CTI BIOPHARMA CORP
Form 10-Q
October 31, 2014

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: September 30, 2014

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 October 24, 2014
Common Stock, no par value	150,091,946

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)

	September 30, 2014 (unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$29,910	$71,639
Accounts receivable	1,177	235
Other receivable	17,674	—
Inventory	4,542	5,074
Prepaid expenses and other current assets	2,635	3,567
Total current assets	55,938	80,515
Property and equipment, net	4,841	5,478
Other assets	7,815	7,730
Total assets	$68,594	$93,723
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$6,297	$5,051
Accrued expenses	15,350	9,469
Warrant liability	—	991
Current portion of deferred revenue	903	1,010
Current portion of long-term debt	5,865	3,155
Other current liabilities	396	393
Total current liabilities	28,811	20,069
Deferred revenue, less current portion	2,011	1,626
Long-term debt, less current portion	7,846	10,152
Other liabilities	5,989	5,657
Total liabilities	44,657	37,504
Commitments and contingencies		
Common stock purchase warrants	7,890	13,461
Shareholders' equity:		
Common stock, no par value:		
Authorized shares - 215,000,000		
Issued and outstanding shares - 150,135,446 and 145,508,767	1,957,696	1,933,305

at September 30, 2014 and December 31, 2013, respectively		
Accumulated other comprehensive loss	(7,216)	(8,429)
Accumulated deficit	(1,931,501)	(1,879,703)
Total CTI shareholders' equity	18,979	45,173
Noncontrolling interest	(2,932)	(2,415)
Total shareholders' equity	16,047	42,758
Total liabilities and shareholders' equity	$68,594	$93,723

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product sales, net	$2,021	$362	$4,437	$1,794
License and contract revenue	37,513	—	37,851	—
Total revenues	39,534	362	42,288	1,794
Operating costs and expenses:				
Cost of product sold	252	13	599	104
Research and development	16,528	7,245	42,725	23,620
Selling, general and administrative	12,563	8,529	43,104	29,774
Settlement expense	—	60	—	155
Other operating expense	2,719	—	2,719	—
Total operating costs and expenses	32,062	15,847	89,147	53,653
Income (loss) from operations	7,472	(15,485)	(46,859)	(51,859)
Non-operating income (expense):				
Interest expense	(472)	(316)	(1,403)	(680)
Amortization of debt discount and issuance costs	(185)	(162)	(547)	(349)
Foreign exchange gain (loss)	(2,455)	547	(2,621)	(199)
Other non-operating expense	—	(268)	(885)	(433)
Total non-operating expense, net	(3,112)	(199)	(5,456)	(1,661)
Net income (loss) before noncontrolling interest	4,360	(15,684)	(52,315)	(53,520)
Noncontrolling interest	243	140	517	581
Net income (loss) attributable to CTI	$4,603	$(15,544)	$(51,798)	$(52,939)
Deemed dividends on preferred stock	—	(6,900)	—	(6,900)
Net income (loss) attributable to CTI common shareholders	$4,603	$(22,444)	$(51,798)	$(59,839)
Net income (loss) per common share:				
Basic	$0.03	$(0.20)	$(0.36)	$(0.55)
Diluted	$0.03	$(0.20)	$(0.36)	$(0.55)
Shares used in calculation of earnings (loss) per common share:				
Basic	145,138	110,996	143,920	108,489
Diluted	147,097	110,996	143,920	108,489

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net income (loss) before noncontrolling interest	$4,360	$(15,684)	$(52,315)	$(53,520)
Other comprehensive income (loss):				
Foreign currency translation adjustments	1,214	(291)	1,261	196
Net unrealized gain (loss) on securities available-for-sale:	10	(28)	(48)	(195)
Other comprehensive income (loss)	1,224	(319)	1,213	1
Comprehensive income (loss)	5,584	(16,003)	(51,102)	(53,519)
Comprehensive loss attributable to noncontrolling interest	243	140	517	581
Comprehensive income (loss) attributable to CTI	$5,827	$(15,863)	$(50,585)	$(52,938)

CTI BIOPHARMA CORP.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2014	2013
Operating activities		
Net loss	$(52,315)	$(53,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	17,022	6,324
Depreciation and amortization	875	1,207
Noncash interest expense	547	349
Change in value of warrant liability	886	187
Other	317	145
Changes in operating assets and liabilities:		
Accounts receivable	(1,033)	(525)
Other receivable	(17,674)	—
Inventory	115	(1,995)
Prepaid expenses and other current assets	851	5,749
Other assets	(753)	(857)
Accounts payable	1,384	(763)
Accrued expenses	6,106	(2,468)
Deferred revenue	278	—
Other liabilities	(5)	(26)
Total adjustments	8,916	7,327
Net cash used in operating activities	(43,399)	(46,193)
Investing activities		
Purchases of property and equipment	(258)	(1,373)
Proceeds from sales of property and equipment	—	123
Net cash used in investing activities	(258)	(1,250)
Financing activities		
Issuance of long-term debt, net	(73)	9,501
Proceeds from issuance of Series 18 preferred stock, net of issuance costs	—	15,000
Other	(106)	(326)
Net cash provided by (used in) financing activities	(179)	24,175
Effect of exchange rate changes on cash and cash equivalents	2,107	8
Net decrease in cash and cash equivalents	(41,729)	(23,260)
Cash and cash equivalents at beginning of period	71,639	50,436
Cash and cash equivalents at end of period	$29,910	$27,176

Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$1,383	$618
Supplemental disclosure of noncash financing and investing activities		
Conversion of Series 18 preferred stock to common stock	$—	$14,859
Issuance of common stock upon exercise of common stock purchase warrants	$1,877	$—

CTI BIOPHARMA CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Description of Business and Summary of Significant Accounting Policies

CTI BioPharma Corp., also referred to 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 healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are primarily focused on commercializing PIXUVRI® (pixantrone), or PIXUVRI, in the European Union, or the E.U., for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, and conducting a Phase 3 clinical trial program of pacritinib for the treatment of patients with myelofibrosis to support regulatory submission for approval in the United States, or the U.S., and Europe.

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 in the E.U. and comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain and may take many years and may involve expenditure of substantial resources.

Basis of Presentation

The accompanying unaudited financial information of CTI as of September 30, 2014 and for the three and nine months ended September 30, 2014 and 2013 has been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial position at such date and the operating results and cash flows for such periods. Operating results for the three and nine months ended September 30, 2014 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 disclosure 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, 2013 included in our Annual Report on Form 10-K filed with the SEC on March 4, 2014.

The condensed consolidated balance sheet at December 31, 2013 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, Cell Therapeutics Inc. – 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 September 30, 2014, 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 September 30, 2014 and December 31, 2013, 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. We did not record an allowance for doubtful accounts as of September 30, 2014 and December 31, 2013.

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, tosedostat and brostallicin.

Our available cash and cash equivalents were $29.9 million as of September 30, 2014. Subsequent to period end, we borrowed $5.0 million in additional outstanding principal under our senior secured term loan agreement, and we received an upfront payment 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 connection with our exclusive license and collaboration agreement with Servier. See Note 4, Long-term Debt, and Note 9, Collaborations, for additional information. We believe that our present financial resources (including the $17.8 million we received in October 2014 under the Servier Agreement), together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net contribution from commercial operations in connection with PIXUVRI, will only be sufficient to fund our operations into the 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 and are currently exploring alternative sources of financing. We may seek to raise such capital through public or private equity financings, partnerships, 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, 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 $5.3 million and $5.7 million as of September 30, 2014 and December 31, 2013, of which $5.1 million and $5.6 million is included in other assets and $0.2 million and $0.1 million is included in prepaid expenses and other current assets as of September 30, 2014 and December 31, 2013, 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 September 30, 2014, the VAT receivable related to operations in Italy is approximately $5.1 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 regularly review our inventories 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.

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

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. To date, there have been no PIXUVRI product returns.

Collaboration agreements

We evaluate collaboration agreements to determine whether the multiple elements and associated deliverables can be considered separate units of accounting in accordance with ASC 605-25 Revenue Recognition – Multiple-Element Arrangements. If it is determined that the deliverables under the collaboration agreement are a single unit of accounting, all amounts received or due, including any upfront payments, are recognized as revenue over the performance obligation periods of each agreement. Following the completion of the performance obligation period, such amounts will be recognized as revenue when collectability is reasonably assured.

The assessment of multiple element arrangements requires judgment in order to determine the allocation of revenue to each deliverable and the appropriate point in time, or period of time, that revenue should be recognized. In order to account for these agreements, we identify deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on whether certain criteria are met, including whether the delivered element has standalone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

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

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable development and regulatory milestones that are expected to be achieved as a result of our efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met.

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. We did not record an allowance for excess inventory as of September 30, 2014 and 2013.

Net 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.

Fair Value Measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 – Observable inputs, such as unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities, or other inputs that are observable directly or indirectly.

Level 3 – Unobservable inputs that are supported by little or no market activity, requiring an entity to develop its own assumptions.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Concentrations of Credit Risk

Financial instruments which potentially subject us to concentrations of credit risk consist of accounts receivable. We have accounts receivable from the sale of PIXUVRI from a small number of distributors and health care providers. Further, we do not require collateral on amounts due from our distributors and are therefore subject to credit risk. We have not experienced any significant credit losses to date as a result of credit risk concentration and do not consider an allowance for doubtful accounts to be necessary.

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.

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.

Recently Adopted Accounting Standards

In March 2013, the FASB issued guidance to clarify when to release cumulative foreign currency translation adjustments when an entity ceases to have a controlling financial interest in a subsidiary or group of assets within a foreign entity. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013 and should be applied prospectively to derecognition events occurring after the effective date, with early adoption permitted. The adoption of this guidance did not have an impact on our consolidated financial statements.

In July 2013, the FASB issued guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss or tax carryforward exists. The FASB concluded that an unrecognized tax benefit should be presented as a reduction of a deferred tax asset except in certain circumstances the unrecognized tax benefit should be presented as a liability and should not be combined with deferred tax assets. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. The adoption of this guidance did not have an impact on our consolidated financial statements.

Reclassifications

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

2. Earnings (Loss) Per Share

The numerator for both basic and diluted earnings (loss) per share, or EPS, is net income (loss). The denominator for basic EPS (referred to as basic shares) is the weighted-average number of common shares outstanding during the period, whereas the denominator for diluted EPS (referred to as diluted shares) also takes into account the dilutive effect of outstanding stock options and restricted stock awards using the treasury stock method. Basic and diluted shares as of the three and nine months ended September 30, 2014 are as follows (in thousands):

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Basic shares	145,138	110,996	143,920	108,489
Effect of dilutive securities	1,959	—	—	—
Diluted shares	147,097	110,996	143,920	108,489

The effect of dilutive securities included unexercised stock options and unvested restricted stock. The computation of diluted EPS excluded equity awards, warrants and unvested share rights aggregating 9.4 million shares for the three months ended September 30, 2014, as their inclusion would have been anti-dilutive. Equity awards, warrants, and unvested share rights aggregating 12.6 million shares, 15.1 million shares and 11.3 million shares for the three months ended September 30, 2013 and the nine months ended September 30, 2014 and 2013, respectively, prior to the application of the treasury stock method, are excluded from the calculation of diluted EPS because they are anti-dilutive.

3. Inventory

The components of PIXUVRI inventory consisted of the following as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014	December 31, 2013
Finished goods	$ 885	$ 601
Work-in-process	3,657	4,473
Total inventories	$ 4,542	$ 5,074

4. Long-term Debt

In March 2014, we entered into a First Amendment, or the Amendment, to Loan and Security Agreement, or the Original Loan Agreement (and as amended by the Amendment, the Loan Agreement) with Hercules Capital Funding Trust 2012-1, or Hercules, which was assigned from the original lender, Hercules Technology Growth Capital, Inc. The Amendment modified certain terms applicable to the loan balance then-outstanding of $15.0 million, or the Original Loan, as described below and provided us with the option to borrow an additional $5.0 million, or the 2014 Term Loan, through October 31, 2014, subject to certain conditions. We exercised such option and received the funds in October 2014. In connection with the Amendment, we paid a facility charge of $72,500 of which $35,000 was refunded to us in October 2014 pursuant to the terms of the Amendment.

Pursuant to the Amendment, the interest-only period of the Original Loan has been extended by six months such that the 24 equal monthly installments of principal and interest (mortgage style) will now commence on November 1, 2014 (rather than May 1, 2014). In addition, the interest rate on the Original Loan (which is currently 12.25% plus the amount by which the prime rate exceeds 3.25%) will, upon Hercules' receipt of evidence of the achievement of positive Phase 3 data in connection with our PERSIST-1

clinical trial for pacritinib, be reduced to 11.25% plus the amount by which the prime rate exceeds 3.25%. The modified terms were not considered substantially different pursuant to ASC 470-50, Modification and Extinguishment.

The interest on the 2014 Term Loan floats at a rate per annum equal to 10.00% plus the amount by which the prime rate exceeds 3.25%. The 2014 Term Loan is repayable in 24 equal monthly installments of principal and interest (mortgage style) commencing on November 1, 2014.

Subject to certain exceptions, all loan obligations under the Loan Agreement are secured by a first priority security interest on substantially all of our personal property (excluding our intellectual property).

As of December 31, 2013, the fair value of the warrant issued in connection with the consummation of the Original Loan Agreement in March 2013 was $1.0 million and was classified as a liability since it did not meet the considerations necessary for equity classification. The warrant was categorized as Level 2 in the fair value hierarchy as the significant inputs used in determining fair value were considered observable market data. In January 2014, all of the warrant was exercised into 0.5 million shares of common stock via cashless exercise.

As of September 30, 2014 and December 31, 2013, unamortized debt discount was $1.3 million and $1.7 million, unamortized issuance costs were $0.2 million and $0.3 million, respectively.

5. 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 $6,000 and $631,000 upon conversion from euros as of September 30, 2014. 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. 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 €430,118, 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 Supreme Court both on procedural grounds and on the merits of the case.

2005, 2006 and 2007. The ITA has appealed to the 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 Supreme Court for the VAT Assessments are unfavorable to us, we may incur up to $11.9 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of September 30, 2014.

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 is scheduled to be heard on November 21, 2014. At this stage of the litigation, no probability of loss can be predicted.

6. Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three and nine months ended September 30, 2014 and 2013, which was allocated as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Research and development	$801	$685	$2,617	$1,540
Selling, general and administrative	3,036	1,243	14,405	4,784
Total share-based compensation expense	$3,837	$1,928	$17,022	$6,324

For the three and nine months ended September 30, 2014 and 2013, we incurred share-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Performance rights	$427	$280	$1,121	$885
Restricted stock	2,864	1,394	12,512	4,845
Options	546	254	3,389	594
Total share-based compensation expense	$3,837	$1,928	$17,022	$6,324

7. Other Comprehensive Income (Loss)

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

	Net Unrealized	Foreign Currency	Accumulated Other

	Loss on Securities Available-For-Sale	Translation Adjustments	Comprehensive Loss
December 31, 2013	$ (422)	$ (8,007)	$ (8,429)
Current period other comprehensive income (loss)	(48)	1,261	1,213
September 30, 2014	$ (470)	$ (6,746)	$ (7,216)

8. Leases

Our deferred rent balance was $4.5 million as of September 30, 2014, of which $0.4 million was included in other current liabilities and $4.1 million was included in other liabilities. As of December 31, 2013, our deferred rent balance was $4.8 million, of which $0.4 million was included in other current liabilities and $4.4 million was included in other liabilities.

9. Collaborations

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. Under the Servier Agreement, we granted Servier an exclusive and sublicensable (subject to certain conditions) royalty-bearing license with respect to the development and commercialization of PIXUVRI for use in pharmaceutical products outside of the CTI Territory (defined below). We retained rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the United Kingdom and the U.S., or collectively, the CTI Territory.

In October 2014, we received a non-refundable, non-creditable cash upfront payment of €14.0 million (or $17.7 million using the currency exchange rate as of September 30, 2014, which is recorded as Other receivable in the balance sheet as of September 30, 2014). In addition, subject to the achievement of certain conditions, we are eligible to receive milestone payments under the Servier

Agreement in the approximate 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 ongoing confirmatory Phase 3 clinical trial for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. All of these milestones were determined to be substantive at the inception of the arrangement. 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 products containing PIXUVRI, subject to certain reductions of up to mid-double digit percentages under certain circumstances. As previously disclosed, we owe royalties on net sales of products containing PIXUVRI as well as other payments to certain third parties, including the €2.1 million payment (or $2.7 million using the currency exchange rate as of September 30, 2014) due to Novartis International Pharmaceutical Ltd., which is recorded in Accrued expenses as of September 30, 2014.

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, in each case, be shared equally by the parties, subject to a maximum dollar obligation of each party. We record reimbursements received from Servier as revenue and record the full amount of costs as operating expenses in the statements of operations.

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.

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

·a license with respect to the development and commercialization of PIXUVRI in certain countries; and
·development services under the development plans.
We have determined that our regulatory, commercial, and manufacturing and supply responsibilities, as well as our joint committee obligations also have standalone value but are insignificant.

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

We allocated the arrangement consideration of $18.1 million (€14.0 million converted into U.S. dollar using the currency exchange rate as of September 16, 2014, the date of the Servier Agreement) based on the percentage of the relative selling price of each unit of accounting as follows (in thousands):

License	$17,277
Development and other services	852
Total upfront payment	$18,129

We estimated the selling price of the license using the income approach that values the license by discounting direct cash flow expected to be generated over the remaining life of the license, net of cash flow adjustments related to working capital. The estimates and assumptions include, but are not limited to, estimated market opportunity, expected market share, and contractual royalty rates. We estimated the selling price of the development services deliverable, which includes personnel costs as well as third party costs for applicable services and supplies, by discounting estimated expenditures for services to the date of the Servier Agreement. We concluded that a change in the key assumptions used to determine the best estimate of selling price for the license deliverable would not have a significant effect on the allocation of the arrangement consideration.

During the three and nine months ended September 30, 2014, we recognized $17.3 million of the arrangement consideration allocated to the license as revenue since the delivery of the license occurred upon the execution of the Servier Agreement in September 2014 and the remaining revenue recognition criteria were satisfied. The amount allocated to the development and other services is expected to be recognized as revenue through approximately 2022 on a straight-line basis. During the three and nine

months ended September 30, 2014, $4,000 of development services was recognized as revenue, and the remaining $0.8 million was recorded as deferred revenue in the balance sheet as of September 30, 2014.

10. Subsequent Event

In October 2014, we entered into an Asset Purchase Agreement, or the Chroma APA, with Chroma Therapeutics Limited, or 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 discussed below). Pursuant to the Chroma License Agreement, we had held an exclusive license with respect to tosedostat, including the right to develop and commercialize tosedostat in North, Central and South America. The Chroma License Agreement was effectively a sublicense of rights to us, as Chroma had held its rights to tosedostat pursuant to an exclusive license agreement between Vernalis and Chroma, or the Vernalis/Chroma Agreement.

As consideration under the Chroma APA, we issued an aggregate of 9,000 shares of our Series 20 preferred stock convertible into shares of common stock, or the Series 20 Preferred Stock, of which 7,920 shares 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.

Concurrently with the termination of the Chroma License Agreement and the consummation of the Chroma APA, we also entered into an amended and restated 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 the Vernalis/Chroma Agreement 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.

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 2013 Annual Report on Form 10-K, or the 2013 Form 10-K, particularly in "Factors Affecting Our Operating Results and Financial Condition," 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 healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are primarily focused on 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 of pacritinib for the treatment of patients with myelofibrosis to support regulatory submission for approval in the United States, or the U.S., and Europe.

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. In connection with the conditional marketing authorization, we are conducting the required post-approval commitment trial, which compares pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL. As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, France, Germany, Israel, Italy, Netherlands, Norway, Sweden and the United Kingdom, or the U.K., and has achieved reimbursement decisions under varying conditions in England/Wales, Italy, France, Germany and the Netherlands. 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. PIXUVRI is not approved in the U.S.

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, to develop and commercialize 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., with Servier having exclusive rights to commercialize PIXUVRI in all other countries. In October 2014, we received an upfront payment

from Servier of €14.0 million (or $17.8 million using the currency exchange rate as of the date we received the funds in October 2014), and as a result of having received such payment, we were obligated to pay Novartis International Pharmaceutical Ltd., or Novartis, €2.1 million (or $2.7 million using the currency exchange rate as of the date of payment in October 2014) under the terms of the Novartis Termination Agreement. We also have the potential to receive milestone payments under the Servier Agreement 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 ongoing confirmatory Phase 3 clinical trial for PIXUVRI); and up to €40.0 million in sales-based milestone payments. We are also 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 products containing PIXUVRI (subject to reduction in certain instances). We also agreed to share certain development expenses and certain marketing costs equally with Servier. For additional information on our collaboration with Servier, please see the discussion in Part I, Item 2, License Agreements and Additional Milestone Activities – Servier.

Pacritinib

Our lead development candidate, pacritinib, is an oral tyrosine kinase inhibitor with dual activity against Janus Kinase 2, or JAK2, and FMS-like tyrosine kinase (also known as FLT3), which demonstrated meaningful clinical benefit and good tolerability in myelofibrosis patients in Phase 2 clinical trials. 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 relief of symptoms with less treatment-emergent thrombocytopenia and anemia.

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 patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, or PERSIST-1, and the other in patients with low platelet counts, or PERSIST-2. PERSIST-1 enrollment has completed and top-line results are expected in the first quarter of 2015. In October 2013, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment for PERSIST-2, which is actively enrolling patients. The two clinical trials are intended to support a New Drug Application, or NDA, planned regulatory submission in the U.S. in late 2015, followed by a planned Marketing Authorization Application submission in Europe in 2016. 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.

In August 2014, we received a $20 million development milestone payment under the Baxter Agreement following completion of enrollment in PERSIST-1. For additional information on our collaboration with Baxter, please see the discussion in Part I, Item 2, License Agreements and Additional Milestone Activities – Baxter.

We are also currently evaluating pacritinib in acute myeloid leukemia, or AML, through an ongoing investigator-sponsored trial, or IST, and intend to evaluate it in other blood cancers in the future.

Tosedostat

Tosedostat is a novel oral aminopeptidase inhibitor that has demonstrated significant responses in patients with AML. It is currently being evaluated in several Phase 2 cooperative group-sponsored trials and ISTs. 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 the appropriate design for a Phase 3 trial.

In October 2014, we acquired worldwide rights with respect to tosedostat through concurrent transactions with Vernalis R&D Limited, or Vernalis, and Chroma Therapeutics Limited, or Chroma. Prior to these transactions, we previously held a limited sublicense with respect to tosedostat in North, Central and South America. As a result of these transactions, we terminated such sublicense agreement with Chroma and entered into a direct license agreement with Vernalis, the originator of tosedostat, pursuant to which we acquired exclusive worldwide rights with respect to tosedostat. For further information on these transactions, including a discussion of the equity consideration we paid to Chroma and our future royalty obligations to Vernalis, see the discussion under the headings “Chroma” and “Vernalis” in Part I, Item 2, License Agreements and Additional Milestone Activities.

Paclitaxel Poliglumex (Opaxio)

Opaxio is a novel biologically-enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. Development of Opaxio is currently being conducted through cooperative group trials and ISTs focusing on certain solid tumors. Opaxio is being evaluated in a Phase 3 trial, GOG-0212, as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This trial is being conducted and managed by the Gynecologic Oncology Group, or the GOG, which is one of the National Cancer Institute's funded cooperative cancer research groups focused on the study of gynecologic malignancies. The first interim analysis was conducted in January 2013, which passed the futility boundary and continued with no changes. In January 2014, we were informed by the GOG that enrollment in the trial had been completed with 1,150 patients enrolled.

Financial summary

Our product sales are currently generated solely from the sales of PIXUVRI in Europe. We recorded $2.0 million in total net product sales for the three months ended September 30, 2014. Our product sales may vary significantly from period to period as the commercialization and reimbursement negotiations for PIXUVRI progress. Total revenues were $39.5 million for the three months

ended September 30, 2014 compared to $0.4 million for the same period in 2013. Total revenues for the nine months ended September 30, 2014 included $37.9 million in license and contract revenue comprised of a $20.0 million development milestone earned and received under the Baxter Agreement following completion of enrollment in PERSIST-1, the recognition of $0.6 million of the upfront payment under the Baxter Agreement and the recognition of $17.3 million of the upfront payment under the Servier Agreement. Our income from operations for the three months ended September 30, 2014 was $7.5 million, compared to a loss of $15.5 million for the same period in 2013. 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 September 30, 2014, we had cash and cash equivalents of $29.9 million. For accounting purposes, due to the timing of the consummation of the Servier Agreement, we recognized license and contract revenue from the upfront licensing fee in the third quarter of 2014, while the associated payment of $17.8 million subsequently received in October 2014 will be reflected in the year-end cash balance.

As of September 30, 2014, we had an outstanding principal balance under our senior secured term loan agreement of $15.0 million, and on October 28, 2014, we borrowed an additional $5.0 million. Consequently, we have a presently outstanding balance under our senior secured term loan agreement of $20.0 million. Such agreement contains customary events of default (subject, in certain instances, to specified grace periods) including, but not limited to, the failure to make payments of interest or premium, if any, on, or principal under, the agreement, the failure to comply with certain covenants and agreements, the occurrence of a material adverse effect, defaults in respect of certain other indebtedness and certain events of insolvency. If any event of default occurs, the principal, premium, if any, interest and any other monetary obligations on all the then-outstanding amounts may become due and payable immediately. For further information relating to our senior secured term loan agreement, including the recently funded $5.0 million, please refer to Note 4, Long-term Debt, under Part I, Item 1 in this Quarterly Report on Form 10-Q, which note is incorporated herein by reference.

RESULTS OF OPERATIONS

Three months ended September 30, 2014 and 2013

Product sales, net. Net product sales from PIXUVRI for the three months ended September 30, 2014 and 2013 were $2.0 million and $0.4 million, respectively. We sell PIXUVRI directly to health care providers and through a limited number of wholesale distributors in the E.U. Of our product sales during the three months ended September 30, 2014, forty-seven percent were made to a single customer. All sales of PIXUVRI during the periods presented were made in Europe. 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. 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.

As of September 30, 2014, the balance from activity in returns, discounts and rebates is reflected in accounts receivable and accrued expenses. Balances and activity for the components of our gross to net sales adjustments for the three months ended September 30, 2014 and 2013 are as follows (in thousands) where gross sales is defined as our contracted reimbursement price in each country:

	Product returns	Discounts, rebates and other	Total
Balance at June 30, 2014	$ 77	$ 101	$178
Provision for current period sales	—	32	32
Adjustments to provision for prior period sales	—	—	—
Payments/credits for current period sales	—	(32)	(32)
Payments/credits for prior period sales	—	(11)	(11)
Balance at September 30, 2014	$ 77	$ 90	$167

	Product returns	Discounts, rebates and other	Total
Balance at June 30, 2013	$ 37	$ 142	$179
Provision for current period sales	1	50	51
Adjustments to provision for prior period sales	—	5	5
Payments/credits for current period sales	—	(45)	(45)
Payments/credits for prior period sales	—	—	—
Balance at September 30, 2013	$ 38	$ 152	$190

Provision for product returns relates to a limited right of return or replacement that we offer to certain customers. To date, there have been no PIXUVRI product returns.

Provision for discounts and rebates decreased $11,000 during the three months ended September 30, 2014 as compared to an increase of $10,000 during the three months ended September 30, 2013 due to a decline in rebates and discounts offered on products sold. Provision for discounts, rebates and other during the three months ended September 30, 2014 and 2013 primarily relates to distributor discounts and government-mandated rebates on PIXUVRI product sold. All rebate payments made during the three months ended September 30, 2014 relate to 2013 sales activity.

Please refer to Note 1, Description of Business and Summary of Significant Accounting Policies, under Part I, Item 1 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 was $37.5 million for the three months ended September 30, 2014. We had no such revenue during the three months ended September 30, 2013. The following table illustrates the components of license and contract revenue (in thousands):

		Three Months Ended September 30, 2014
Baxter	License revenue	$ 18,183
	Development services revenue	2,049
	Total Baxter	20,232
Servier	License revenue	17,277
	Development services revenue	4
	Total Servier	17,281
Total license and contract revenue		$ 37,513

In August 2014, we received a $20 million milestone payment from Baxter in connection with the first treatment dosing of the last patient enrolled in PERSIST-1. Of the $20 million milestone payment, $18.2 million was allocated to license revenue and $1.8 million was allocated to development services revenue in the table above based on the relative-selling-price percentages originally used to allocate the arrangement consideration under the Baxter Agreement.

In connection with the execution of the Baxter Agreement in 2013, we allocated and recorded $2.7 million of the upfront payment we received under the Baxter Agreement to deferred revenue. For the Baxter Agreement, we recognize revenue based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred. The development services under the Baxter Agreement are expected to be performed through approximately 2018, with the majority of development services expected to be completed by approximately the end of 2015. During the three months ended September 30, 2014, approximately $0.2 million was recognized as revenue and included in development services revenue in the table above. We had no such revenue during the three months ended September 30, 2013.

In addition, in connection with the execution of the Servier Agreement in September 2014, we allocated and recorded $17.3 million and $0.8 million from the upfront payment we received under the Servier Agreement to license revenue and deferred revenue, respectively. For deferred revenue under the Servier Agreement, we recognize revenue based on a straight-line method through approximately 2022. During the three months ended September 30, 2014, $4,000 was recognized as revenue and included in development services revenue in the table above. We had no such revenue during the three months ended September 30, 2013.

The following table illustrates such balances of deferred revenue under each of the Baxter Agreement and the Servier Agreement as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014	December 31, 2013
Current portion of deferred revenue		
Baxter	$ 800	$ 1,010
Servier	103	—
Total current portion of deferred revenue	903	1,010
Deferred revenue, less current portion		
Baxter	1,266	1,626

Servier	745	—
Total deferred revenue, less current portion	2,011	1,626
Total deferred revenue	$ 2,914	$ 2,636

Operating costs and expenses

Cost of product sold. Cost of product sold is related to sales of PIXUVRI. This expense increased to $252,000 for the three months ended September 30, 2014 as compared to $13,000 for the three months ended September 30, 2013, primarily due to an increase in sales activity. 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 European Medicines Agency, or the EMA. The manufacturing costs of PIXUVRI product prior to receipt of the CHMP's positive opinion was expensed as research and development as incurred. While we tracked the quantities of individual PIXUVRI product lots, we did not track manufacturing costs in our inventory system 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 revenue 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 for the three months ended September 30, 2014 and 2013 were as follows (in thousands):

	Three Months Ended September 30,	
	2014	2013
Compounds:		
PIXUVRI	$1,761	$1,038
Pacritinib	9,444	2,148
Opaxio	29	(147)
Tosedostat	123	287
Brostallicin	1	(5)
Operating expenses	4,908	3,833
Research and preclinical development	262	91
Total research and development expenses	$16,528	$7,245

Costs for our compounds include external direct expenses such as principal investigator fees, clinical research organization charges and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, the EMA or other regulatory agencies outside the U.S. and Europe, as well as upfront license fees for acquired technology. Subsequent to receiving a positive opinion for conditional marketing authorization 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 other compounds. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us as of September 30, 2014 were $90.6 million for PIXUVRI (excluding costs prior to our merger with Novuspharma S.p.A in January 2004), $35.3 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 such acquisition), $227.2 million for Opaxio, $11.2 million for tosedostat (excluding costs for tosedostat prior to the effectiveness of our now terminated sublicense arrangement with Chroma (see License Agreements and Additional Milestone Activities – Chroma below)) and $9.6 million for brostallicin (excluding costs for brostallicin prior to our acquisition of Systems Medicine, LLC in July 2007).

Research and development expenses increased to $16.5 million for the quarter ended September 30, 2014 compared to $7.2 million for the quarter ended September 30, 2013. This $9.3 million increase was primarily due to development costs for the pacritinib program, which includes the initiation of clinical and non-clinical studies in support of the planned U.S. regulatory submission, an increase in start-up costs for PERSIST-2 and an increase in manufacturing activity. The increase in operating expenses is primarily due to additional non-cash share-based compensation and discretionary bonus expense between the periods. The increase in PIXUVRI research and development expenses is primarily associated with European medical affairs activities.

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 drug 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-approval commitment study. 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-approval commitment study 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 are also unable to control the amount and timing of resources any of our collaborators devote to product candidates, where applicable, which may 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 begin on page 33 of this Quarterly Report on Form 10-Q and, in particular, in the following risk factors: “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.”, “Product candidates 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.”; “We or our collaboration partners may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our compounds.”; “Even if our drug candidates are successful in clinical trials and receive regulatory approvals, we or our collaboration partners may not be able to successfully commercialize them.”; and “Post-approval 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-approval commitment trial for PIXUVRI, could negatively affect our business, financial condition, operating results or prospects.”

Selling, general and administrative expenses. Selling, general and administrative expenses were $12.6 million for the three months ended September 30, 2014 as compared to $8.5 million for the three months ended September 30, 2013. This increase was due in part to a $1.8 million increase in non-cash share-based compensation. The remaining increase includes operating expenses supporting our marketing and sales program for PIXUVRI, pre-commercial activity for pacritinib and other administrative and legal expenses associated with the Baxter Agreement and the Servier Agreement.

Other operating expense. Other operating expense for the three months ended September 30, 2014 relates to the payment owed to Novartis as a result of the upfront payment we received under the Servier Agreement. We had no such amount for the three months ended September 30, 2013. Certain payments are required under the Novartis Termination Agreement. See Part I, Item I2, License Agreements and Additional Milestone Activities - Novartis for further details.

Non-operating income and expenses

Interest expense. Interest expense is related to the portions of our senior secured term loan issued in March 2013 and December 2013. This expense increased to $0.5 million for the three months ended September 30, 2014 as compared to $0.3 million for the three months ended September 30, 2013 primarily due to the additional $5.0 million senior secured term loan that was issued in December 2013.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs for the three months ended September 30, 2014 and 2013 is related to the amortization of debt discount and issuance costs incurred on our senior secured term loan originally issued in 2013.

Foreign exchange gain (loss). The foreign exchange loss for the three months ended September 30, 2014 and foreign exchange gain for the three months ended September 30, 2013 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

Other non-operating expense. Other expense for the three months ended September 30, 2013 is primarily related to the change in fair value of the warrant issued in connection with the original issuance of our senior secured term loan in

March 2013 and loss on disposal of property and equipment. There was no significant activity for the comparable period in 2014.

Nine months ended September 30, 2014 and 2013

Product sales, net. Net product sales from PIXUVRI for the nine months ended September 30, 2014 and 2013 were $4.4 million and $1.8 million, respectively.

As of September 30, 2014, the balance from activity in discounts, returns and rebates is reflected in accounts receivable and accrued expenses. Balances and activity for the components of our gross to net sales adjustments for the nine months ended September 30, 2014 and 2013 are as follows (in thousands) where gross sales is defined as our contracted reimbursement price in each country:

	Product returns	Discounts, rebates and other	Total
Balance at December 31, 2013	$ 39	$ 177	$216
Provision for current period sales	38	60	98
Adjustments to provision for prior period sales	—	—	—
Payments/credits for current period sales	—	(60)	(60)
Payments/credits for prior period sales	—	(87)	(87)
Balance at September 30, 2014	$ 77	$ 90	$167

	Product returns	Discounts, rebates and other	Total
Balance at December 31, 2012	$ —	$ —	$—
Provision for current period sales	38	122	160
Adjustments to provision for prior period sales	—	119	119
Payments/credits for current period sales	—	(89)	(89)
Payments/credits for prior period sales	—	—	—
Balance at September 30, 2013	$ 38	$ 152	$190

Provision for product returns relates to a limited right of return or replacement that we offer to certain customers. To date, there have been no PIXUVRI product returns.

Provision for discounts and rebates decreased $87,000 during the nine months ended September 30, 2014 as compared to an increase of $152,000 during the nine months ended September 30, 2013. The decrease in the nine months ended September 30, 2014 is due to the reduction of rebate and discount programs offered on products sold. Provision for discounts, rebates and other during the nine months ended September 30, 2014 and 2013 primarily relates to distributor discounts and government-mandated rebates on PIXUVRI product sold. All rebate payments made during the nine months ended September 30, 2014 relate to 2013 sales activity.

Please refer to Note 1, Description of Business and Summary of Significant Accounting Policies, under Part I, Item 1 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 was $37.9 million for the nine months ended September 30, 2014. We had no such revenue during the nine months ended September 30, 2013. The following table illustrates the components of license and contract revenue (in thousands):

		Nine Months Ended September 30, 2014
Baxter	License revenue	$ 18,183
	Development services revenue	2,387
	Total Baxter	20,570
Servier	License revenue	17,277
	Development services revenue	4
	Total Servier	17,281
Total license and contract revenue		$ 37,851

In August 2014, we received a $20 million milestone payment from Baxter in connection with the first treatment dosing of the last patient enrolled in PERSIST-1. Of the $20 million milestone payment, $18.2 million was allocated to license revenue and $1.8 million was allocated to development services revenue in the table above based on the relative-selling-price percentages originally used to allocate the arrangement consideration under the Baxter Agreement.

In connection with the execution of the Baxter Agreement in 2013, we allocated and recorded $2.7 million of the upfront payment we received under the Baxter Agreement to deferred revenue. For the Baxter Agreement, we recognize revenue based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred. The development services under the Baxter Agreement are expected to be performed through approximately 2018, with the majority of development services expected to be completed by approximately the end of 2015. During the nine months ended September 30, 2014, $0.6 million was recognized as revenue and included in development services revenue in the table above. We had no such revenue during the nine months ended September 30, 2013.

In addition, in connection with the execution of the Servier Agreement in September 2014, we allocated and recorded $17.3 million and $0.8 million of the upfront payment we received under the Servier Agreement to license revenue and deferred revenue, respectively. For deferred revenue under the Servier Agreement, we recognize revenue based on a straight-line method through approximately 2022. During the nine months ended September 30, 2014, $4,000 was recognized as revenue and included in development services revenue in the table above. We had no such revenue during the nine months ended September 30, 2013.

Operating costs and expenses

Cost of product sold. Cost of product sold for the nine months ended September 30, 2014 and 2013 was $599,000 and $104,000 for the sales of PIXUVRI, respectively. We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional marketing authorization by the CHMP. The

manufacturing costs of PIXUVRI product prior to receipt of the CHMP's positive opinion was expensed as research and development as incurred. While we tracked the quantities of individual PIXUVRI product lots, we did not track manufacturing costs in our inventory system 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 revenue 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 our compounds are as follows (in thousands):

	Nine Months Ended September 30,	
	2014	2013
Compounds:		
PIXUVRI	$4,340	$3,566
Pacritinib	22,580	5,998
Opaxio	270	835
Tosedostat	408	893
Brostallicin	3	41
Operating expenses	14,449	12,029
Research and preclinical development	675	258
Total research and development expenses	$42,725	$23,620

Research and development expenses increased to approximately $42.7 million for the nine months ended September 30, 2014 from approximately $23.6 million for the nine months ended September 30, 2013. This $19.1 million increase was primarily due to development costs for the pacritinib program, which includes the initiation of clinical and non-clinical studies in support of the planned U.S. regulatory submission, completion of patient enrollment in PERSIST-1, start-up costs for PERSIST-2 and an increase in manufacturing activity. The increase in operating expenses is primarily due to additional non-cash share-based compensation, an increase in discretionary bonus, consulting and other professional services. The increase in PIXUVRI research and development expense is primarily associated with European medical affairs activities. The offsets to these increases were primarily attributable to a decrease in Opaxio development costs resulting from a reduction in manufacturing costs, as well as a decrease in tosedostat development costs primarily attributable to a reduction in clinical and manufacturing costs.

Selling, general and administrative expenses. Selling, general and administrative expenses were $43.1 million for the nine months ended September 30, 2014 compared to $29.8 million for the nine months ended September 30, 2013. This increase was primarily related to a $9.6 million increase in non-cash share-based compensation. The remaining increase includes operating expenses supporting our marketing and sales program for PIXUVRI, pre-commercial activity for pacritinib, a $0.6 million provision for value added tax, or VAT, assessments related to our E.U. operations and other administrative and legal expenses associated with the Baxter Agreement and the Servier Agreement.

Other operating expense. The amount for the nine months ended September 30, 2014 relates to the payment owed to Novartis as a result of the upfront payment we received under the Servier Agreement. We had no such amount for the nine months ended September 30, 2013. Certain payments are required under the termination agreement with Novartis. See Part I, Item 2, License Agreements and Additional Milestone Activities - Novartis for further details.

Non-operating income and expenses

Interest expense. Interest expense is related to the portions of our senior secured term loan issued in March 2013 and December 2013. This expense increased to $1.4 million for the nine months ended September 30, 2014 as compared to $0.7 million for the nine months ended September 30, 2013 primarily due to the additional $5.0 million senior secured term loan that was issued in December 2013.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs for the nine months ended September 30, 2014 and 2013 is related to the amortization of debt discount and issuance costs incurred on our senior secured term loan originally issued in 2013.

Foreign exchange gain (loss). The foreign exchange losses for the nine months ended September 30, 2014 and 2013 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

Other non-operating expense. The expense amount for the nine months ended September 30, 2014 is primarily related to the change in fair value of the warrant issued in connection with the issuance of our senior secured term loan in March 2013. The expense amount for the nine months ended September 30, 2013 is primarily related to the change in fair value of the warrant issued in connection with the original issuance of our senior secured term loan in March 2013 and a loss on disposal of property and equipment.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Cash and cash equivalents. As of September 30, 2014, we had $29.9 million in cash and cash equivalents.

Net cash used in operating activities. Net cash used in operating activities decreased to $43.4 million during the nine months ended September 30, 2014 as compared to $46.2 million for the same period in 2013. This decrease is primarily due to a $20 million milestone payment received from Baxter in the third quarter of 2014, which was primarily offset by an increase in research and development activities related to pacritinib in 2014 and an increase in interest paid on our long term debt.

Net cash used in investing activities. Net cash used in investing activities decreased to $0.3 million for the nine months ended September 30, 2014 compared to $1.3 million for the same period in 2013 due to a decrease in purchases of property and equipment.

Net cash provided by (used in) financing activities. Net cash used in financing activities was $0.2 million for the nine months ended September 30, 2014. Net cash provided by financing activities of $24.2 million for the nine months ended September 30, 2013 was primarily due to the issuance of long-term debt during the period and proceeds received from the issuance of our Series 18 Preferred Stock, net of issuance costs.

As of September 30, 2014, we had an outstanding principal balance under our senior secured term loan agreement of $15.0 million, and in October 2014, we borrowed an additional $5.0 million. Consequently, we have a presently outstanding balance under our senior secured term loan agreement of $20.0 million. For additional information on this loan, please refer to Note 4, Long-term Debt, under Part I, Item 1 in this Quarterly Report on Form 10-Q.

Capital Resources and Requirements

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 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, tosedostat and brostallicin. As of September 30, 2014, our available cash and cash equivalents were $29.9 million. In October 2014, we received an upfront payment of $17.8 million in connection with the Servier Agreement.

As of September 30, 2014, we had an outstanding principal balance under our senior secured term loan agreement of $15.0 million, and in October 2014, we exercised our option to borrow an additional $5.0 million. Consequently, we have a presently outstanding principal balance under our senior secured term loan agreement of $20.0 million.

We believe that our present financial resources (including the $17.8 million we received in October 2014 under the Servier Agreement), together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net contribution from commercial operations in connection with PIXUVRI, will only be sufficient to fund our operations into the 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 and are currently exploring alternative sources of financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we may not have sufficient authorized shares.

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

- changes in manufacturing;
- results of, and other developments with respect to, our clinical trials (including changes in clinical trial expenses);
- acquisitions of compounds or other assets;
- any expansion of our sales and marketing organization in Europe;
- regulatory approval developments;
- failure to receive projected milestone payments under our contractual agreements;
- failure to achieve projected sales of PIXUVRI; and
- other unplanned business developments.

These and other factors may consume resources earlier than planned, and as a result, our forecast for the period for which we will have sufficient resources to fund our business may fail.

If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. 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 may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection, which could harm our business, financial condition, operating results and prospects.

The following table includes information relating to our contractual obligations as of September 30, 2014 (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	$18,668	$2,632	$4,628	$4,814	$6,594
Long-term debt	15,000	6,417	8,583	—	—
Interest on long-term debt(1)	2,172	1,537	635	—	—
Purchase commitments(2)	5,720	5,677	43	—	—
Other obligations(3)	1,276	—	1,276	—	—
	$42,836	$16,263	$15,165	$4,814	$6,594

(1) The interest rate on our long-term debt currently floats at a rate per annum equal to 12.25% 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 $1.275 million payable to Hercules Capital Funding Trust 2012-1 on the date on which the senior secured term loan is paid or becomes due and payable in full. Other obligations do not include $4.5 million deferred rent associated with our operating lease for office space.

Some of our licensing agreements obligate us to pay a royalty on net sales of products utilizing licensed technology. 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 “License Agreements and Additional Milestone Activities.”

27

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 United Kingdom and the United States, 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 development and regulatory milestone payments (of which €9.5 million is payable upon occurrence of certain enrollment events in connection with the ongoing confirmatory Phase 3 clinical trial for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. 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 products containing PIXUVRI, 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, in each case, 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 milestones, we have received $20 million to date relating to the achievement of a clinical milestone. We and Baxter will jointly commercialize and share 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. 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 additional third party licenses, on which it is obligated to pay royalties, 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 there is no longer any obligation for Baxter 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 Australia, Canada, China, France, Germany, Italy, Japan, Spain, the U.K. or the U.S., we may terminate the Baxter Agreement as to one or more particular 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 license, with the right to sublicense, 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, 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 Terminated Chroma License Agreement, previously entered into on March 11, 2011, thereby eliminating potential future developmental and sales milestone payments thereunder of up to $209.0 million, and we acquired an exclusive worldwide license with respect to tosedostat directly from Vernalis. Pursuant to the Terminated Chroma License Agreement, we had held an exclusive license with respect to tosedostat, including the right to develop and commercialize tosedostat in North, Central and South America. The Terminated Chroma License Agreement was effectively a sublicense of rights to us, as Chroma had held its rights to tosedostat pursuant to an exclusive license agreement between Vernalis and Chroma, or the Vernalis/Chroma Agreement. The Chroma APA contains various

representations and warranties, covenants, indemnification obligations and other provisions.

As consideration under the Chroma APA, we issued an aggregate of 9,000 shares of the Company's Series 20 convertible preferred stock, or the Series 20 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 Terminated Chroma License Agreement and the consummation of the Chroma APA, we also entered into an amended and restated 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 the Vernalis/Chroma Agreement 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. The Vernalis License Agreement contains various representations and warranties, covenants, indemnification obligations and other provisions.

Gynecologic Oncology Group

We entered into an agreement with the GOG in March 2004, as amended, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, which the GOG is conducting. We recorded a $0.9 million obligation due to the GOG based on the 1,100 patient enrollment milestone achieved in the third quarter of 2013 which was subsequently paid in the first half of 2014. In the first quarter of 2014, we also recorded a $0.3 million obligation to the GOG as required under the agreement based on the additional 50 patients enrolled, with such amount being paid in April 2014. 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 September 30, 2014.

PG-TXL

In November 1998, we entered into an agreement, or the PG-TXL Agreement, with PG-TXL Company, L.P., or PG-TXL, as amended, which grants us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL's polymer technology. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we 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 payments 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 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 for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement upon advance written notice in the event certain license fee payments are not made; in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or in the event of liquidation or bankruptcy of the other 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, or collectively, the Compounds, previously granted to Novartis under our License and Co-Development 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 the Compounds 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. Pursuant to the foregoing contractual provision, as a result of having received the upfront payment under the Servier Agreement, we were obligated to pay Novartis €2.1 million (or $2.7 million using the currency exchange rate as of the date of payment in October 2014). Novartis is entitled to receive potential payments of up to $16.6 million upon the successful achievement of certain sales milestones of the Compounds. 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 Compound, 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. Notwithstanding the foregoing, 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.

Cephalon

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. In November 2013, we received a $5.0 million payment related to achievement of a sales milestone.

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 2013 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 2013 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. Changes in the value of the U.S. dollar as compared to 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. In addition, the reported carrying value of our euro denominated 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. Furthermore, 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. As of September 30, 2014, we had a net asset balance, excluding intercompany payables and receivables, in our European branches and subsidiaries denominated in euros. For example, if the euro were to weaken 20 percent against the dollar, our net asset balance would decrease by approximately $1.9 million as of this date.

Interest Rate Risk

As of September 30, 2014, we had an outstanding balance under our senior secured term loan of $15.0 million, and we have a presently outstanding balance of $20.0 million. The senior secured term loan bears interest at variable rates. Based on the presently outstanding balance, a 1.0 percent increase in interest rates would result in additional annualized interest expense of $0.2 million. For a detailed discussion of our senior secured term loan, including a discussion of the applicable interest rate, please refer to Note 4, Long-term Debt, under Part I, Item 1 in this Quarterly Report on Form 10-Q.

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 the rules and forms of the U.S. Securities and Exchange Commission, or the SEC, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our President and Chief Executive Officer and 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 President and 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 third fiscal quarter ended September 30, 2014 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 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 sanction established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violation could require us to pay a pecuniary administrative sanction amounting to between $6,000 and $631,000 upon conversion from euros as of September 30, 2014. 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.

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007. 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. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case, although we can make no assurances regarding the ultimate outcome of these cases. If the final decision of the Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to €9.4 million, or approximately $11.9 million converted using the currency exchange rate as of September 30, 2014, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. Following is a summary of the status of the legal proceedings surrounding each respective VAT year return at issue:

2003 VAT. In September 2011, the Provincial Tax Court issued decision no. 229/3/2011, which (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us and (iii) found the ITA liable to pay us €10,000, as partial refund of the legal expenses we incurred for our appeal. In October 2012, the ITA appealed this decision. In June 2013, the Regional Tax Court issued decision no. 119/50/13, which accepted the appeal of the ITA and reversed the previous decision of the Provincial Tax Court. In January 2014, we appealed such decision to the Supreme Court both on procedural grounds and on the merits of the case. In March 2014, we paid a deposit in respect

of the 2003 VAT matter of €0.4 million, or approximately $0.5 million upon conversion from euros as of the date of payment following the ITA's request for such payment.

2005 VAT. In January 2011, the Provincial Tax Court issued decision No. 4/2010 which (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the ITA to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. Both the ITA and CTI appealed to the higher court against the decision. In October 2012, the Regional Tax Court issued a decision no. 127/31/2012, which (i) fully accepted the merits of our appeal and (ii) confirmed that no penalties can be imposed against us. On April 15, 2013, the ITA appealed the decision to the Italian Supreme Court.

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

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

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 is scheduled to be heard on November 21, 2014.

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 following 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, operating results and prospects and the market price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, operating results and prospects and the market price of our securities.

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

We 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 product candidates and the commercialization of PIXUVRI, and we have significant contractual payment obligations. Our available cash and cash equivalents were $29.9 million as of September 30, 2014. We believe that our present financial resources (including the $17.8 million we received in October 2014 under the Servier Agreement), together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs

and expected net contribution from commercial operations in connection with PIXUVRI, will only be sufficient to fund our operations into the 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, clinical trial expenses, acquisitions of compounds or other assets, any expansion of our sales and marketing organization for PIXUVRI, regulatory approval developments and other unplanned business developments may consume capital resources earlier than planned. Additionally, we may not receive projected milestone payments under the applicable contractual agreements or 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.

We have $20.0 million outstanding under our senior secured term loan agreement. Based on the current outstanding balance, on the first of each month going forward through October 1, 2016, we will be required to make monthly interest plus principal payments in the aggregate amount of approximately $0.9 million. The senior secured term loan agreement also requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required loan payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

We need to acquire additional funds in order to operate our business. We may seek to raise such capital through equity or debt financings, partnerships, collaborations, joint ventures, disposition of assets or other sources, but our ability to do so is subject to a number of risks, uncertainties 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 securities or convertible securities will dilute the proportionate ownership of existing shareholders;
- our ability to raise debt capital is limited by our existing senior secured term loan agreement;
- some of such arrangements may require us to relinquish rights to certain assets; 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 and/or refrain from making our contractually required payments when due, which could harm our business, financial condition, operating results and prospects.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of September 30, 2014, we had an accumulated deficit of $1.9 billion. We are pursuing certain regulatory approvals for PIXUVRI, pacritinib, tosedostat and Opaxio. We will need to continue to conduct research, development, testing and regulatory compliance activities and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, may 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 commercial 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: 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 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, after providing requisite notice, elect to terminate their respective agreements with us pursuant to “at-will” termination clauses. Furthermore, the contingent financial returns under our collaborations with Servier and Baxter depend in large part on the achievement of development and commercialization milestones, plus a share of revenues from any sales. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large in part on the performance of each of Servier and Baxter. If we fail to maintain our existing collaborations, or if we do not successfully enter into additional collaborations when needed in the future, we may be unable to further develop and commercialize our compounds, generate revenues to grow, sustain our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

Product candidates 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.

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. Product candidates 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 product candidate, 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 product candidate compared to alternative treatments;
- obstacles resulting from proprietary rights held by others with respect to a product candidate, 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, a collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons; or
- failure of third parties, such as contract research organizations, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials and results.

If the development of our product candidates is delayed or fails, our development costs may increase and the ability to commercialize our product candidates 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 (and we are not currently pursuing FDA marketing approval of PIXUVRI). Information about the regulatory status of our compounds can be found in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations and is incorporated by reference herein. 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 drug candidate, the disease or condition that the drug candidate is designed to address and the regulations applicable to any particular drug candidate. 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 drug candidate for many reasons, including, but not limited to:

- a drug candidate 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;
- they may not approve the manufacturing process of a drug candidate;
- they may interpret data from pre-clinical and clinical trials in different ways than we do;
- a drug candidate may fail to comply with regulatory requirements; or
- they might change their approval policies or adopt new regulations.

Any delay or failure by us or, where applicable, a collaboration partner, to obtain regulatory approvals of our products could adversely affect the marketing of our products. If our products 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.

35

Even if our drug candidates 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 amount approvals or pricing that is cost effective for patients as compared to other available forms of treatment;
- they may not compete effectively with existing or future alternatives to our products;
- we may be unable to sell marketing rights or develop commercial operations;
- they may fail to achieve market acceptance; or
- we may be precluded from commercialization of our products 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 product, 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 healthcare 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 (HR 3590) instituted comprehensive health care reform commencing in 2010 and 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 healthcare 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 on our ability and that of our collaborator, Servier, to successfully commercialize our only marketed product, PIXUVRI. PIXUVRI is not approved for marketing in the U.S. and is presently available only in those countries identified in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations. For a discussion of the reimbursement status in the applicable countries, also see such section. However, the ability to continue to commercialize PIXUVRI in the E.U. will depend on our ability to obtain an annual renewal of our conditional marketing authorization for PIXUVRI and to timely complete the post-marketing study of PIXUVRI aimed at confirming the clinical benefit previously observed in PIXUVRI. A failure of such study could result in a cessation of commercialization of PIXUVRI in the E.U.

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:

- increase and maintain 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 enter into additional, commercial manufacturing arrangements with third parties, cost-effectively manufacture necessary quantities and build 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.

The notes to the financial statements included in this Quarterly Report on Form 10-Q contain, and we received an audit report for each of the years ended December 31, 2007 through December 31, 2011 containing, an explanatory paragraph on our consolidated financial statements for each of the associated periods regarding substantial doubt as to our ability to continue as a going concern.

The notes to the financial statements included in this Quarterly Report on Form 10-Q contain, and we received an audit report for each of the years ended December 31, 2007 through December 31, 2011 containing, an explanatory paragraph on our consolidated financial statements for each of the associated periods regarding 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.

We may be unable to obtain a quorum for meetings of our shareholders or obtain necessary shareholder approvals and therefore be unable to take certain corporate actions.

Our articles of incorporation require that a quorum, generally consisting of one-third of the outstanding shares of voting stock, be represented in person, by telephone or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our articles of incorporation, such as an amendment to increase our authorized capital stock, generally require the approval of a majority of our outstanding shares. Failure to meet a quorum or obtain shareholder approval can prevent us from raising capital through equity financing or otherwise taking certain actions that may be in the best interest of the company and shareholders.

A substantial majority 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 2006, we were unable to obtain a quorum at two scheduled annual meetings. Following that failure to obtain a quorum, we contacted certain depository banks in Italy where significant numbers of shares of our common stock were held and asked them to cooperate by making a book-entry transfer of their share positions at Monte Titoli 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 contacted agreed to make the share transfer pursuant to these arrangements as of the record date of the 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 will 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 participate in custody transfer arrangements in the future.

As a result of the foregoing, we may be unable to obtain a quorum or shareholder approval of proposals, when needed, 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. For example, a proposal to

approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting. Any failure to obtain a quorum or the requisite vote on a proposal in question could harm us.

We could fail in financing efforts if we fail to receive shareholder approval when needed.

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 or NASDAQ 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 the historical

difficulties we have experienced in obtaining a quorum and holding shareholder meetings discussed above. If we are unable to obtain financing due to shareholder approval difficulties, such failure may harm our ability to continue operations.

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

Because our common stock is traded on the MTA in Italy, we are required to also comply with the rules and regulations of 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 that have to be approved by CONSOB prior to issuing common stock that 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 because 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, any changes to Italian regulatory requirements, exemptions or interpretations 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. 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 owe additional amounts for VAT related to our operations in Europe.

Our European operations are subject to the VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was $5.3 million and $5.7 million as of September 30, 2014 and December 31, 2013, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the ITA issued notices of

assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are €0.5 million, €5.5 million, €2.5 million and €0.8 million. 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 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 $11.9 million converted using the currency exchange rate as of September 30, 2014) 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.

Post-approval 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-approval commitment trial for PIXUVRI, could negatively affect our business, financial condition, operating results or prospects.

Even if a product receives regulatory approval, 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 products, including PIXUVRI, are subject to extensive labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping regulations. 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 commitment clinical trials, such as our ongoing PIX306 trial of PIXUVRI required by the EMA. We cannot predict the outcome of PIX306 or whether we will be able to complete the associated requirements in a timely manner. Although we have requested an extension of the completion date of PIX306 from the currently agreed-upon date of June 2015 to July 2016, there can be no guarantees that the EMA will agree with such extension. If we are unable to submit the requisite PIX306 study report by the applicable due date or are otherwise unable to satisfy all applicable requirements, our conditional marketing authorization for PIXUVRI may be revoked. A revocation of PIXUVRI's or any other product's conditional marketing authorization or any other failure to maintain applicable regulatory approvals could result in the respective product being withdrawn from the market, product seizures, monetary penalties or possible criminal prosecution, which could negatively affect our business, financial condition, operating results or prospects.

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

Our business and future growth depend on the development, ultimate sale and use of products that are subject to FDA, EMA and or other regulatory agencies regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that in the U.S., we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome, generate negative publicity and may result in fines or payments of settlement awards. 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 laws and regulations that govern our cross-border conduct, as well as with healthcare fraud and abuse and anti-corruption and false claims laws and regulations, 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, 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 drugs. 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 healthcare 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 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 these laws or regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

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

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships, including, in particular, for the manufacture and distribution of our compounds and associated activities. For example, we do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of drug products in compliance with current Good Manufacturing Practices, or cGMPs. 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 cGMPs 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 cGMPs. 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, distribution and cash collection services. For example, Quintiles Commercial Europe Limited provides a variety of key services to us related to the commercialization of PIXUVRI in certain countries in Europe.

With respect to certain 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 individual, independent vendors. As a result, engaging in operations subject to this concentration risk could harm our business.

If the third parties on which we depend were to default on the performance of their contractual obligations to us or otherwise fail in properly executing their duties on our behalf, including, but not limited to, those relating to the manufacture, distribution and other core operational activities, our business could be harmed.

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 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. In addition, PIXUVRI may face competition in the E.U. (and, if applicable in the future, the U.S.) if new anti-cancer drugs with reduced toxicity and/or increased efficacy are developed and marketed in the E.U. and/or the U.S.
- If we are successful in bringing pacritinib to market, pacritinib will face competition from ruxolitinib (Jakafi®) and new drugs targeting similar diseases that may be developed and marketed.

.

If we are successful in bringing tosedostat to market, tosedostat will face competition from currently marketed products, such as cytarabine, Dacogen®, Vidaza®, Clolar®, Revlimid®, Thalomid® and new anti-cancer drugs that may be developed and marketed.

- If we are successful in bringing Opaxio to market, we will face direct competition from oncology-focused multinational corporations. Opaxio will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products. Such corporations include, among others, Bristol-Myers Squibb Co., which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis U.S. LLC, which markets docetaxel; Genentech, Inc., Hoffmann-La Roche Inc. and Astellas Pharma US, Inc., which market Tarceva™; Genentech, Inc. and Hoffmann-La Roche Inc., which market Avastin™; Eli Lilly & Company, which markets Alimta®; and Celgene Corporation, which markets Abraxane™. In addition, other companies such as Telik, Inc. are also developing products, which could compete with Opaxio.

Many of our competitors, particularly the 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 are making to develop 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 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 one or more 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 expire from 2015 through 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 will, 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 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 drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from any third parties. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

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

We are currently and may in the future be subject to regulatory or legal proceedings that could harm our financial condition and operating results.

We may be subject to regulatory matters or legal claims, including possible securities, 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 unfavorable rulings could occur. 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 presently are subject to a derivative lawsuit. In addition, we settled a shareholder derivative lawsuit in May 2013 pursuant to which we agreed to implement certain corporate governance measures and were required to pay $1.4 million in plaintiffs' attorneys' fees and reimbursement of expenses, all of which amount was covered by our insurance.

We cannot predict with certainty the eventual outcome of pending litigation. 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 an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

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

We have substantial tax loss carryforwards for U.S. federal income tax purposes, but our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended, as a result of prior changes in the stock ownership of 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 increased 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. 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 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 products, 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 product or product candidate 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.

Since we use hazardous materials in our business, we may be subject to claims relating to improper handling, storage or disposal of these materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to international, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by the 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 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 as a result of a data privacy breach or theft of intellectual property 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

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended October 24, 2014, our stock price has ranged from a low of $1.60 to a high of $4.25. 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 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;
- 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 by NASDAQ or on the MTA by CONSOB, or the Borsa Italiana; and
- general economic and market conditions.

Shares of 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 LLC, or NASDAQ, 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. 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 LLC, 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.

Anti-takeover provisions in our charter documents, in our shareholder rights agreement, or rights plan, and under Washington law 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 the 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. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
Stock Repurchases in the Third Quarter

The following table sets forth information with respect to purchases of our common stock during the three months ended September 30, 2014:

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
July 1 - July 31, 2014	—	—	—	—
August 1 - August 31, 2014	5,548	$ 2.56	—	—
September 1 - September 30, 2014	17,066	$ 2.60	—	—
Total	22,614	$ 2.59	—	—

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

Item 3. Defaults Upon Senior Securities
None.

Item 4. Mine Safety Disclosures
Not applicable.

Item 5. Other Information
Not applicable.

On October 28, 2014, we borrowed an additional $5.0 million under our senior secured term loan agreement. For further information, please refer to Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations – OVERVIEW – Financial Summary.

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 June 24, 2008.
3.2	Articles of Amendment to 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 September 4, 2008.
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series F Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on February 9, 2009.
3.4	Amendment to 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 27, 2009.
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 1 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 13, 2009.
3.6	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 2 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 21,

		2009.
3.7	Articles of Amendment to Amended and Restated Articles of Incorporation; Certificate of Designation, Preferences and Rights of Series ZZ Junior Participating Cumulative Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form 8-A, filed on December 28, 2009.
3.8	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 3 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on January 19, 2010.
3.9	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 4 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 5, 2010.
3.10	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 5 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
3.11	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 6 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2010.
3.12	Amendment to 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 September 17, 2010.

Exhibit Number	Exhibit Description	Location
3.13	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 7 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
3.14	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 8 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
3.15	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 9 Preferred Stock.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
3.16	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 10 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on February 24, 2011.
3.17	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 11 Preferred Stock.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on February 24, 2011.
3.18	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 12 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 2, 2011.
3.19	Articles of Amendment to 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 May 18, 2011.
3.20	Amendment to 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 June 17, 2011.
3.21	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 13 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on July 6, 2011.
3.22	Amendment to 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 November 15, 2011.
3.23	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 14 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 14, 2011.
3.24	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 15-1 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 31, 2012.
3.25	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences,	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form

	Rights and Limitations of Series 16 Preferred Stock.	8-K, filed on June 5, 2012.
3.26	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 15-2 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.
3.27	Amendment to 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 August 31, 2012.
3.28	Amendment to 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 September 4, 2012.
3.29	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 17 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 11, 2012.
3.30	Amendment to 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 June 26, 2013.

Exhibit Number	Exhibit Description	Location
3.31	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 18 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on September 18, 2013.
3.32	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 19 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 15, 2013.
3.33	Amendment to 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 May 22, 2014.
3.34	Amendment to 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 June 2, 2014.
3.35	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	Class B Common Stock Purchase Warrant, dated April 13, 2009.	Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed on April 13, 2009.
4.5	Common Stock Purchase Warrant, dated May 11, 2009.	Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2009.
4.6	Form of Common Stock Purchase Warrant, dated May 27, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
4.7	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.

4.8	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.
4.9	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.
4.10	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.
4.11	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.
4.12	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.
4.13	Form of Warrant to Purchase Common Stock, dated July 30, 2012.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.
4.14	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	CTI BioPharma Corp. 2007 Equity Incentive Plan, effective as of June 20, 2003 and amended and restated as of September 17, 2014.	Filed herewith.

Exhibit Number	Exhibit Description	Location
10.2†	Exclusive License and Collaboration Agreement by and between CTI BioPharma Corp., CTI Life Sciences Limited, Laboratoires Servier and Institut de Recherches Internationales Servier dated as of September 16, 2014.	Filed herewith.
15	Letter regarding Unaudited Interim Financial Information.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101. INS	XBRL Instance	Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101. CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101. DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101. LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101. PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

†Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

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: October 30, 2014 By: /s/ James A. Bianco, M.D.
James A. Bianco, M.D.
President and Chief Executive Officer

Dated: October 30, 2014 By: /s/ Louis A. Bianco
Louis A. Bianco
Executive Vice President,
Finance and Administration