps. A full clinical hold is a suspension of the clinical work requested under an investigational new drug application. Under the full clinical hold, all patients currently on pacritinib were required to discontinue pacritinib, and we are not permitted to enroll any new patients or start pacritinib as initial or crossover treatment. In its written notification, the FDA noted interim overall survival results from PERSIST-2 showing a detrimental effect on survival consistent with the results from PERSIST-1, and that deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. On January 3, 2017, the full clinical hold was removed. Our complete response submission included, among other items, final Clinical Study Reports for both PERSIST-1 and 2 trials and the dose-exploration clinical trial protocol requested by the FDA. In July 2017, we enrolled the first patient in the PAC203 trial. We plan to enroll up to approximately 105 patients in our PAC203 trial with primary myelofibrosis who have failed prior ruxolitinib therapy to evaluate the dose response relationship for safety and efficacy (spleen volume reduction at 12 or 24 weeks) of three dose regimens: 100 mg once-daily, 100 mg twice-daily (BID) and 200 mg BID. The 200 mg BID dose regimen was used in PERSIST-2. The results of PAC203 may not address all of the FDA’s concerns regarding appropriate safe and efficacious dosage for pacritinib, 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. 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 ruxolinitib 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 our original MAA, and we submitted a new MAA that seeks to address the major objections by including data from PERSIST-2. The new application is 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.

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.

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.

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.

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, on February 8, 2016, the FDA placed pacritinib on full clinical hold and the clinical hold was not removed until January 3, 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. 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.

In the event that 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 were seeking accelerated approval and requested Priority Review of our NDA for pacritinib. However, on February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib. On January 3, 2017, the full clinical hold was removed. In July 2017, we enrolled the first patient in a new trial, PAC203, and we plan to enroll up to approximately 105 patients with primary myelofibrosis who have failed prior ruxolitinib therapy to evaluate the dose response relationship for safety and efficacy (spleen volume reduction at 12 and 24 weeks) of three dose regimens: 100 mg once-daily, 100 mg twice-daily (BID) and 200 mg BID. The 200 mg BID dose regimen was used in PERSIST-2.

We may in the future decide to seek 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.

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 emerging after the recent election of the President of the United States 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.

In particular, with respect to the commercialization of PIXUVRI, we will be heavily dependent on our collaboration partner, Servier. The failure of Servier (or any other applicable collaboration partner) to fulfill its commercialization obligations with respect to a compound, or the occurrence of any of the events in the list above, could adversely affect the commercialization of our products. Additionally, uncertainty and speculation regarding the possible repeal of all or a portion of the Patient Protection and Affordable Care Act has emerged after the recent election of the President of the United States. Members of the Trump administration, including the President, have made statements suggesting the administration plans to seek repeal of all or portions of the Affordable Care Act, and have stated that they will ask Congress to replace the current legislation with new legislation. 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.

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, require all individuals to have health insurance (with limited exceptions) 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 government and insurance companies, health maintenance organizations and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers and collaborative partners, as well as the availability of capital.

We may never be able to generate significant product revenues from the sale of PIXUVRI.

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend, in part, on our ability and that of our collaborator, Servier, to successfully commercialize our only currently marketed product, PIXUVRI. PIXUVRI is not approved for marketing in the U.S., is presently available only in a limited number of countries and is reimbursed in even fewer countries.

In addition, the successful commercialization of PIXUVRI depends heavily on the ability to obtain and maintain favorable reimbursement rates for users of PIXUVRI, as well as on various additional factors, including, without limitation, the ability to:

- obtain an annual renewal of our conditional marketing authorization for PIXUVRI;
- increase demand for and sales of PIXUVRI and obtain greater acceptance of PIXUVRI by physicians and patients;
- establish and maintain agreements with wholesalers and distributors on reasonable terms;
- maintain, and where necessary, enter into additional, commercial manufacturing arrangements with third parties, cost-effectively manufacture necessary quantities and secure distribution, managerial and other capabilities; and

- further develop and maintain a commercial organization to market PIXUVRI.

If we are unable to successfully commercialize PIXUVRI as planned, our business, financial condition, operating results and prospects could be harmed.

Post-approval or authorization regulatory reviews and obligations often result in significant expense and marketing limitations, and any failure to satisfy such ongoing obligations, including, in particular, our post-authorization commitment trial for PIXUVRI, 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, including PIXUVRI, 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 our ongoing PIX306 trial of PIXUVRI required by the EMA. We cannot predict the outcome of PIX306 or whether we will be able to complete the associated requirements in a timely manner. If we are unable to submit the requisite PIX306 clinical study report by the due date in December 2018 and are unable to obtain an extension of such deadline, or if we are otherwise unable to satisfy all applicable requirements, our conditional marketing authorization for PIXUVRI may be revoked.

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 not be able to maintain our listings on The NASDAQ Capital Market and the Mercato Telematico Azionario, or MTA, in Italy, or trading on these exchanges 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 NASDAQ in March 2016.

We have in the past and may in the future fail to comply with the NASDAQ Stock Market LLC, or NASDAQ. If our common stock ceases to be listed for trading on The NASDAQ Capital Market 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 Capital Market may constitute an event of default under our senior secured term loan 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 Capital Market or if our public float falls below $75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC 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. Delisting from The NASDAQ Capital Market could also affect our ability to maintain our listing or trading on the MTA in Italy. Trading in our common stock has been halted or suspended on both The NASDAQ Capital Market and MTA in the past and may also be halted or suspended in the future due to market or trading conditions at the discretion of The NASDAQ Stock Market, CONSOB or the Borsa Italiana (which ensures the development of the managed markets in Italy). Any halt or suspension in the trading in our common stock may negatively impact the market price of our common stock.

We may be unable to obtain a quorum for meetings of our shareholders or obtain requisite shareholder approval and, consequently, be unable to take certain corporate actions, including financing activities.

Failure to meet the requisite quorum or obtain requisite shareholder approval can prevent us from raising capital through equity financing or otherwise taking certain actions that may be in our best interest and that of our shareholders. We have experienced such difficulties in the past.

We are required under the NASDAQ Marketplace Rules to obtain shareholder 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 the greater of book or 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 shareholder approval for any future issuance that requires shareholder approval pursuant to applicable rules and regulations, particularly in light of difficulties we have had in the past in obtaining a quorum and obtaining the requisite vote. If we are unable to obtain financing or our financing options are limited due to shareholder approval difficulties, such failure may harm our ability to continue operations.

Additionally, a portion of our common shares are held by Italian institutions and, under Italian laws and regulations, it is difficult to communicate with the beneficial holders of those shares to obtain votes. In recent years, certain depository banks in Italy holding shares of our common stock have facilitated book-entry transfers of their share positions at Monte Titoli, S.p.A., the Italian central clearing agency, to their U.S. correspondent bank, who would then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks we contacted to facilitate these arrangements agreed to make the share transfers pursuant to these arrangements as of the record date of the shareholder meeting, subject to the relevant beneficial owner being given notice before such record date and taking no action to direct the voting of such shares. Obtaining a quorum and necessary shareholder approvals at shareholder meetings may depend in part upon the willingness of the Italian depository banks to continue participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to do so in the future.

As a result of the foregoing or for other reasons, we may be unable to obtain a quorum at annual or special meetings of shareholders. Even if we are able to obtain a quorum at our shareholder meetings, we may not obtain enough votes to approve matters to be resolved upon at those meetings. Any failure to obtain a quorum or the requisite vote on a proposal in question could harm us.

We are subject to Italian regulatory requirements, which limit our ability to issue additional shares of our common stock, could result in administrative and other challenges and additional expenses and/or could limit our ability to undertake other business initiatives.

Because our common stock is traded on the MTA in Italy, we are required to also comply with the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or CONSOB, and the Borsa Italiana S.p.A., or Borsa Italiana, which regulate companies listed on Italy's public markets. Compliance with these regulations and responding to periodic information requests from Borsa Italiana and CONSOB requires us to devote additional time and resources to regulatory compliance matters and to incur additional expenses of engaging additional outside counsel, accountants and other professional advisors. Actual or alleged failure to comply with Italian regulators can also subject us to regulatory investigations and fines or other sanctions from time to time.

Additionally, compliance with Italian regulatory requirements may restrict additional issuances of our common stock or other business initiatives. Under Italian law, in order to have newly issued shares listed on the Italian Stock

Exchange, we must publish a registration document, securities note and summary (which jointly compose a listing prospectus) that have to be approved by CONSOB prior to issuing common stock that is equal to or exceeds, in any twelve-month period, 20% of the number of shares of our common stock outstanding at the beginning of that period, subject to certain exceptions. If we are unable to obtain and maintain a registration document, securities note or summary for the listing of the newly issued shares and to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. In the past, we have issued convertible preferred stock in numerous prior offerings because the common stock resulting from the conversion of such securities, subject to the provisions of European Directive No. 71/2003, was not subject to the then-existing 10% limitation imposed by E.U. and Italian law. However, the European Union Parliament and the European Council recently published regulation proposals, which became effective in July 2017, that raised the limitation to 20% and significantly limited the scope of the exception to the listing prospectus requirement in relation to the stock resulting from the conversion or exchange of securities. This new regulation proposal may limit our ability to issue

convertible securities or impose additional costs on future issuances.

Any of such regulatory requirements of CONSOB and the Borsa Italiana could result in administrative and other challenges and additional expenses, limit our ability to undertake other business initiatives and negatively affect our business, financial condition, operating results and prospects.

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.

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.

A failure to comply with the numerous laws and regulations that govern our business, including those related to cross-border conduct, health care fraud and abuse, anti-corruption and false claims and the protection of health information, could result in substantial penalties and prosecution.

We are subject to risks associated with doing business outside of the U.S., which exposes us to complex foreign and U.S. regulations. For example, we are subject to regulations imposed by the Foreign Corrupt Practices Act, or the FCPA, the Bribery Act 2010 and other anti-corruption laws. These laws generally prohibit U.S. companies and their intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business. The SEC and U.S. Department of Justice have increased their enforcement activities with respect to the FCPA. Internal control policies and procedures and employee training and compliance programs that we have implemented to deter prohibited practices may not be effective in prohibiting our employees, contractors or agents from violating or circumventing our policies and the law.

In addition, 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.

We may also be subject to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, or HIPAA, which established uniform standards for certain “covered entities” (health care providers, health plans and health care clearinghouses) governing the conduct of certain electronic health care transactions and protecting the security and privacy of protected health information. Among other things, HIPAA’s privacy and security standards are directly applicable to “business associates” - independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. 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 attorney’s 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.

We are unable to predict whether we could be subject to actions under any of the foregoing or similar laws and regulations, or the impact of such actions. If we were to be found to be in violation of applicable laws or regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

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 PIXUVRI and pacritinib drug supply to successor vendors, respectively, 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 particular, our current business structure contemplates, at least in the foreseeable future, use of a single commercial supplier for PIXUVRI drug substance. In addition, in the event pacritinib is approved, we are initially preparing to 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.

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 March 2017, we announced the appointment of Bruce J. Seeley as Executive Vice President, Chief Commercial and Administrative Officer and Secretary. 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. We may not be able to effectively manage our transition to a new president and chief executive officer.

Directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and shareholder 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. If we are unable to continue to provide directors and officers sufficient liability insurance at affordable rates or at all, or if directors and officers perceive our ability to do so in the future to be limited, it may become increasingly more difficult to attract and retain management and qualified directors to serve on our Board of Directors.

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

We 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:

- In Europe, PIXUVRI faces competition from existing treatments for adults with multiply relapsed or refractory aggressive B-cell NHL. For example, patients are currently being treated with ibrutinib, idelalisib, lenolidimide, bendamustine, oxaliplatin and gemcitabine, although these particular agents do not have regulatory approval in Europe

for the foregoing indication. If we were to pursue bringing PIXUVRI to market in the U.S. (which is not currently part of our near-term plan), PIXUVRI would face similar competition.

- If we are successful in bringing pacritinib to market, pacritinib will face competition from the currently approved JAK1/JAK2 inhibitor, Jakafi®.

- If we are successful in bringing tosedostat to market, we will face competition from currently marketed products, such as cytarabine, Dacogen®, Vidaza®, Clolar®, Revlimid® and Thalomid®.

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 PIXUVRI or 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.

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.

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. PIXUVRI, pacritinib and tosedostat have all 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.

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, tosedostat 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 PIXUVRI-directed patents currently in force in Europe began to expire in late March 2015 and will continue to expire through a portion of 2023. Some of these European patents are also subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. In the United States, our PIXUVRI-directed U.S. patent will expire in 2024. Our PIXUVRI-directed patents outside of Europe and the U.S. began to expire in 2015 and will continue to expire through 2023.

Our U.S. and various foreign pacritinib-directed patents expire from 2026 through 2030. Our U.S. and various foreign tosedostat-directed patents expire from 2017 to 2018.

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 are they 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.

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 $4.4 million as of June 30, 2017 and December 31, 2016, 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, 2005, 2006 and 2007 are €0.5 million, €5.5 million, €2.5 million and €0.8 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. Further information pertaining to these cases can be found in Part II, Item 1, "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 €9.4 million (or approximately $10.7 million upon conversion from euros as of June 30, 2017) plus collection fees, notification expenses and additional interest 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 II, Item 1, "Legal Proceedings," we are currently engaged in certain pending legal proceedings, including the purported class action lawsuits filed against us and certain of our current and former directors and officers in February 2016 and the four derivative lawsuits filed against us in March, May, June and August 2016. In addition, we are in the process of supplying documents in response to a subpoena from the SEC in connection with an investigation into potential federal securities law violations as described in Part II, Item 1, "Legal Proceedings." 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 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.

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 effect on investor 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, and expect changes to occur in 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. In addition, our management is conducting an internal investigation regarding certain expense reimbursements. We are currently seeking to recover certain amounts that we determined were not reimbursable to an executive under the policy applicable to the executive management team. We are in the process of completing our investigation, and may seek reimbursement of additional amounts. The outcome of the investigation could result in the identification of significant deficiencies or material weaknesses in the design or operation of our internal controls over financial reporting or the identification of deficiencies in our expense reimbursement procedures. 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.

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 the 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.

Due to the fact that we have European branches and subsidiaries 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 branches and subsidiaries 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 (including with regard to sales of PIXUVRI) may increase our exposure to fluctuations in foreign currency exchange rates. In

addition, certain of our contractual arrangements, such as the Restated Agreement with Servier, 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. In particular, as a result of the commercialization of PIXUVRI, our risk with respect to potential product liability has increased. 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.

Risks Related to the Securities Markets

Shares of our common stock are subordinate to existing and any future indebtedness and to any preferred stock we may issue.

Shares of our common stock rank junior to our existing indebtedness, including under our senior secured term loan agreement and any future indebtedness we may incur, as well as to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding. Our senior secured term loan agreement restricts, and any future indebtedness and preferred stock may restrict, payment of dividends on our common stock. Shares of our common stock will also rank junior to any shares of our preferred stock that we may issue in the future.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our Board of Directors or a duly authorized committee of our Board of Directors and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our

ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to our shareholders generally.

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 July 27, 2017, our stock price ranged from a low of $2.70 to a high of $6.48. 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 Capital Market or on the MTA;
- 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.

Anti-takeover provisions in our charter documents, in our shareholder rights agreement, or rights plan, under Washington 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 articles of incorporation and bylaws may have the effect of deterring or delaying attempts by our shareholders 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 shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue shares of preferred stock without shareholder 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% shareholder, 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 shareholders might believe to be in their best interest or that could give our shareholders the opportunity to realize a premium over the then-prevailing market prices for their shares.

In addition, as a Washington corporation, we are subject to Washington's anti-takeover statute, which imposes restrictions on some transactions between a corporation and certain significant shareholders. 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.

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

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

Stock Repurchases in the Second Quarter

The following table sets forth information with respect to purchases of our common stock during the three months ended June 30, 2017:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or	Maximum Number of Shares that May Yet Be Purchased Under the

			Programs	Plans or Programs
April 1 - April 30, 2017	9,600	$ 4.04	—	—
May 1 - May 31, 2017	1,703	4.14	—	—
June 1 - June 30, 2017	162	3.31	—	—
Total	11,465	$ 4.05	—	—

(1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees granted under our Equity Incentive Plans.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures
Not applicable.

Item 5. Other Information

Effective August 1, 2017, David Kirske, 63, was appointed our principal financial and accounting officer. Mr. Kirske has been an independent chief financial officer consultant since January 2013. As a consultant, he has provided financial management services to public and private companies in several industries during this time. Mr. Kirske has served as a financial consultant to our company since April 2017. Prior to Mr. Kirske's time as a consultant, he served as chief financial officer of Mad Fiber, Inc. from April to December 2012. Mr. Kirske also served a Vice President and Chief Financial Officer of Helix BioMedix from 2004 to 2008. Mr. Kirske holds a Bachelor's of Arts, Business Administration, from the University of Puget Sound. There are no family relationships involving Mr. Kirske that would require disclosure under Item 401(d) of Regulation S-K, and there are no current or proposed transactions in which he or any member of his immediate family has, or will have, a direct or indirect material interest that would require disclosure under Item 404(a) of Regulation S-K. Mr. Kirske will report to Adam R. Craig, M.D., Ph.D., our President and Chief Executive Officer, and replaces Bruce J. Seeley in the role as principal financial and accounting officer. Mr. Kirske has agreed to serve in this role for a renewable term of six months. We are currently conducting a search for a candidate to serve as our chief financial officer and principal financial and accounting officer on a permanent basis.
In connection with his appointment as our principal financial and accounting officer, we entered into an offer letter with Mr. Kirske. The letter provides that his employment with the Company is on a temporary basis (for six months as noted above, subject to extension in six-month increments) and on a part-time basis (for 30 hours per week). Mr. Kirske will receive base salary at an annual rate of $185,000 and will be eligible for a short-term discretionary bonus at a target of 24% of his base salary. He will also be eligible to participate in the Company's standard employee benefit programs. In addition, Mr. Kirske was granted, effective August 1, 2017, a stock option grant under our 2017 Equity Incentive Plan to purchase 25,000 shares of our common stock at a per share exercise price equal to the closing trading price of a share of our common stock on the grant date of the award. The stock option has a maximum term of ten years from the date of grant and will vest over a period of one year from the grant date in twelve equal monthly installments. The grant will accelerate and fully vest should Mr. Kirske's employment be terminated by us without cause within the first six months after his start date. The foregoing description is qualified in its entirety by the provisions of Mr. Kirske's offer letter, which is attached hereto as Exhibit 10.3 and incorporated by reference. Additionally, in connection with his appointment, Mr. Kirske will enter into a standard indemnification agreement with us, substantially in the form previously approved by the Board, which is filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on June 2, 2014, and is incorporated by reference herein.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Location
3.1	Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on March 23, 2015.
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation, dated October 29, 2015 (Series N Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 30, 2015.
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation, dated October 29, 2015 (Series N-1 Preferred Stock).	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on October 30, 2015.
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation, dated December 8, 2015 (Series N-2 Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 9, 2015.
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation, dated April 29, 2016.	Incorporated by reference to Exhibit 3.5 to the Registrant's Quarterly Report on Form 10-Q, filed on May 10, 2016.
3.6	Amendment to Amended and Restated Articles of Incorporation of CTI BioPharma Corp.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 21, 2016.
3.7	Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 3, 2015.
3.8	Articles of Amendment to Amended and Restated Articles of Incorporation, dated May 16, 2017.	Filed herewith.
3.9	Articles of Amendment to Amended and Restated Articles of Incorporation of CTI BioPharma Corp. (Series N-3 Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on June 9, 2017.
4.1	Shareholder Rights Agreement, dated December 28, 2009, between the Registrant and Computershare Trust Company, N.A.	Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 8-A, filed on December 28, 2009.
4.2	First Amendment to Shareholder Rights Agreement, dated as of August 31, 2012, between the Registrant and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2012.

4.3	Second Amendment to Shareholder Rights Agreement, dated as of December 6, 2012, between the Registrant and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 7, 2012.
4.4	Third Amendment to Shareholder Rights Agreement, dated as of December 1, 2015, between the Registrant and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 1, 2015.

Exhibit Number	Exhibit Description	Location
4.5	Specimen Common Stock Certificate.	Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (File No. 333-200452), filed on November 21, 2014.
4.6	Form of Common Stock Purchase Warrant, dated December 13, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on December 14, 2011.
4.7	Warrant Agreement, dated June 9, 2015, by and between Registrant and Hercules Technology Growth Capital, Inc.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on June 10, 2015.
10.1	Letter Agreement, dated June 9, 2017, by and between CTI BioPharma Corp. and BVF Partners L.P.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on June 9, 2017.
10.2	2017 Equity Incentive Plan of the Company	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 16, 2017.
10.3†	Amended and Restated Exclusive	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on May 3, 2017.

	License and Collaboration Agreement by and between the Company, CTI Life Sciences Limited, Laboratoires Servier and Institut de Recherches Internationales Servier dated as of April 21, 2017.	
10.4*	Offer Letter, by and between the Registrant and David Kirske, dated August 1, 2017.	Filed herewith.
15	Letter regarding Unaudited Interim Financial Information.	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	Filed herewith.

	Sarbanes-Oxley Act of 2002.	
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.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.
* Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

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

CTI BIOPHARMA CORP.
(Registrant)

Dated: August 3, 2017 By: /s/ Adam R. Craig
Adam R. Craig
President and Chief Executive Officer

Dated: August 3, 2017 By: /s/ David H. Kirske
David H. Kirske
Principal Financial and Accounting Officer