CTI BIOPHARMA CORP
Form 10-Q
May 06, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended: March 31, 2015

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 (State or other jurisdiction of incorporation or organization)	91-1533912 (I.R.S. Employer Identification No.)
3101 Western Avenue, Suite 600 Seattle, Washington (Address of principal executive offices)	98121 (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 x 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 x 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 x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Outstanding at April 29, 2015
Common Stock, no par value	180,242,408

CTI BIOPHARMA CORP.

TABLE OF CONTENTS

2

PART 1 – FINANCIAL INFORMATION

Item 1. Financial Statements

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	March 31, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$44,395	$70,933
Accounts receivable, net	1,272	2,011
Inventory	3,591	4,182
Prepaid expenses and other current assets	4,209	3,379
Total current assets	53,467	80,505
Property and equipment, net	4,391	4,646
Other assets	5,212	7,136
Total assets	$63,070	$92,287
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$10,279	$6,356
Accrued expenses	14,607	19,734
Current portion of deferred revenue	779	826
Current portion of long-term debt	9,294	9,014
Other current liabilities	424	410
Total current liabilities	35,383	36,340
Deferred revenue, less current portion	1,612	1,779
Long-term debt, less current portion	5,943	8,363
Other liabilities	5,775	5,882
Total liabilities	48,713	52,364
Commitments and contingencies		
Common stock purchase warrants	240	1,445
Shareholders' equity:		
Common stock, no par value:		
Authorized shares - 315,000,000 and 215,000,000		
at March 31, 2015 and December 31, 2014, respectively		
Issued and outstanding shares - 180,247,408 and 176,761,099	2,028,975	2,023,949

at March 31, 2015 and December 31, 2014, respectively		
Accumulated other comprehensive loss	(7,001)	(6,499)
Accumulated deficit	(2,004,291)	(1,975,695)
Total CTI shareholders' equity	17,683	41,755
Noncontrolling interest	(3,566)	(3,277)
Total shareholders' equity	14,117	38,478
Total liabilities and shareholders' equity	$63,070	$92,287

See accompanying notes.

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenues:		
Product sales, net	$805	$1,268
License and contract revenue	1,923	143
Total revenues	2,728	1,411
Operating costs and expenses:		
Cost of product sold	190	145
Research and development	17,471	12,179
Selling, general and administrative	12,297	16,750
Other operating expense	253	—
Total operating costs and expenses	30,211	29,074
Loss from operations	(27,483)	(27,663)
Non-operating expense:		
Interest expense	(494)	(464)
Amortization of debt discount and issuance costs	(180)	(178)
Foreign exchange loss	(728)	(5)
Other non-operating expense	—	(886)
Total non-operating expense, net	(1,402)	(1,533)
Net loss before noncontrolling interest	(28,885)	(29,196)
Noncontrolling interest	288	194
Net loss	$(28,597)	$(29,002)
Basic and diluted net loss per common share	$(0.16)	$(0.20)
Shares used in calculation of basic and diluted net loss per common share	173,936	142,138

See accompanying notes.

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2015	2014
Net loss before noncontrolling interest	$(28,885)	$(29,196)
Other comprehensive income (loss):		
Foreign currency translation adjustments	2,247	(29)
Unrealized foreign exchange loss on intercompany balance	(2,754)	—
Net unrealized gain on securities available-for-sale:	5	8
Other comprehensive loss	(502)	(21)
Comprehensive loss	(29,387)	(29,217)
Comprehensive loss attributable to noncontrolling interest	288	194
Comprehensive loss attributable to CTI	$(29,099)	$(29,023)

See accompanying notes.

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2015	2014
Operating activities		
Net loss	$(28,885)	$(29,196)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	4,336	7,829
Depreciation and amortization	261	360
Noncash interest expense	180	178
Change in value of warrant liability	—	886
Other	(93)	499
Changes in operating assets and liabilities:		
Accounts receivable	537	(267)
Inventory	125	50
Prepaid expenses and other current assets	(939)	(139)
Other assets	1,219	(504)
Accounts payable	4,331	(410)
Accrued expenses and other	(4,861)	68
Deferred revenue	(214)	(143)
Total adjustments	4,882	8,407
Net cash used in operating activities	(24,003)	(20,789)
Investing activities		
Purchases of property and equipment	(24)	(35)
Net cash used in investing activities	(24)	(35)
Financing activities		
Cash paid for long-term debt issuance costs	—	(73)
Cash paid for Series 21 preferred stock issuance costs	(225)	—
Repayment of long-term debt	(2,297)	—
Payment of tax withholding obligations related to stock compensation	(527)	(105)
Other	12	(28)
Net cash used in financing activities	(3,037)	(206)
Effect of exchange rate changes on cash and cash equivalents	526	(8)
Net decrease in cash and cash equivalents	(26,538)	(21,038)
Cash and cash equivalents at beginning of period	70,933	71,639
Cash and cash equivalents at end of period	$44,395	$50,601

Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$524	$439
Cash paid during the period for taxes	$—	$—
Supplemental disclosure of noncash financing and investing activities		
Issuance of common stock upon exercise of common stock purchase warrants	$—	$1,877

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 CTI, the Company, we, us or our, 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 commercializing PIXUVRI® (pixantrone), or PIXUVRI, in the European Union, or the E.U., for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial program evaluating pacritinib for the treatment of adult patients with myelofibrosis to support regulatory submission for approval in the United States, or the U.S., and Europe. We are also evaluating pacritinib in earlier clinical trials as treatment for other blood-related cancers.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are 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 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 of CTI as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 has been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial position at such date and the operating results and cash flows for such periods. Operating results for the three months ended March 31, 2015 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 annual financial statements for the year ended December 31, 2014 included in our Annual Report on Form 10-K filed with the SEC on March 12, 2015.

The condensed consolidated balance sheet at December 31, 2014 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. In addition, CTI Commercial LLC, a wholly-owned subsidiary, was included in the consolidated financial statements until dissolution in March 2012.

As of March 31, 2015, we also had a 61% 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 consolidated financial statements.

All intercompany transactions and balances are eliminated in consolidation.

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 customers' country of origin to determine if an allowance is required. We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt crisis in certain European countries and associated impacts on the financial markets and our business. As of March 31, 2015 and December 31, 2014, our accounts receivable did not include any balance from a customer in a country that has exhibited financial stress that would have had a material impact on our financial results. Our allowance for doubtful accounts balance was $25,000 as of March 31, 2015 and $0.1 million as of December 31, 2014.

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 for the twelve-month period following the date of these condensed consolidated financial statements. However, we have incurred net losses since inception and expect to generate losses for the next few years primarily due to research and development costs for pacritinib, PIXUVRI, Opaxio, and tosedostat.

Our available cash and cash equivalents were $44.4 million as of March 31, 2015. We believe that our present financial resources, together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net sales of PIXUVRI, will only be sufficient to fund our operations into the mid-third quarter of 2015. 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, 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 any adjustments that may result from the outcome of this uncertainty.

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 is approximately $4.4 million and $4.9 million as of

March 31, 2015 and December 31, 2014, of which $4.2 million and $4.7 million is included in other assets and $0.2 million and $0.2 million is included in prepaid expenses and other current assets as of March 31, 2015 and December 31, 2014, respectively. 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 March 31, 2015, the VAT receivable related to operations in Italy is approximately $4.3 million. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

Inventory

We carry inventory at the lower of cost or market. 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 production and 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 our 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 unsaleable inventory, the value is written down to the net realizable value. Based on assessment of shelf lives and net realizable value of the product, $33,000 reserve for excess, obsolete or unsalesable inventory was recorded as of March 31, 2015.

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 through a limited number of distributors and directly to health care providers in Austria, Denmark, Finland, Germany, Norway, Sweden and the United Kingdom, or the U.K. 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.

Government-mandated discounts and rebates

Our products are subject to certain programs with government entities in the E.U. whereby pricing on products is discounted below distributor list price to participating health care providers. These discounts are provided to participating health care providers either at the time of sale or through a claim by the participating health care providers for a rebate. Due to estimates and assumptions inherent in determining the amount of government-mandated discounts and rebates, the actual amount of future claims may be different from our estimates, at which time we would adjust our reserves accordingly.

Product returns and other deductions

At the time of sale, we also record estimates for certain sales deductions such as product returns and distributor discounts and incentives. We offer certain customers a limited right of return or replacement of product that is damaged in certain instances. When we cannot reasonably estimate the amount of future product returns and/or other sales deductions, we do not recognize revenue until the risk of product return and additional sales deductions have been substantially eliminated.

Milestone payments

In February 2015, under our exclusive license and collaboration agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or the Servier Agreement, we received a €1.5 million milestone payment (or $1.7 million using the currency exchange rate as of the date we received the funds) relating to the attainment of reimbursement approval for PIXUVRI in Spain. We allocated the milestone payment based on the relative-selling-price percentages originally used to allocate the arrangement consideration under the Servier Agreement. This revenue was accounted for under the milestone method of accounting since this milestone was determined to be substantive at the inception of the arrangement. There were no such milestone payments received for the three months ended March 31, 2014.

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 any necessary allowances 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' equity (deficit), 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 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 consolidated statements of operations related to the recurring measurement and settlement of such transactions.

Using most recent information available to date, we have determined that the intercompany balance of €21.9 million due from CTILS may no longer be considered of a short-term nature. In accordance with this change in accounting estimate, unfavourable unrealized foreign exchange loss of $2.8 million was recorded in cumulative foreign currency translation adjustment account for the three months ended March 31, 2015.

Net Income (Loss) Per Share

Basic net income (loss) per share 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 any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted net income (loss) per common share 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.

Equity awards, warrants, and unvested share rights aggregating 14.5 million shares and 16.3 million shares for the three months ended March 31, 2015 and 2014, respectively, prior to the application of the treasury stock method, were excluded from the calculation of diluted EPS because they are anti-dilutive.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or 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 supersedes current revenue recognition guidance. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of this accounting standard on our 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 (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact of this accounting standard on our consolidated financial statements.

In April 2015, the FASB issued a new accounting standard which changes the presentation of debt issuance costs in financial statements. Under the new standard, an entity presents such costs in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Amortization of the costs is reported as interest expense. The

accounting standard is effective for annual reporting periods beginning after December 15, 2015 and interim periods beginning after December 15, 2016. Early adoption is allowed for all entities for financial statements that have not been previously issued. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

Reclassifications

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

2. Inventory

The components of inventories are composed of the following as of March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015	December 31, 2014
Finished goods	709	$ 850
Work-in-process	$2,882	3,332
Total inventories	$3,591	$ 4,182

3. Legal Proceedings

On December 10, 2009, the Commissione Nazionale per le Società e la Borsa (which is the public authority responsible for regulating the Italian securities markets), or CONSOB, sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial

statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations could require us to pay a pecuniary administrative sanction amounting to between $5,000 and $537,000 upon conversion from euros as of March 31, 2015. Until CONSOB's right is barred, CONSOB may, at any time, confirm the occurrence of the asserted violation and apply a pecuniary administrative sanction within the foregoing range. To date, we have not received any such notification.

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 outcomes of these cases. As of December 31, 2012, we reversed the entire reserve we had previously recorded relating to the VAT Assessments after having received favorable court rulings. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us. The current status of the legal proceedings surrounding each respective VAT year return at issue is as follows:

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 were notified that the ITA requested partial payment of the 2003 VAT assessment in the amount of €0.4 million translated to $0.6 million, which we paid in March 2014. We believe that the decision of the Regional Tax Court did not carefully take into account our arguments and the documentation we filed, and in January 2014, we appealed such decision to the Italian Supreme Court both on procedural grounds and on the merits of the case.

2005, 2006 and 2007. The ITA has appealed to the Italian Supreme Court the decisions of the respective appellate court with respect to each of the 2005, 2006 and 2007 VAT returns.

If the final decisions of the Italian Supreme Court for the VAT Assessments are unfavorable to us, we may incur up to $10.1 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of March 31, 2015.

In July 2014, Joseph Lopez and Gilbert Soper, shareholders of the Company, filed a derivative lawsuit purportedly on behalf of the Company, which is named a nominal defendant, against all current and one past member of the Company's Board of Directors in King County Superior Court in the State of Washington, docketed as Lopez & Gilbert v. Nudelman, et al ., Case No. 14-2-18941-9 SEA. The lawsuit alleges that the directors exceeded their authority under the Company's 2007 Equity Incentive Plan, or the Plan, by improperly transferring 4,756,137 shares of the Company's common stock from the Company to themselves. It alleges that the directors breached their fiduciary duties by granting themselves fully vested shares of Company common stock, which the plaintiffs allege were not among the six types of grants authorized by the Plan, and that the non-employee directors were unjustly enriched by these grants. The lawsuit also alleges that from 2011 through 2014, the non-employee members of the Board of Directors granted themselves grossly excessive compensation, and in doing so breached their fiduciary duties and

were unjustly enriched. Among other remedies, the lawsuit seeks a declaration that the specified grants of common stock violated the Plan, rescission of the granted shares, disgorgement of the compensation awards to the non-employee directors from 2011 through 2014, disgorgement of all compensation and other benefits received by the defendant directors in the course of their breaches of fiduciary duties, damages, an order for certain corporate reforms and plaintiffs' costs and attorneys' fees. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. In September 2014, the director defendants moved to dismiss the complaint. The motion to dismiss was heard on November 21, 2014, and the Court entered an order denying the motion to dismiss on December 5, 2014. Defendants' answer to the complaint was filed on January 13, 2015. The trial date is currently set for August 24, 2015. At this stage of the litigation, no probability of loss can be predicted.

4. Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three months ended March 31, 2015 and 2014, which was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2015	2014
Research and development	$990	$782
Selling, general and administrative	3,346	7,047
Total share-based compensation expense	$4,336	$7,829

For the three months ended March 31, 2015 and 2014, we incurred share-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended March 31,	
	2015	2014
Performance rights	$418	$503
Restricted stock	3,372	5,969
Options	546	1,357
Total share-based compensation expense	$4,336	$7,829

5. Other Comprehensive Income (Loss)

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

	Net Unrealized Loss on Securities Available-For-Sale	Foreign Currency Translation Adjustments	Unrealized foreign exchange loss on intercompany balance	Accumulated Other Comprehensive Loss
December 31, 2014	$ (490)	$ (6,009)	$ -	$ (6,499)
Current period other comprehensive income	5	2,247	(2,754)	(502)
March 31, 2015	$ (485)	$ (3,762)	$ (2,754)	$ (7,001)

6. Leases

Our deferred rent balance was $4.3 million as of March 31, 2015, of which $0.4 million was included in other current liabilities and $3.9 million was included in other liabilities. As of December 31, 2014, our deferred rent balance was $4.4 million, of which $0.4 million was included in other current liabilities and $4.0 million was included in other liabilities.

12

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, which include statements concerning sufficiency of cash resources and related projections, product sales, research and development expenses, selling, general and administrative expenses, additional financings and additional losses, 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, 2014, or the 2014 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 commercializing PIXUVRI in the E.U. for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial program evaluating pacritinib for the treatment of adult patients with myelofibrosis to support regulatory submission for approval in the U.S. and Europe. We are also evaluating pacritinib in early phase clinical trials as treatment for other blood-related cancers.

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 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 part of the conditional marketing authorization, we are required to conduct a post-authorization trial, or PIX306, which compares PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

PIXUVRI is currently available in Austria, Denmark, Finland, France, Germany, Israel, Italy, Netherlands, Norway, Sweden and the U.K., and has achieved reimbursement decisions under varying conditions in England/Wales, Italy, France, Germany the Netherlands and Spain. In almost all European markets, pricing and availability of prescription pharmaceuticals are subject to governmental control. Decisions by governmental authorities will impact the price and market acceptance of PIXUVRI. Accordingly, any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by the governmental authorities in each country where PIXUVRI is available for sale and other factors. 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.

We have established a commercial organization, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize PIXUVRI in certain countries in the E.U. In September 2014, we entered into an exclusive license and collaboration agreement, or the Servier Agreement, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively, Servier, with respect to the development and commercialization of PIXUVRI. Under the Servier Agreement, we retain full commercialization rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S., while Servier has exclusive rights to commercialize PIXUVRI in all other countries. For additional information on our collaboration with Servier, see Part I, Item 2, “License Agreements and Additional Milestone Activities – Servier.”

Pacritinib

Our lead development candidate, pacritinib, is an oral multikinase inhibitor with activity against Janus Kinase 2, or JAK2, and FMS-like tyrosine kinase, or FLT3, as well as other kinases, and is currently being evaluated in adult patients with myelofibrosis.

Myelofibrosis is a blood-related cancer caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response, scarring the bone marrow and limiting its ability to produce red blood cells prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue, itching and pain. We believe pacritinib may offer an advantage over other JAK inhibitors through effective treatment of symptoms while having less treatment-emergent thrombocytopenia and anemia than has been seen in the currently approved JAK inhibitor.

In collaboration with Baxter International Inc., or Baxter, pursuant to our worldwide license agreement to develop and commercialize pacritinib, or the Baxter Agreement, we are pursuing a broad approach to advancing pacritinib for adult patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial; and the other in patients with low platelet counts, the PERSIST-2 trial. In October 2013, we reached an agreement with the Food and Drug Administration, or the FDA, on a Special Protocol Assessment for PERSIST-2.

In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including but not limited to patients with disease-related thrombocytopenia, patients experiencing treatment-emergent thrombocytopenia on other JAK2 therapy or patients who are intolerant of, or whose symptoms are sub-optimally managed on, other JAK2 therapy. The FDA’s Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The PERSIST-1 and PERSIST-2 clinical trials are intended to support a potential regulatory submission to the FDA or EMA.

In March 2015, we reported top-line results for the primary endpoint from PERSIST-1 for the treatment of adult patients with myelofibrosis. The primary endpoint of the trial was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by magnetic resonance imaging, or MRI, or computerized tomography, or CT, when compared with physician-specified best available therapy, excluding treatment with JAK2 inhibitors. The trial met its primary endpoint in the intent-to-treat population with statistically significant activity observed in patients irrespective of their initial platelet count, including patients with very low platelet counts at study entry. A clinical abstract with further details on the trial results was accepted as a late-breaker to be presented at the American Society of Clinical Oncology Annual Meeting in June 2015.

Under the Baxter Agreement, we share joint commercialization rights to pacritinib with Baxter in the U.S., while Baxter has exclusive commercialization rights for all indications outside the U.S. For additional information relating to the Baxter Agreement, see Part I, Item 2, “License Agreements and Additional Milestone Activities—Baxter”.

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 acute myeloid leukemia, or 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 myelodysplastic syndrome, 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.

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 increased to $2.7 million for the three months ended March 31, 2015, compared to $1.4 million for the same period in 2014. We recorded $0.8 million and $1.3 million in total net product sales for the first quarter of 2015 and 2014, respectively. Our product sales may vary significantly from period to period due to foreign currency exchange rate fluctuations related to translation of sales denominated in the Euro as well as pricing and volume variances. Our loss from operations for the three months ended March 31, 2015 was $27.5 million, compared to a loss of $27.7 million for the same period in 2014. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

As of March 31, 2015, we had cash and cash equivalents of $44.4 million and the outstanding principal balance under our senior secured term loan agreement, which is discussed below, of $16.2 million.

RESULTS OF OPERATIONS

Three months ended March 31, 2015 and 2014

Product sales, net. Net product sales from PIXUVRI for the three months ended March 31, 2015 and 2014 were $0.8 million and $1.3 million, respectively. We sell PIXUVRI through a limited number of wholesale distributors and directly to health care providers in Austria, Denmark, Finland, Germany, Norway, Sweden and England. Servier is responsible for distribution of PIXUVRI

in the respective countries in its territory. 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.

Product sales are recorded net of distributor discounts, estimated government-mandated discounts and rebates, trade discounts and estimated product returns. The decrease in net product sales of $0.5 million for the three months ended March 31, 2015 compared to the same period in 2014 is primarily related to the decline in average exchange rate of the euro for our euro-denominated sales as well as pricing and volume variances between the periods presented. 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. Any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by governmental authorities in each country where PIXUVRI is available for sale and other factors.

Gross sales is defined as our contracted reimbursement price in each country. Gross sales from PIXUVRI for the three months ended March 31, 2015 and 2014 were $0.8 million and $1.3 million, respectively.

Product sales, net for the three months ended March 31, 2015 includes a provision for discounts, rebates and other of $8,000 for current period sales. There was no such provision recorded in the same period of 2014. The provision for discounts, rebates and other during the three months ended March 31, 2015 and 2014 primarily relates to distributor discounts on PIXUVRI product sold.

The provision for product returns relates to a limited right of return or replacement that we offer to certain customers. During the three months ended March 31, 2015, the provision of $1,000 was recorded for current period sales and the reversal adjustment for the same amount was recorded for prior period sales. Product sales, net for the same period of 2014 includes a provision for product returns of $3,000 for current period sales.

During the three months ended March 31, 2015, payments and credits of $8,000 were applied towards provision for discounts, rebates and other for current period sales and $6,000 for prior period sales. During the three months ended March 31, 2014, payments and credits of $69,000 were applied towards such provision for prior year sales only. All rebate payments made during the three months ended March 31, 2015 and 2014 relate to 2013 sales activity.

As of March 31, 2015, the balances of reserve for product returns of $10,000, and reserve for discounts, rebates and other of $30,000 are reflected in accounts receivable and accrued expenses, respectively. As of March 31, 2014, the balances were $42,000 and $0.1 million for product returns reserve and reserve for discounts, rebates and other, respectively.

Please refer to Part I, Item 1, Note 1, Description of Business and Summary of Significant Accounting Policies, in this Quarterly Report on Form 10-Q, which note is incorporated herein by reference, for further information.

License and contract revenue. License and contract revenue are as follows (in thousands):

		Three Months Ended March 31,	
		2015	2014
Baxter	Development services revenue	$188	$143
	Total Baxter	188	143
Servier	License revenue	1,622	—
	Development services revenue	106	—
	Royalty revenue	7	—
	Total Servier	1,735	—
Total license and contract revenue		$1,923	$143

Baxter

The license and contract revenue under the Baxter Agreement for the three months ended March 31, 2015 and 2014 includes $0.2 million and $0.1 million, respectively, of development services revenue recognized from the upfront payment we received in connection with the Baxter Agreement in 2013.

Servier

The license and contract revenue under the Servier Agreement for the three months ended March 31, 2015 includes $1.6 million of license revenue and $0.1 million of development services revenue. In February 2015, we received a €1.5 million milestone payment (or $1.7 million using the currency exchange rate as of the date we received the funds) relating to the attainment of reimbursement approval for PIXUVRI in Spain. We allocated the milestone payment in the table above based on the relative-selling-price percentages originally used to allocate the arrangement consideration under the Servier Agreement. There were no such milestone payments received for the three months ended March 31, 2014.

The following table illustrates the balances of deferred revenue under each of the Baxter Agreement and the Servier Agreement as of March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015	December 31, 2014
Current portion of deferred revenue		
Baxter	$677	$ 724
Servier	102	102
Total current portion of deferred revenue	779	826
Deferred revenue, less current portion		
Baxter	919	1,059
Servier	693	720
Total deferred revenue, less current portion	1,612	1,779

Total deferred revenue	$2,391	$ 2,605

Operating costs and expenses

Cost of product sold. Cost of product sold for the three months ended March 31, 2015 and 2014 was $0.2 million and $0.1 million, respectively, related to sales of PIXUVRI. This expense increased primarily due to the reserve of $33,000 recorded for expiring inventory, as well as inventory with a higher cost being sold during the three months ended March 31, 2015. We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional marketing authorization by The Committee for Medicinal Products for Human Use, or the CHMP, which is a committee of the EMA. 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. Most of this reduced-cost inventory is expected to be available for us to use commercially. 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 will increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold. At this time, we cannot reasonably estimate the timing or rate of consumption of reduced-cost PIXUVRI product manufactured and expensed prior to capitalization, and we are unable to provide our estimate of cost of goods sold as a percentage of product revenue once such inventory is exhausted.

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

	Three Months Ended March 31,	
	2015	2014
Compounds:		
PIXUVRI	$4,176	$1,201
Pacritinib	7,881	5,964
Opaxio	22	107
Tosedostat	33	160
Operating expenses	5,026	4,647
Research and preclinical development	333	100
Total research and development expenses	$17,471	$12,179

Costs for our compounds include external direct expenses such as principal investigator fees, clinical research organization, or CRO, charges and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of New Drug Applications, or NDAs, or similar regulatory filings to the FDA, the

16

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 licensed to and under development by Aequus. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us as of March 31, 2015 were $98.1 million for PIXUVRI (excluding costs prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, in January 2004), $54.7 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S*BIO Pte Ltd, or S*BIO, in May 2012 and $29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S*BIO), $227.3 million for Opaxio, $11.4 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). External direct costs incurred by us as of March 31, 2015 were $9.6 million for brostallicin. We did not expend material resources on brostallicin during the periods presented. Research and development expenses increased to $17.5 million for the quarter ended March 31, 2015 compared to $12.2 million for the quarter ended March 31, 2014. This $5.3 million increase was primarily due to increased costs incurred with our pacritinib development program and our post-authorization PIX306 trial for PIXUVRI. The increase in the pacritinib program is primarily due to clinical and non-clinical phase 1 studies to support an NDA filing, in addition to the achievement of full enrollment in PERSIST-1. The increase in PIXUVRI research and development expenses is primarily associated with our on-going PIX306 trial. The increase in operating expenses is primarily attributed to personnel costs and other expenses in support of our development programs.

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, tosedostat and Opaxio 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, tosedostat and Opaxio, 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. 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. 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, tosedostat or Opaxio to generate material net cash inflows. In order to generate revenue from these products, 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 of this Quarterly Report on Form 10-Q.

Selling, general and administrative expenses. Selling, general and administrative expenses were $12.3 million for the three months ended March 31, 2015 as compared to $16.8 million for the three months ended March 31, 2014. This decrease was primarily due to a $3.7 million decrease in non-cash share-based compensation and a $0.6 million decrease in a provision for tax assessments.

Other operating expense. Other operating expense of $0.3 million for the three months ended March 31, 2015 relates to the payment made to Novartis International Pharmaceutical Ltd., or Novartis, as a result of the milestone payment we received under the Servier Agreement relating to the attainment of reimbursement approval for PIXUVRI in Spain. We had no such amount for the three months ended March 31, 2014. Certain payments are required under the Novartis Termination Agreement (defined below). For additional information on our collaboration with Novartis, see Part I, Item 2, “License Agreements and Additional Milestone Activities – Novartis.”

Non-operating income and expenses

Interest expense. Interest expense for the three months ended March 31, 2015 and 2014 was $0.5 million, respectively. Interest expense is primarily related to our senior secured term loan.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs for the three months ended March 31, 2015 and 2014 was $0.2 million, respectively, and is related to our senior secured term loan.

Foreign exchange loss. The foreign exchange loss for the three months ended March 31, 2015 and 2014 is 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 for the three months ended March 31, 2014 was primarily related to the change in fair value of the warrant issued to Hercules Technology Growth Capital, Inc., or HTGC. We had no such amount for the three months ended March 31, 2015.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Cash and cash equivalents. As of March 31, 2015, we had $44.4 million in cash and cash equivalents.

Net cash used in operating activities. Net cash used in operating activities increased to $24.0 million during the three months ended March 31, 2015 as compared to $20.8 million for the same period in 2014. This increase is primarily

due to research and development activities incurred in connection with our pacritinib development program and our post-authorization PIX306 trial for PIXUVRI, as well as due to an increase in personnel-related and other expenditures to support our development programs.

Net cash used in investing activities. Net cash used in investing activities decreased to $24,000 for the three months ended March 31, 2015 compared to $35,000 for the same period in 2014 due to a decrease in purchases of property and equipment.

Net cash used in financing activities. Net cash used in financing activities increased to $3.0 million for the three months ended March 31, 2015 compared to $0.2 million for the same period in 2015 primarily due to the repayment of long-term debt during the period. There was no such repayment during the three months ended March 31, 2014.

As of March 31, 2015, we had an outstanding principal balance under our senior secured term loan agreement of $16.2 million. For a discussion of such loan agreement, including applicable interest rates, covenants and events of default, please see Part II, Item 8, Note 8 in our 2014 Form 10-K, which is incorporated herein by reference.

Capital Resources

We have prepared our 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 additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net sales of PIXUVRI, will only be sufficient to fund our operations into the mid-third quarter of 2015. 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 next few years primarily due to research and development costs for PIXUVRI, pacritinib, Opaxio and tosedostat. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of March 31, 2015, our available cash and cash equivalents were $44.4 million, and we had an outstanding principal balance under our senior secured term loan agreement of $16.2 million. We do not have any borrowing capacity under our senior secured loan agreement.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, clinical trial expenses 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, our 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, 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:

- changes in manufacturing;
- developments in and expenses associated with our clinical trials and other research and development activities;
- acquisitions of compounds or other assets;
- ability to generate sales of PIXUVRI and any expansion of our sales and marketing organization for PIXUVRI;

- regulatory approval developments;
- ability to consummate 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.

The following table includes information relating to our contractual obligations as of March 31, 2015 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases:					
Facilities	$17,887	$2,536	$4,913	$4,994	$5,444
Long-term debt	16,177	9,868	6,309	—	—
Interest on long-term debt(1)	1,549	1,311	238	—	—
Purchase commitments(2)	7,384	7,272	98	14	—
Other obligations(3)	1,277	—	1,277	—	—
	$44,274	$20,987	$12,835	$5,008	$5,444

(1) The interest rates on our senior secured term loan currently float at a rate per annum equal to 10% and 11.25% plus the amount by which the prime rate exceeds 3.25%. The amounts presented for interest payments in future periods assume a prime rate of 3.25%.

(2) Purchase commitments include obligations related to manufacturing supply, insurance and other purchase commitments.

(3) Other obligations include a fee in the amount of $1.3 million payable to HTGC on the date on which the senior secured term loan is paid or becomes due and payable in full. Other obligations do not include $4.3 million deferred rent associated with our operating lease for office space.

Certain of our licensing agreements obligate us to pay a royalty on net sales of products utilizing licensed compounds. Such royalties are dependent on future product sales and are not provided for in the table above as they are not estimable. For additional information, please see discussion below in Part I, Item II, “License Agreements and Additional Milestone Activities.”

In February 2015, we entered into a manufacturing and supply agreement with Baxter Oncology GmbH, which obligates us, commencing in 2018, to purchase from Baxter Oncology GmbH a certain percentage of all PIXUVRI products sold by CTI Life Sciences Limited or its sublicensees in certain territories. Such obligation is dependent on future product sales and is not provided for in the table above as it is not estimable as of March 31, 2015.

20

LICENSE AGREEMENTS AND ADDITIONAL MILESTONE ACTIVITIES

Servier

In September 2014, we entered into the Servier 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 the CTI Territory (defined below). We retained rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S., or collectively, the CTI Territory.

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 October 2014). In addition, subject to the achievement of certain conditions, we are eligible to receive milestone payments under the Servier Agreement in the aggregate amount of up to €89.0 million, which is comprised of the following: up to €49.0 million in potential clinical and regulatory milestone payments (of which €9.5 million is 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. Of the foregoing potential milestone payments, we received a €1.5 million milestone payment in February 2015 relating to the attainment of reimbursement approval for PIXUVRI in Spain. In addition, for a number of years following the first commercial sale of a product containing PIXUVRI in the respective country, regardless of patent expiration or expiration of regulatory exclusivity rights, we are eligible to receive tiered royalty payments ranging from a low double-digit percentage up to a percentage in the mid-twenties based on net sales of PIXUVRI products, subject to certain reductions of up to mid-double digit percentages under certain circumstances.

Unless otherwise agreed by the parties, (i) certain development costs incurred pursuant to a development plan and (ii) certain marketing costs incurred pursuant to a marketing plan will be shared equally by the parties, subject to a maximum dollar obligation of each party.

The Servier Agreement will expire on a country-by-country basis upon the expiration of the royalty terms in the countries outside of the CTI Territory, at which time all licenses granted to Servier would become perpetual and royalty-free. Each party may terminate the Servier Agreement in the event of an uncured repudiatory breach (as defined under English law) of the other party’s obligations. Servier may terminate the Servier Agreement without cause on a country-by-country basis upon written notice to us within a specified time period or upon written notice within a certain period of days in the event of (i) certain safety or public health issues involving PIXUVRI or (ii) cessation of certain marketing authorizations. In the event of a termination prior to the expiration date, rights granted to Servier will terminate, subject to certain exceptions.

Baxter

In November 2013, we entered into the Baxter Agreement for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. Under the Baxter Agreement, we granted Baxter an exclusive, worldwide (subject to co-promotion rights discussed below), royalty-bearing, non-transferable license (which is sub-licensable under certain circumstances) relating to pacritinib. Licensed products under the Baxter Agreement consist of products in which pacritinib is an ingredient.

Baxter paid us an upfront payment of $60 million, which included a $30 million investment in our equity. The Baxter Agreement also provides for us to receive potential additional payments of up to $302 million upon the successful achievement of certain development and commercialization milestones, comprised of $112 million of potential clinical, regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to $190 million. Of such potential milestone payments, we have received $20 million to date relating to the achievement of a clinical milestone. We and Baxter will jointly commercialize and share any profits and losses on sales of pacritinib in the U.S.

We were responsible for all development costs incurred prior to January 1, 2014, and are responsible for approximately $96 million in U.S. and E.U. development costs incurred thereafter, subject to potential adjustment in certain circumstances. All development costs exceeding the $96 million threshold will generally be shared as follows: (i) costs generally applicable worldwide will be shared 75 percent to Baxter and 25 percent to us, (ii) costs applicable to territories exclusive to Baxter will be 100 percent borne by Baxter and (iii) costs applicable exclusively to co-promotion in the U.S. will be shared equally between the parties, subject to certain exceptions.

Outside the U.S., we are eligible to receive tiered high single digit to mid-teen percentage royalty payments based on net sales for myelofibrosis, and higher double-digit royalties for other indications, subject to reduction by up to 50 percent if (i) Baxter is required to obtain third party royalty-bearing licenses to fulfill its obligations under the Baxter Agreement and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or patent protection.

The Baxter Agreement will expire when Baxter has no further obligation to pay royalties to us in any jurisdiction, at which time the licenses granted to Baxter will become perpetual and royalty-free. We or Baxter may terminate the Baxter Agreement prior to its expiration in certain circumstances. Following the one-year anniversary of receipt of regulatory approval in certain countries, we may terminate the Baxter Agreement as to one or more such countries if Baxter has not undertaken requisite regulatory or commercialization efforts in the applicable country and certain other conditions are met. Baxter may terminate the Baxter Agreement earlier than its expiration in certain circumstances including (i) in the event development costs for myelofibrosis for the period commencing January 1, 2014 are reasonably projected to exceed a specified threshold, (ii) as to some or all countries in the event of commercial failure of the licensed product or (iii) without cause following the one-year anniversary of the effective date of the Baxter Agreement, provided that such termination will have a lead-in period of six months before it becomes effective. Additionally, either party may terminate the Baxter Agreement prior to its expiration in events of force majeure, or the other party's uncured material breach or insolvency. In the event of a termination prior to the expiration date, rights in pacritinib will revert to us.

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 percent 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.

Chroma

In October 2014, we entered into an asset purchase agreement, or the Chroma APA, with Chroma, pursuant to which we acquired all of Chroma's right, title and interest in the compound tosedostat and certain related assets. Concurrently, we and Chroma terminated our Co-Development and License Agreement relating to tosedostat, or the Chroma License Agreement, previously entered into on March 11, 2011, thereby eliminating potential future milestone payments thereunder of up to $209.0 million, and we acquired an exclusive worldwide license with respect to tosedostat directly from Vernalis R&D Limited, or Vernalis.

As consideration under the Chroma APA, we issued an aggregate of 9,000 shares of the Company's Series 20 convertible preferred stock, of which 7,920 have been delivered to Chroma. The remaining 1,080 shares are being held in escrow for nine months and will be applied towards any indemnification obligations of Chroma as set forth in the Chroma APA.

Vernalis

Concurrently with the termination of the Chroma License Agreement and the execution of the Chroma APA, we also entered into an amended and restated exclusive license agreement with Vernalis, 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, as well as a deed of novation pursuant to which all rights of Chroma under its prior license agreement with Vernalis relating to tosedostat were novated to us. 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 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 $1.1 million in milestone payments during 2014 based on certain enrollment milestones achieved. We may be required to pay up to an additional $1.0 million upon the attainment of certain other milestones, of which $0.5 million has been recorded in accrued expenses as of March 31, 2015.

PG-TXL

In November 1998, we entered into an agreement with PG-TXL Company, L.P., or PG-TXL, as amended in February 2006, which grants us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL's polymer technology, or the PG-TXL Agreement. 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 are 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 is 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 are required to make royalty payments to PG-TXL based on net sales. Our royalty obligations range from low to mid-single digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are payable to PG-TXL. We may terminate the PG-TXL Agreement (i) upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL

Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans, or (ii) for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement (a) upon advance written notice in the event certain license fee payments are not made; (b) in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or (c) in the event of liquidation or bankruptcy of a party.

Novartis

In January 2014, we entered into a Termination Agreement, or the Novartis Termination Agreement, with Novartis to reacquire the rights to PIXUVRI and Opaxio previously granted to Novartis under our agreement with Novartis entered into in September 2006, as amended, or the Original Agreement. Pursuant to the Novartis Termination Agreement, the Original 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, respectively; 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 in annual net sales, and ten percent 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 or Opaxio to fall by a percentage in the high double-digits. To the

extent we are required to pay royalties on net sales of Opaxio pursuant to the PG-TXL Agreement, we may credit a percentage of the amount of such royalties paid to those payable to Novartis, subject to certain exceptions. Royalty payments for both PIXUVRI and Opaxio are subject to certain minimum floor percentages in the low single digits.

Nerviano Medical Sciences

Our license agreement dated October 6, 2006 with Nerviano Medical Sciences, S.r.l. for brostallicin, a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity, provides for the potential payment by us of up to $80 million in milestone payments based on the achievement of certain product development results. Due to the early stage of development of brostallicin, we cannot make a determination that the milestone payments are reasonably likely to occur at this time.

Teva

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon, pursuant to which we divested of 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 $20.0 million of such potential milestone payments as a result of having achieved certain sales milestones.

Other Agreements

We have several agreements with contract research organizations, third party manufacturers, and distributors which 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. There have been no material changes to our critical accounting estimates discussed in our 2014 Form 10-K. 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 2014 Form 10-K.

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 compared to the euro. In addition, certain of our contractual arrangements, such as the Servier Agreement, 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. 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. 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 March 31, 2015, 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 $1.6 million as of this date.

Interest Rate Risk

Our senior secured term loan bears interest at variable rates. Based on the outstanding principal balance under such loan at March 31, 2015 of $16.2 million, and assuming such amount had been outstanding as of April 1, 2015, a 1.0 percent increase in interest rates would result in additional annualized interest expense of $0.1 million. For a discussion of such loan, including applicable interest rates, covenants and events of default, please see Part II, Item 8, Note 8 in our 2014 Form 10-K, which is incorporated herein by reference.

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 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 Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, 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 Chief Executive Officer and EVP of Finance 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.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the first fiscal quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

On December 10, 2009, the CONSOB, sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations could require us to pay a pecuniary administrative sanction amounting to between $5,000 and $537,000 upon conversion from euros as of March 31, 2015. Until CONSOB's right is barred, CONSOB may, at any time, confirm the occurrence of the asserted violation and apply a pecuniary administrative sanction within the foregoing range. To date, we have not received any such notification.

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 outcomes of these cases. As of December 31, 2012, we reversed the entire reserve we had previously recorded relating to the VAT Assessments after having received favorable court rulings. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us. The current status of the legal proceedings surrounding each respective VAT year return at issue is as follows:

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 were notified that the ITA requested partial payment of the 2003 VAT assessment in the amount of €0.4 million

translated to $0.6 million which we paid in March 2014. We believe that the decision of the Regional Tax Court did not carefully take into account our arguments and the documentation we filed, and in January 2014, we appealed such decision to the Italian Supreme Court both on procedural grounds and on the merits of the case.

2005, 2006 and 2007. The ITA has appealed to the Italian Supreme Court the decisions of the respective appellate court with respect to each of the 2005, 2006 and 2007 VAT returns.

If the final decisions of the Italian Supreme Court for the VAT Assessments are unfavorable to us, we may incur up to $10.1 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of March 31, 2015.

In July 2014, Joseph Lopez and Gilbert Soper, shareholders of the Company, filed a derivative lawsuit purportedly on behalf of the Company, which is named a nominal defendant, against all current and one past member of the Company's Board of Directors in King County Superior Court in the State of Washington, docketed as Lopez & Gilbert v. Nudelman, et al ., Case No. 14-2-18941-9 SEA. The lawsuit alleges that the directors exceeded their authority under the Company's 2007 Equity Incentive Plan, or the Plan, by improperly transferring 4,756,137 shares of the Company's common stock from the Company to themselves. It alleges that the directors breached their fiduciary duties by granting themselves fully vested shares of Company common stock, which the plaintiffs allege were not among the six types of grants authorized by the Plan, and that the non-employee directors were unjustly enriched by

these grants. The lawsuit also alleges that from 2011 through 2014, the non-employee members of the Board of Directors granted themselves grossly excessive compensation, and in doing so breached their fiduciary duties and were unjustly enriched. Among other remedies, the lawsuit seeks a declaration that the specified grants of common stock violated the Plan, rescission of the granted shares, disgorgement of the compensation awards to the non-employee directors from 2011 through 2014, disgorgement of all compensation and other benefits received by the defendant directors in the course of their breaches of fiduciary duties, damages, an order for certain corporate reforms and plaintiffs' costs and attorneys' fees. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. In September 2014, the director defendants moved to dismiss the complaint. The motion to dismiss was heard on November 21, 2014, and the Court entered an order denying the motion to dismiss on December 5, 2014. Defendants' answer to the complaint was filed on January 13, 2015. The trial date is currently set for August 24, 2015. At this stage of the litigation, no probability of loss can be predicted.

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 $44.4 million as of March 31, 2015. We believe that our present financial resources, together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net sales of PIXUVRI, will only be sufficient to fund our operations into the mid-third quarter of 2015. Cash forecasts and capital requirements 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 other research and development activities, acquisitions of compounds or other assets, any expansion of our sales and marketing organization for PIXUVRI, regulatory approval developments, ability to consummate appropriate collaborations for development and commercialization activities, litigation and other disputes, competitive market developments and other unplanned business developments may consume capital resources earlier than planned. Additionally, we may not receive anticipated milestone payments or achieve projected net sales from PIXUVRI. Due

to these and other factors, our 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 March 31, 2015, we had an outstanding principal balance under our senior secured term loan agreement of $16.2 million, and we are required to make monthly interest plus principal payments in the aggregate amount of approximately $0.9 million through October 1, 2016. Such 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, under which we have no additional borrowing capacity, 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. For a discussion of such loan, including applicable interest rates, covenants and events of default, please see Part II, Item 8, Note 8 in our 2014 Form 10-K, which is incorporated herein by reference.

We will need to acquire additional funds in order 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:

- 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.

We received an audit report for the years ended December 31, 2007 through December 31, 2011 and December 31, 2014 containing an explanatory paragraph on our consolidated financial statements raising substantial doubt as to our ability to continue as a going concern.

We received an audit report for each of the years ended December 31, 2007 through December 31, 2011 and December 31, 2014 containing an explanatory paragraph on our consolidated financial statements raising substantial doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing. In the event our operations were to cease, you would suffer a complete loss of your investment in our securities.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of March 31, 2015, we had an accumulated deficit of $2.0 billion and we expect to continue to incur net losses. As a 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.

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 the applicable compound(s), 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 Servier Agreement and the Baxter Agreement, we rely heavily on Servier and Baxter, respectively, to collaborate with us to develop and commercialize PIXUVRI and pacritinib. As a result of our dependence on our relationships with Servier and Baxter, the success or commercial viability of PIXUVRI and pacritinib 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 and Baxter, 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; possible disagreements regarding ownership of proprietary rights; and the possibility that Servier or Baxter could elect to terminate their respective agreements with us pursuant to certain “at-will” termination clauses or otherwise breach their respective agreements with us. Furthermore, the contingent financial returns under our collaborations with Servier and Baxter depend 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 each of Servier and Baxter. If our existing collaborations fail, or if

we do not successfully enter into additional collaborations when needed, we may be unable to further develop and commercialize the applicable compounds, generate revenues to sustain or grow our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

Compounds that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once existing data are more fully evaluated.

Successful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process and obtaining manufacturing approval, pricing, 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, while we have reported top-line data for PERSIST-1 in this Quarterly Report on Form 10-Q and in our 2014 Form 10-K and may report additional top-line data for other trials from time to time, 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 is based on important assumptions, estimations, calculations and information then available to us to the extent we have, at the time of such reporting, had 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 observed to date may differ from future results, or different conclusions or considerations may qualify such results once existing

data has 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. Pacritinib and 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. The number 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;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- such regulatory agencies may not approve the manufacturing process of a compound and may interpret data from pre-clinical and clinical trials in different ways than we do;
- 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 quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

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 be uneconomical to produce;
- 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 and the future potential commercialization of pacritinib, we will be heavily dependent on our collaboration partners, Servier and Baxter, respectively. The failure of Servier or Baxter (or any other applicable collaboration partner) to fulfill its respective 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. 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 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 marketed product, PIXUVRI. As disclosed elsewhere herein, 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 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 good manufacturing practices, or GMPs, 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, or the MHRA, 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 study 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 November 2016 or 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 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, revocation of the applicable product’s approval or authorization, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditure to resolve shortcomings, which could negatively affect our business, financial condition, operating results or prospects.

We may be 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 percent 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 percent of the total shares of our common stock outstanding in order to fund our operations. However, we might not be successful in obtaining the required 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 Mercato Telematico Azionario in Italy, we are required to also comply with the rules and regulations of CONSOB and the Borsa Italiana, which regulate companies listed on Italy's public markets. Compliance with Italian regulatory requirements may delay additional issuances of our common stock or other business initiatives. Under Italian law, we must publish a registration document, securities note and summary (which jointly compose a prospectus) that have to be approved by CONSOB prior to issuing common stock that is equal to or exceeds, in any twelve-month period, 10 percent 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 to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. For example, we have issued convertible preferred stock in numerous prior offerings and may in the future issue convertible securities; the common stock resulting from the conversion of such securities, subject to current provisions of European Directive No. 71/2003 and according to the current interpretations of the Committee of European Securities Regulators, is not subject to the 10 percent limitation imposed by E.U. and Italian law. However, this exception to the prospectus requirement could change or cease to be available as a result of changes in regulations, interpretive positions, and policies or otherwise. Any such change may increase compliance costs or limit our ability to issue securities. 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. For more information on a current investigation, see Part II, Item 1, Legal Proceedings.

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, including common stock and preferred stock, 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. For example, in April 2007, we paid a civil penalty of $10.6 million and entered into a settlement agreement with the U.S. Attorney’s Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of the Inspector General, Health and Human Services, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct. 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 FCPA, the U.K. Bribery Act 2010, and other anti-corruption laws that 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.

If we are unable to hire, 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. 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 are dependent on third party service providers for a number of critical operational activities including, in particular, for clinical trial activities and for the manufacture, testing and distribution of our compounds and associated supply chain operations. 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 depend on medical institutions and CROs (together with their respective employees, subcontractors and other agents, as applicable) 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. In

addition, 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.

We also rely heavily on third parties for the manufacture, testing and distribution of our compounds and associated supply chain operations. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of drug products in compliance with GLPs and GMPs. As a result, we are reliant on third parties to supply us in a timely manner with manufactured products/product candidates. We depend on these third parties to conduct their operations in compliance with GLPs and GMPs or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of such regulatory authorities may take action against a contract manufacturer who violates GLPs and GMPs. 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 also rely on third party service providers for certain warehousing, transportation, sales, order processing and cash collection services. With regard to the distribution of our compounds, we depend on third party distributors to act in accordance with GDPs, and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

With respect to certain of the foregoing clinical trial operations and steps in the manufacturing and distribution chain of our compounds, we rely on single vendors. The use of single vendors for these core operational activities and the resulting lack of diversification expose us to the risk of an interruption in service related to these single, outside vendors. As a result, our exposure to this concentration risk could harm our business.

Although we periodically monitor the compliance of our third party service providers performing the aforementioned services, we cannot be certain that our present or future third parties will consistently comply with applicable regulatory requirements. The

failure of third parties on which we depend to properly and timely perform their obligations to us, including, but not limited to, those relating to the clinical trials, manufacturing, distribution and other core operational activities, could result in 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, 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. Such consequences could have a significant impact on our business, financial condition, operating results or prospects.

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, 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 ruxolitinib (Jakafi®).
- If we are successful in bringing tosedostat to market, tosedostat will face competition from currently marketed products, such as cytarabine, Dacogen®, Vidaza®, Clolar®, Revlimid® and Thalomid®.
- If we are successful in bringing Opaxio to market, we will face competition from other taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products such as paclitaxel and generic forms of paclitaxel, docetaxel, Tarceva®, Avastin ®, Alimta® and Abraxane ®.

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. We have also licensed the intellectual property for our drug delivery technology relating to Opaxio, which uses polymers that are linked to drugs known as polymer-drug conjugates. 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, tosedostat and Opaxio 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, Opaxio 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. The patent status of our compounds follows:

- 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. Certain of such European patents are also subject to Supplementary Protection Certificates that extend the life of the applicable patents such that they will instead expire from 2020 to 2027. In addition, we are seeking to obtain Supplementary Protection Certificates for certain other of our PIXUVRI-directed European patents that, if obtained, could provide extensions of the applicable patents through 2027. However, no assurances can be made that such extensions will be granted. Our PIXUVRI-directed U.S. patents expired in 2014, and although we have a pending PIXUVRI-directed U.S. patent application (which, if granted, would expire in 2023), we have to date been unable to obtain issuance of a patent for such application (and no assurances can be made that we will ever receive such patent). Our PIXUVRI-directed patents outside of Europe and the U.S. expire from 2015 to 2023.
- Our U.S. and various foreign pacritinib-directed patents expire from 2026 through 2029.
- Our U.S. and various foreign tosedostat-directed patents expire from 2017 to 2018.
- Our U.S. and various foreign Opaxio-directed patents expire on various dates ranging from 2017 through 2018.
- Our U.S. and various foreign brostallicin-directed patents expire on various dates ranging between 2017 through 2021.

In the absence of a patent, as in the case of PIXUVRI in the U.S., 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, which does 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 value added tax, or 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 $4.4 million and $4.9 million as of March 31, 2015 and December 31, 2014, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to our branch, Cell Therapeutics Inc.—Sede Secondaria, or 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 $10.1 million converted using the currency exchange rate as of March 31, 2015) 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 and our ability to procure or afford directors and officers liability insurance.

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 a number of pending legal matters. Litigation is subject to inherent uncertainties, and we have had and may in the future have unfavorable rulings and settlements. Adverse outcomes in some or all of such pending cases 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, and 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. We are subject to a variety of claims and lawsuits from time to time, some of which arise in the ordinary course of our business. The ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future.

Securities class action and shareholder derivative lawsuits are often instituted against issuers. We have been subjected to such actions and we, together with our directors and one former director, presently are subject to a derivative lawsuit.

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 we are liable. 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.

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 perceived risks, directors and management 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 certain 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 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.

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 Servier Agreement, 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 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. For example, paclitaxel, a material used to produce Opaxio, is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. 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 any preferred stock we may issue and to existing and any future indebtedness.

Shares of our common stock rank junior to any shares of our preferred stock that we may issue in the future and 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.

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.

We may not be able to maintain our listings on The NASDAQ Capital Market and the 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.

Maintaining the listing of our common stock on The NASDAQ Capital Market requires that we comply with certain listing requirements. We have in the past and may in the future fail to continue to meet one or more listing requirements. For example, in June 2012, we received a notification from The NASDAQ Stock Market indicating non-compliance with the requirement to maintain a minimum closing bid price of $1.00 per share and that we would be delisted if we did not timely regain compliance. In connection therewith, we regained compliance through a reverse stock split in September 2012, but we could fail to meet the continued listing requirements as a result of a decrease in our stock price or otherwise.

If our common stock ceases to be listed for trading on The NASDAQ Capital Market for any 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.

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended April 29, 2015, our stock price has ranged from a low of $1.77 to a high of $3.23. 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;
- 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;
- 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;
- halting or suspension of trading in our common stock on The NASDAQ Capital Market or on the MTA; 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 percent 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 percent 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.

40

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

Stock Repurchases in the First Quarter

The following table sets forth information with respect to purchases of our common stock during the three months ended March 31, 2015:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
January 1 - January 31, 2015	1,338	$ 2.29	—	—
February 1 - February 28, 2015	5,224	$ 2.20	—	—
March 1 - March 31, 2015	264,444	$ 1.94	—	—
Total	271,006	$ 1.95	—	—

(1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Location
2.1	Agreement and Plan of Merger by and between Cell Therapeutics, Inc. and Novuspharma, S.p.A., dated as of June 16, 2003.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on June 17, 2003.
2.2	Acquisition Agreement by and among Cell Therapeutics, Inc., Cell Technologies, Inc. and Cephalon, Inc., dated June 10, 2005.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 14, 2005.
2.3	Acquisition Agreement among Cell Therapeutics, Inc., Cactus Acquisition Corp., Saguaro Acquisition Company LLC, Systems Medicine, Inc. and Tom Hornaday and Lon Smith dated July 24, 2007.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2007.
2.4	Second Amendment to the Acquisition Agreement, dated as of August 6, 2009, by and among Cell Therapeutics, Inc. and each of Tom Hornaday and Lon Smith, in their capacities as Stockholder Representatives.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 7, 2009.
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	Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on June 2, 2014.
4.1	Shareholder Rights Agreement, dated December 28, 2009, between Cell Therapeutics, Inc. 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 Cell Therapeutics, Inc. 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 Cell Therapeutics, Inc. 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	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.

4.5	Form of Common Stock Purchase Warrant, dated July 27, 2010.	Incorporated by reference to Exhibit 4.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
4.6	Form of Common Stock Purchase Warrant, dated October 22, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
4.7	Form of Common Stock Purchase Warrant, dated May 3, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 2, 2011.
4.8	Form of Common Stock Purchase Warrant, dated July 5, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on July 6, 2011.
4.9	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.
4.10	Form of Warrant to Purchase Common Stock, dated May 29, 2012.	Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed on May 31, 2012.
4.11	Form of Warrant to Purchase Common Stock, dated July 30, 2012 (expiry date on May 27, 2015).	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.

Exhibit Number	Exhibit Description	Location
4.12	Warrant Agreement, dated March 26, 2013, by and between Cell Therapeutics, Inc. 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 March 28, 2013.
10.1†	Amendment No. 2 to Employment Agreement between the Registrant and James A. Bianco, dated as of January 6, 2015.	Incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, filed on March 12, 2015.
10.2†	Form of Severance Agreement for the Registrant's Executive Officers other than James A. Bianco (as in effect as of January 6, 2015).	Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, filed on March 12, 2015.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101. INS	XBRL Instance	Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101. CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101. DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101. LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101. PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

†Indicates a management contract or compensatory plan 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: May 6, 2015 By: /s/ James A. Bianco, M.D.
James A. Bianco, M.D.
President and Chief Executive Officer

Dated: May 6, 2015 By: /s/ Louis A. Bianco
Louis A. Bianco
Executive Vice President,
Finance and Administration