CELL THERAPEUTICS INC
Form 10-Q
October 30, 2013
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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, 2013

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

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington	**91-1533912**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**
3101 Western Avenue, Suite 600	
Seattle, Washington	**98121**
(Address of principal executive offices)	**(Zip Code)**

(206) 282-7100

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 25, 2013**
Common Stock, no par value	129,878,669

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	September 30, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,176	$ 50,436
Accounts receivable	540	
Inventory	3,720	1,626
Prepaid expenses and other current assets	2,310	8,249
Total current assets	33,746	60,311
Property and equipment, net	5,838	6,785
Other assets	7,655	6,617
Total assets	$ 47,239	$ 73,713
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 10,364	$ 12,065
Accrued expenses	7,854	10,209
Warrant liability	702	
Current portion of long-term debt	1,216	
Other current liabilities	393	393
Total current liabilities	20,529	22,667
Long-term debt, less current portion	7,126	
Other liabilities	5,736	4,641
Total liabilities	33,391	27,308
Commitments and contingencies		
Common stock purchase warrants	13,461	13,461
Shareholders equity:		
Common stock, no par value:		
Authorized shares - 215,000,000 and 150,000,000 at September 30, 2013 and December 31, 2012, respectively		
Issued and outstanding shares - 129,865,869 and 109,823,748 at September 30, 2013 and December 31, 2012, respectively	1,900,746	1,872,885
Accumulated other comprehensive loss	(8,272)	(8,273)
Accumulated deficit	(1,889,899)	(1,830,060)

Total CTI shareholders equity		2,575		34,552
Noncontrolling interest		(2,188)		(1,608)
Total shareholders equity		387		32,944
Total liabilities and shareholders equity	$	47,239	$	73,713

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Product sales, net	$ 362	$	$ 1,794	$
Total revenues	362		1,794	
Operating costs and expenses:				
Cost of product sold	13		104	
Research and development	7,245	6,951	23,620	24,080
Selling, general and administrative	8,529	7,763	29,774	29,024
Acquired in-process research and development				29,108
Settlement expense	155	435	155	435
Total operating costs and expenses	15,942	15,149	53,653	82,647
Loss from operations	(15,580)	(15,149)	(51,859)	(82,647)
Other income (expense):				
Investment and other income (expense), net	(173)	(270)	(433)	(179)
Interest expense	(316)	(43)	(680)	(51)
Amortization of debt discount and issuance costs	(162)		(349)	
Foreign exchange gain (loss)	547	216	(199)	(96)
Total other expense, net	(104)	(97)	(1,661)	(326)
Net loss before noncontrolling interest	(15,684)	(15,246)	(53,520)	(82,973)
Noncontrolling interest	140	57	581	200
Net loss attributable to CTI	(15,544)	(15,189)	(52,939)	(82,773)
Deemed dividends on preferred stock	(6,900)	(5,014)	(6,900)	(13,472)
Net loss attributable to CTI common shareholders	$ (22,444)	$ (20,203)	$ (59,839)	$ (96,245)
Basic and diluted net loss per common share	$ (0.20)	$ (0.38)	$ (0.55)	$ (2.12)

Shares used in calculation of basic and diluted net loss per common share	110,996	52,921	108,489	45,442

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss before noncontrolling interest	$ (15,684)	$ (15,246)	$ (53,520)	$ (82,973)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(291)	(121)	196	71
Net unrealized gain (loss) on securities available-for-sale:	(28)	48	(195)	(28)
Other comprehensive income (loss):	(319)	(73)	1	43
Comprehensive loss	(16,003)	(15,319)	(53,519)	(82,930)
Comprehensive loss attributable to noncontrolling interest	140	57	581	200
Comprehensive loss attributable to CTI	$ (15,863)	$ (15,262)	$ (52,938)	$ (82,730)

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2013	**2012**
Operating activities		
Net loss	$ (53,520)	$ (82,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development		29,108
Share-based compensation expense	6,324	6,084
Depreciation and amortization	1,207	1,745
Provision for VAT assessments		(2,118)
Noncash interest expense	349	
Other	332	(195)
Changes in operating assets and liabilities:		
Accounts receivable	(525)	
Inventory	(1,995)	(509)
Prepaid expenses and other current assets	5,749	(799)
Other assets	(857)	(874)
Accounts payable	(763)	2,207
Accrued expenses	(2,468)	(1,895)
Other liabilities	(26)	4,462
Total adjustments	7,327	37,216
Net cash used in operating activities	(46,193)	(45,757)
Investing activities		
Purchases of property and equipment	(1,373)	(1,966)
Proceeds from sales of property and equipment	123	
Cash paid for acquisition of assets from S*BIO Pte Ltd.		(17,764)
Net cash used in investing activities	(1,250)	(19,730)
Financing activities		
Proceeds from issuance of long-term debt, net	9,501	
Proceeds from issuance of Series 15 preferred stock and warrants, net of issuance costs		32,928
Proceeds from issuance of Series 18 preferred stock, net of issuance costs	15,000	

Other	(326)	(319)
Net cash provided by financing activities	24,175	32,609
Effect of exchange rate changes on cash and cash equivalents	8	115
Net decrease in cash and cash equivalents	(23,260)	(32,763)
Cash and cash equivalents at beginning of period	50,436	47,052
Cash and cash equivalents at end of period	$ 27,176	$ 14,289
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 618	$ 10
Cash paid for taxes	$	$
Supplemental disclosure of noncash financing and investing activities		
Conversion of Series 14 preferred stock to common stock	$	$ 6,736
Conversion of Series 15 preferred stock to common stock	$	$ 15,442
Conversion of Series 16 preferred stock to common stock	$	$ 11,240
Conversion of Series 18 preferred stock to common stock	$ 14,859	$
Issuance of Series 16 preferred stock for acquisition of assets from S*BIO Pte Ltd.	$	$ 11,344
Issuance of common stock upon exercise or exchange of common stock purchase warrants	$	$ 12,351

See accompanying notes.

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CELL THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Description of Business and Summary of Significant Accounting Policies

Cell Therapeutics, Inc., 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 less toxic and more effective ways to treat cancer. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. We are primarily focused on commercializing PIXUVRI® (pixantrone) in the European Union, or E.U., for multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting the first of two planned Phase 3 clinical trials of pacritinib for the treatment of myelofibrosis. As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, Germany, Netherlands, Norway, Sweden and the United Kingdom and had been granted market access in Italy and France.

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 United States, by the European Medicines Agency, or EMA, in the E.U., and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, may take many years and may involve the expenditure of substantial resources.

Basis of Presentation

The accompanying unaudited financial information of CTI as of September 30, 2013 and for the three and nine months ended September 30, 2013 and 2012 has been prepared in accordance with accounting principles generally accepted in the United States 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, 2013 are not necessarily indicative of the results that may be expected for the entire year.

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, 2012 included in our Annual Report on Form 10-K filed with the SEC on February 28, 2013.

The condensed consolidated balance sheet at December 31, 2012 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 United States 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, or SM, and CTI Life Sciences Limited. CTI Life Sciences Limited opened a branch in Italy in December 2009. 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 condensed consolidated financial statements until dissolution in March 2012.

As of September 30, 2013, 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 condensed consolidated financial statements.

All intercompany transactions and balances are eliminated in consolidation.

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Reverse Stock Splits

On May 15, 2011 and September 2, 2012, we effected one-for-six and one-for-five reverse stock splits, respectively, collectively referred to as the Stock Splits. Unless otherwise noted, all impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the Stock Splits. Unless otherwise noted, impacted amounts include shares of common stock authorized and outstanding, share issuances and cancellations, shares underlying preferred stock, convertible notes, warrants and stock options, shares reserved, conversion prices of convertible securities, exercise prices of warrants and options, and net loss per share. Additionally, the Stock Splits impacted preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the applicable reverse stock split).

Accounts Receivable

Our accounts receivable balance as of September 30, 2013 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 based on the uncertainty associated with the recent European financial crisis. As of September 30, 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, 2013.

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. Our VAT receivable was $5.7 million and $8.1 million as of September 30, 2013 and December 31, 2012, of which $0.2 million and $3.0 million was included in *prepaid expenses and other current assets,* respectively, and $5.5 million and $5.1 million was included in *other assets*, 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, 2013, the VAT receivable related to operations in Italy was $5.5 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 began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional approval by the EMA s Committee for Medicinal Products for Human Use, or CHMP. Based on the CHMP s positive opinion, we estimated the likelihood of receiving conditional approval to market PIXUVRI in the E.U. to be probable. 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 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. 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 approval to market 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.

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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 discounts and rebates, 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 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, discounts and incentives. We offer certain distributors 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 has been substantially eliminated. To date, there have been no PIXUVRI product returns.

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, 2013.

Net Loss per Share

Basic net income (loss) per common 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 share awards using the treasury stock method. As of September 30, 2013 and 2012, options, warrants, unvested share awards and unvested share rights aggregating 12.2 million and 9.6 million common share equivalents, respectively, prior to the application of the as-if converted method for convertible securities and the treasury stock method for other dilutive securities, such as options and warrants, are not included in the calculation of diluted net loss per share as they are anti-dilutive.

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.

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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.

Recently Adopted Accounting Standards

In February 2013, the FASB issued guidance requiring presentation of amounts reclassified from each component of accumulated other comprehensive income. In addition, disclosure is required of the effects of significant reclassifications on income statement line items either on the face of the statement where net income is presented or as a separate disclosure in the notes to the financial statements. For public entities, this guidance was effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this guidance did not have a material impact on our consolidated financial statements.

Recently Issued Accounting Standards

In March 2013, the Financial Accounting Standards Board, or 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. Early adoption is permitted. We do not expect the adoption of this guidance to have a material 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. 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. We are currently evaluating the impact this amendment may have on our consolidated financial statements.

Reclassifications

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

2. Inventory

The components of inventories are composed of the following as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013	December 31, 2012
Finished goods	$ 610	$ 220
Work-in-process	3,110	1,406
Total inventories	$ 3,720	$ 1,626

3. Long-term Debt

In March 2013, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or HTGC, for a senior secured term loan of up to $15.0 million. The first $10.0 million was funded in March 2013, and we have the option to borrow an additional $5.0 million any time from November 30, 2013 through

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December 15, 2013, subject to satisfaction of certain conditions. The interest rate on the term loan floats at a rate per annum equal to 12.25% plus the amount by which the prime rate exceeds 3.25%. The term loan is repayable over 42 months after closing, including an initial interest-only period of 12 months after closing. The loan obligations are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions. We paid a facility charge of $150,000 at closing and a fee in the amount of $1.3 million is payable to HTGC on the date on which the term loan is paid or becomes due and payable in full. We recorded debt discount of $1.9 million, of which $1.7 million is unamortized as of September 30, 2013. We recorded issuance costs of $0.3 million, of which $0.3 million is unamortized as of September 30, 2013.

In addition, we issued a warrant to HTGC to purchase shares of common stock. The warrant is exercisable for five years from the date of issuance for (i) 0.5 million shares of common stock, plus (ii) an amount of shares of common stock equal to (x) $150,000 if any additional funds are borrowed, divided by (y) the exercise price in effect on and as of such date. The initial exercise price of the warrant is $1.1045 per share of common stock. The exercise price and number of shares of common stock issuable upon exercise are subject to antidilution adjustments in certain events, including if within 12 months after closing the Company issues shares of common stock or securities that are exercisable or convertible into shares of common stock in transactions not registered under the Securities Act of 1933, as amended, at an effective price per share of common stock that is less than the exercise price of the warrant, then the exercise price shall automatically be reduced to equal the price per share of common stock in such transaction and the number of shares will be increased proportionately. Since the warrant did not meet the considerations necessary for equity classification in the applicable authoritative guidance, we determined the warrant is a liability instrument that is marked to fair value with changes in fair value recognized through earnings at each reporting period. We estimated the fair value of the warrant to be $0.5 million and $0.7 million as of the issuance date and September 30, 2013, respectively. We classified the warrant as Level 2 in the fair value hierarchy as the significant inputs used in determining fair value are considered observable market data.

4. Legal Proceedings

On August 3, 2009, SICOR Società Italiana Corticosteroidi S.R.L., or Sicor, filed a lawsuit in the Court of Milan to obtain the Court s assessment that we were bound to source a chemical compound, BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma S.p.A, or Novuspharma, a pharmaceutical company located in Italy, on October 4, 2002. We are the successor in interest to such agreement by virtue of our merger with Novuspharma in January 2004. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. We are unable to estimate the loss, if any, at this time in the event we do not prevail.

On December 10, 2009, CONSOB sent us a notice claiming, among other now resolved claims, 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 $7,000 and $677,000 upon conversion from euros as of September 30, 2013.

The Italian Tax Authority, or 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). 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. We received favorable rulings in 2012, which remain subject to further appeal, and our remaining deposit for the VAT assessments was refunded to us in January 2013. Due to the change of the position for the VAT assessment cases, we reversed the entire reserve for VAT assessed as of December 31, 2012. 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. We believe that such decision has not carefully taken into account our arguments and the documentation we filed, therefore we plan to appeal such decision in front of the Supreme Court both on procedural grounds and on the merits of the case. If the final decisions of the Supreme Court are unfavorable to us, we may incur up to $12.7 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of September 30, 2013.

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5. Preferred Stock

In September 2013, we issued 15,000 shares of Series 18 preferred stock, or Series 18 Preferred Stock, for gross proceeds of $15.0 million in a registered direct offering. Issuance costs related to this transaction were $0.1 million. Each share of Series 18 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of $1,000 per share of Series 18 Preferred Stock, plus any accrued and unpaid dividends, before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 18 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on common stock or any pari passu or junior securities. The Series 18 Preferred Stock was convertible to common stock, at the option of the holder, at an initial conversion price of $1.00 per share, subject to a 9.99% blocker provision. The Series 18 Preferred Stock had no voting rights except as otherwise expressly provided in the amended articles or as otherwise required by law. For the three and nine months ended September 30, 2013, we recognized $6.9 million in *deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 18 Preferred Stock. In September 2013, all 15,000 shares of Series 18 preferred stock were converted into 15.0 million shares of common stock.

6. Product Revenue

Total revenue from product sales of PIXUVRI consisted of the following for the three and nine months ended September 30, 2013 and 2012 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Product sales, gross	$ 414	$	$ 2,122	$
Discounts, rebates and other adjustments	(51)		(290)	
Returns reserve	(1)		(38)	
Product sales, net	$ 362	$	$ 1,794	$

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7. Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three and nine months ended September 30, 2013 and 2012, which was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development	$ 685	$ 363	$ 1,540	$ 1,379
Selling, general and administrative	1,243	653	4,784	4,705
Total share-based compensation expense	$ 1,928	$ 1,016	$ 6,324	$ 6,084

For the three and nine months ended September 30, 2013 and 2012, we incurred share-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Performance rights	$ 280	$ (111)	$ 885	$ 2,158
Restricted stock	1,394	996	4,845	3,635
Options	254	131	594	291
Total share-based compensation expense	$ 1,928	$ 1,016	$ 6,324	$ 6,084

8. Other Comprehensive Income (Loss)

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

	Net Unrealized Loss on Securities Available-For-Sale	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Income (Loss)
December 31, 2012	$ (235)	$ (8,038)	$ (8,273)
Current period other comprehensive income (loss)	(195)	196	1
September 30, 2013	$ (430)	$ (7,842)	$ (8,272)

9. Leases

As of December 31, 2012, we had a receivable balance of $1.5 million, which was included in *prepaid expenses and other current assets* related to incentives for leasehold improvements and rent reimbursement under the terms of our operating lease for office space entered into January 2012. In addition, our deferred rent balance was $4.8 million as of September 30, 2013, of which $0.4 million was included in *other current liabilities* and $4.4 million was included in *other liabilities*. As of December 31, 2012, our deferred rent balance was $5.0 million, of which $0.4 million was included in *other current liabilities* and $4.6 million was included in *other liabilities*.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q, including the following discussion, contains forward-looking statements, which involve risks and uncertainties and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item I of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on Form 10-Q, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, potential, predicts, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. Such statements, which include statements concerning product sales, research and development expenses, selling, general and administrative expenses, additional financings and additional losses, are subject to known and unknown risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, 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 less toxic and more effective ways to treat cancer. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. We are primarily focused on commercializing PIXUVRI® (pixantrone) in the European Union, or the E.U., for multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting the first of two planned Phase 3 clinical trials of pacritinib for the treatment of myelofibrosis.

PIXUVRI

Our most clinically advanced compound is PIXUVRI. PIXUVRI is a novel aza-anthracenedione derivative that is structurally related to anthracyclines and anthracenediones, but does not appear to be associated with the same level of cardiotoxic effects. In May 2012, the European Commission granted conditional marketing authorization in the E.U. of PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive NHL, a cancer caused by the abnormal proliferation of lymphocytes, which are cells that are key to the functioning of the immune system. NHL usually originates in lymph nodes and spreads through the lymphatic system. 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. This approval was based on the results from our pivotal Phase 3 clinical trial known as EXTEND or PIX301. In connection with the conditional marketing authorization, we are required to conduct a post-approval commitment study that is intended to confirm PIXUVRI s clinical benefit. We are currently accruing patients into this study which will compare pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

During the fourth quarter of 2012, we began making PIXUVRI available to healthcare providers in certain countries in the E.U. and initiated our commercial operations on a country-by-country basis. As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, Germany, Netherlands, Norway, Sweden and the United Kingdom (U.K.) and had been granted market access in Italy and France. We have established a commercial organization, including sales, marketing, supply chain management, and reimbursement capabilities to commercialize

PIXUVRI in the E.U. PIXUVRI is not approved in the United States (U.S.). We are pursuing potential partners for commercializing PIXUVRI in other markets outside the E.U. and the U.S.

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In almost all European markets, pricing and availability of prescription pharmaceuticals are subject to governmental control. Decisions by governmental authorities will impact the price and market acceptance of PIXUVRI. Accordingly, any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by the governmental authorities in each country where PIXUVRI is available for sale and other factors. We are actively pursuing pricing and reimbursement discussions for PIXUVRI with authorities in Germany and the United Kingdom, the status of which is as follows:

Germany: In May 2013, the Federal Joint Committee, or G-BA, the ultimate authority in determining reimbursement for drugs in Germany, reported that additional benefit could not be determined for PIXUVRI versus the comparator therapies assigned by the G-BA under Germany s AMNOG law. The determination reflected the absence of a comparator under AMNOG law specifically for this stage of aggressive NHL, because prior to the approval of PIXUVRI in the E.U., there was no therapy specifically approved for this stage of aggressive NHL. The G-BA also decided that the prescribability for PIXUVRI should be limited to hematologists and oncologists. We were referred to the GKV-SV, the Federal Association of Statutory Health Insurance Funds, for negotiations, and are currently negotiating the price of PIXUVRI with the GKV-SV.

United Kingdom: In July 2013, the United Kingdom s (UK) Department of Health approved CTI s patient access scheme relating to PIXUVRI. A patient access scheme is a plan that involves innovative pricing agreements designed to improve cost effectiveness and facilitate patient access to specific drugs or other technologies. In October 2013, the National Institute for Health and Care Excellence (NICE), a non-departmental public body of the Department of Health in the UK, issued third draft guidance on PIXUVRI. NICE s independent Appraisal Committee met on September 11, 2013, to consider the cost effectiveness of PIXUVRI taking into consideration our initial patient access scheme. The result is a second appraisal consultation document, or ACD, whereby the Committee concluded that this scheme does not overcome the uncertainties in the evidence for PIXUVRI s clinical effectiveness and once again requests that consultees, including CTI, healthcare professionals and members of the public, comment on the draft guidance via the NICE website. The ACD consultation will close on November 4, 2013, and any comments received will be considered by the NICE appraisal committee to enable them to develop the next stage of guidance. It should be noted that this is not NICE s final guidance on PIXUVRI and that a third Appraisal Committee meeting is expected to be held on November 13, 2013, where subject to approval, we hope the Committee will consider an enhanced patient access scheme to demonstrate the cost effectiveness of PIXUVRI for use by the NHS in the UK.

Pacritinib

Our lead development candidate, pacritinib, is an oral JAK2/FLT3 inhibitor that 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. This process results in the scarring of bone marrow, thereby 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 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. It is our intent to seek to enter into a partnership for pacritinib in the fourth quarter of 2013. If we are able to enter into such a partnership, we believe that it could potentially provide us with additional capital and external validation for the program.

Based on pacritinib s efficacy and tolerability profile demonstrated to date, we are pursuing a broad approach to advancing this therapy for myelofibrosis patients by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, which was initiated in January 2013 and the other in patients with low platelet counts, the PERSIST-2 trial, which is expected to begin in the fourth quarter of 2013.

The PERSIST-1 trial is designed as a 270 patient randomized, open-label, multicenter Phase 3 trial comparing the efficacy and safety of pacritinib with that of best available therapy in patients with myelofibrosis. Best available therapy includes any physician-selected treatment other than JAK inhibitors and there is no exclusion by patient platelet count. Patients will be randomized (2:1) to receive 400 mg pacritinib once daily or best available therapy. The primary endpoint of the study is the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT from baseline to 24 weeks of treatment. The trial is currently enrolling patients at clinical sites in Europe, Australia, Russia and the United States. More details on the PERSIST-1 study can be found at www.clinicaltrials.gov.

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PERSIST-2 will involve a 300 patient randomized, open-label, multi-center pivotal Phase 3 trial in patients with myelofibrosis whose platelet counts are <100,000/μL. In October 2013, we reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the PERSIST-2 pivotal trial. A SPA is a written agreement between CTI and the FDA regarding the design, endpoints and planned statistical analysis approach of the trial to be used in support of a potential New Drug Application (NDA) submission. The trial will evaluate pacritinib as compared to best available therapy, including approved JAK2 inhibitors that are dosed according to the product label for myelofibrosis patients with thrombocytopenia. Patients will be randomized (1:1:1) to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or best available therapy. The agreed upon co-primary endpoints are the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT from baseline to 24 weeks of treatment and the percentage of patients achieving a Total Symptom Score (TSS) reduction of 50 percent or greater using six key symptoms as measured by the modified Myelofibrosis Symptom Assessment Form (MF-SAF) diary from baseline to 24 weeks. The trial is expected to initiate in the fourth quarter of 2013 and to enroll patients at clinical sites in the United States, Europe and Australia.

Financial summary

Our revenues are generated solely from the sales of PIXUVRI in the E.U. We recognized revenue on commercial sales of PIXUVRI during the third quarter of 2013 and recorded $0.4 million in total net revenues for the three months ended September 30, 2013. Our product sales may vary significantly from period to period as the commercialization and reimbursement negotiations for PIXUVRI progress. 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. Our loss from operations for the three months ended September 30, 2013 was $15.6 million compared to $15.1 million for the same period in 2012.

As of September 30, 2013, we had cash and cash equivalents of $27.2 million. See the discussion in Part I, Item 1 Financial Statements for further information relating to our senior secured term loan agreement.

RESULTS OF OPERATIONS

Three months ended September 30, 2013 and 2012

Product sales, net. Net product sales for the three months ended September 30, 2013 were $0.4 million from the sales of PIXUVRI. There were no product sales for the three months ended September 30, 2012 because we did not receive conditional approval to market PIXUVRI in the E.U. until May 2012. We sell PIXUVRI directly to health care providers and through a limited number of wholesale distributors in the E.U. 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, 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.

Cost of product sold. Cost of product sold for the three months ended September 30, 2013 was $13,000 related to sales of PIXUVRI. There were no product sales or related cost of product sold for the same period in 2012. We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional approval by the EMA s 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 prior to capitalization, and therefore the manufacturing costs of PIXUVRI produced prior to capitalization is not reasonably determinable. Most of this reduced-cost inventory is expected to be available for us to use commercially. The timing of the sales of such

reduced-cost inventory and its impact on gross margin is dependent on the level of PIXUVRI sales as well as our ability to utilize this inventory prior to its expiration date. We expect that our cost of product sold as a percentage of product sales will increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold. At this time, we cannot reasonably estimate the timing or rate of consumption of reduced-cost PIXUVRI product manufactured and expensed prior to capitalization.

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

	Three Months Ended September 30,	
	2013	**2012**
Compounds:		
PIXUVRI	$ 1,038	$ 1,319
Pacritinib	2,148	349
Opaxio	(147)	444
Tosedostat	287	884
Brostallicin	(5)	(17)
Operating expenses	3,833	3,967
Research and preclinical development	91	5
Total research and development expenses	$ 7,245	$ 6,951

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, EMA or other regulatory agencies outside the United States and Europe, as well as upfront license fees for acquired technology. Subsequent to receiving a positive opinion for conditional approval of PIXUVRI in the E.U. from the EMA s CHMP, costs associated with commercial batch production, quality control, stability testing, and certain other manufacturing costs of PIXUVRI were capitalized as inventory. Operating expenses include our personnel costs and an allocation of occupancy depreciation and amortization expenses associated with developing these compounds. 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 the individual compounds. External direct costs incurred by us as of September 30, 2013 were $85.9 million for PIXUVRI (excluding costs prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, in January 2004), $8.2 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S*BIO Pte Ltd, or S*BIO, including pacritinib, in May 2012 and $29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S*BIO), $226.7 million for Opaxio, $10.7 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma Therapeutics, Inc., or Chroma) and $9.6 million for brostallicin (excluding costs for brostallicin prior to our acquisition of SM in July 2007).

Research and development expenses increased to $7.2 million for the three months ended September 30, 2013 compared to $7.0 million for the three months ended September 30, 2012. PIXUVRI costs decreased primarily due to a reduction in clinical development costs associated with the PIX306 trial, our on-going confirmatory trial in the E.U. This decrease was partially offset by an increase in medical affairs and pharmacovigilance activities in the E.U. Costs for pacritinib increased primarily due to clinical development costs associated with site initiation, patient enrollment and other start-up costs for the PERSIST-1 trial. Costs for our Opaxio program decreased primarily due to an adjustment in clinical development milestone activity associated with a contract amendment, in addition to a reduction in patient enrollment in investigator-sponsored studies. Development costs for tosedostat decreased primarily due to the compound being placed on partial clinical hold. Operating expenses included in research and development expenses decreased primarily due to a reduction in occupancy costs associated with the relocation of our corporate

office. This decrease was partially offset by increase in noncash share-based compensation expense and employee termination costs.

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 have drug candidates that are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates. Our drug candidates pacritinib, Opaxio, tosedostat and brostallicin 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

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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, Opaxio, tosedostat and brostallicin, and to complete the post-approval commitment study of PIXUVRI, because, among other reasons, we cannot predict with any certainty the pace of 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, Opaxio, tosedostat and brostallicin to generate material net cash inflows. In order to generate revenue from these products, our product candidates need to be developed to a stage that will enable us to commercialize, sell, or license related marketing rights to third parties.

We also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products. Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in the following risk factors, which begin on page 29 of this Quarterly Report on Form 10-Q: *We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.* ; *We may not obtain or maintain the regulatory approvals required to commercialize some or all of our products.* ; *Even if our drug candidates are successful in clinical trials and receive regulatory approvals, we may not be able to successfully commercialize them.* ; *Even if our other products receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review by the FDA, the EMA and other foreign regulatory agencies, as applicable, and may be subject to additional post-marketing obligations, all of which may result in significant expense and limit commercialization of our other products, including PIXUVRI.* ; *We may be delayed, limited or precluded from obtaining regulatory approval of Opaxio as a maintenance therapy for advanced-stage ovarian cancer and as a radiation sensitizer.* ; and *Our financial condition may be harmed if third parties default in the performance of contractual obligations.*

Selling, general and administrative expenses. Selling, general and administrative expenses were $8.5 million for the three months ended September 30, 2013 compared to $7.8 million for the three months ended September 30, 2012. This increase was primarily due to $0.6 million increase in noncash share-based compensation expense and a net $0.1 million increase of selling and marketing expenses for PIXUVRI in the E.U. offset in part by a reduction in general and administrative expenses.

Settlement expense. Settlement expense of $0.2 million and $0.4 million for the three months ended September 30, 2013 and 2012, respectively, was primarily due to costs incurred under settlement agreements with former employees associated with their employment separation.

Interest expense. Interest expense increased to $0.3 million for the three months ended September 30, 2013 compared to $43,000 for the three months ended September 30, 2012. This increase was primarily due to interest incurred on our long-term debt issued in March 2013.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of $0.2 million for the three months ended September 30, 2013 was related to our long-term debt issued in March 2013. We had no amortization of debt discount and issuance costs for the corresponding period in 2012.

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Foreign exchange gain (loss). The foreign exchange gain for the three months ended September 30, 2013 and 2012 were due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

Deemed dividends on preferred stock. Deemed dividends on preferred stock were $6.9 million for the three months ended September 30, 2013 related to the issuance of our Series 18 Preferred Stock (see Note 5, *Preferred Stock* in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of our Series 18 Preferred Stock). Deemed dividends on preferred stock were $5.0 million for the three months ended September 30, 2012 related to the issuance of our Series 15-2 preferred stock. For a discussion of such deemed dividends, see Note 9 in the notes to consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on February 28, 2013.

Nine months ended September 30, 2013 and 2012

Product sales, net. Net product sales for the nine months ended September 30, 2013 were $1.8 million from the sales of PIXUVRI. There were no product sales for the same period in 2012 because we did not receive conditional approval to market PIXUVRI in the E.U. until May 2012.

Cost of product sold. Cost of product sold for the nine months ended September 30, 2013 was $0.1 million related to sales of PIXUVRI in the E.U. There were no product sales or related cost of product sold for the same period in 2012.

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

	Nine Months Ended September 30,	
	2013	**2012**
Compounds:		
PIXUVRI	$ 3,566	$ 7,088
Pacritinib	5,998	363
Opaxio	835	1,314
Tosedostat	893	2,435
Brostallicin	41	107
Operating expenses	12,029	12,623
Research and preclinical development	258	150
Total research and development expenses	$ 23,620	$ 24,080

Research and development expenses decreased to approximately $23.6 million for the nine months ended September 30, 2013 from approximately $24.1 million for the nine months ended September 30, 2012. PIXUVRI costs decreased primarily due to a reduction in clinical consulting activity and a decline in patient enrollment in the PIX306 trial. Further decreases were primarily due to reductions in lab services, regulatory consulting costs and EMA filing fees associated with the marketing authorization in the E.U., which occurred in 2012. These decreases were partially offset by an increase in costs associated with medical affairs activities in the E.U. Costs for pacritinib increased primarily due to clinical development costs associated with site initiation, patient enrollment and other start-up costs for the PERSIST-1 trial. Costs for our Opaxio program decreased primarily due to an adjustment in clinical development milestone activity associated with a contract amendment, in addition to a reduction in patient

enrollment in investigator-sponsored studies. These reductions were partially offset by an increase in manufacturing activity. Development costs for tosedostat decreased primarily due to the compound being placed on partial clinical hold. Operating expenses included in research and development expenses decreased primarily due to reductions in occupancy costs associated with the relocation of our corporate office, depreciation expense, professional services and consulting costs. These decreases were partially offset by increases in the average number of personnel between comparable periods, employee termination costs and noncash share-based compensation expense.

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Selling, general and administrative expenses. Selling, general and administrative expenses were $29.8 million for the nine months ended September 30, 2013 compared to $29.0 million for the nine months ended September 30, 2012. Selling, general and administrative expenses increased by $0.8 million reflecting an increase in selling and marketing expenses for PIXUVRI in the E.U. offset by a reduction in general and administrative expenses such as legal, occupancy and information technology.

Acquired in-process research and development. Acquired in-process research and development for the nine months ended September 30, 2012 related to charges of $29.1 million recorded in connection with our acquisition of assets from S*BIO in May 2012. There was no acquired in-process research and development expense for the corresponding period in 2013.

Settlement expense. Settlement expense of $0.2 million and $0.4 million for the nine months ended September 30, 2013 and 2012, respectively, was primarily due to costs incurred under settlement agreements with former employees associated with their employment separation.

Interest expense. Interest expense increased to $0.7 million for the nine months ended September 30, 2013 from $51,000 for the nine months ended September 30, 2012. This increase was primarily due to interest incurred on our long-term debt issued in March 2013.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of $0.3 million for the nine months ended September 30, 2013 is related to our long-term debt issued in March 2013. We had no similar costs for the corresponding period in 2012.

Foreign exchange gain (loss). The foreign exchange loss for the nine months ended September 30, 2013 and 2012 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.

Deemed dividends on preferred stock. Deemed dividends on preferred stock were $6.9 million for the nine months ended September 30, 2013 related to the issuance of our Series 18 Preferred Stock (see Note 5, *Preferred Stock* in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of our Series 18 Preferred Stock). Deemed dividends on preferred stock were $13.5 million for the nine months ended September 30, 2012 related to the issuance of our Series 15-1 and Series 15-2 preferred stock. For a discussion of such deemed dividends, see Note 9 in the notes to consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on February 28, 2013.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents. As of September 30, 2013, we had $27.2 million in cash and cash equivalents.

Net cash used in operating activities. Net cash used in operating activities increased to $46.2 million during the nine months ended September 30, 2013 compared to $45.8 million for the same period in 2012 due to an increase in commercial activities associated with the launch of PIXUVRI and $0.6 million interest paid primarily on our long-term debt issued in March 2013. These increases were offset by a refund of our VAT deposit and interest of $2.9 million received during the first quarter of 2013 and $1.3 million cash received on sales of PIXUVRI in 2013.

Net cash used in investing activities. Net cash used in investing activities decreased to $1.3 million for the nine months ended September 30, 2013 compared to $19.7 million for the same period in 2012 as a result of $17.8 million cash paid for our acquisition of assets from S*BIO in May 2012.

Net cash provided by financing activities. 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 $10.0 million in long-term debt during the period, net of discount and issuance costs, and proceeds received from the issuance of our Series 18 Preferred Stock, net of issuance costs. Net cash provided by financing activities was $32.6 million for the nine months ended September 30, 2012 primarily as a result of proceeds received from the issuances of our Series 15-1 and 15-2 preferred stock and warrants, net of issuance costs.

Capital Resources

Our 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 consolidated financial statements. At our

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currently planned spending rate, we believe that our existing cash and cash equivalents, together with expected availability under our loan and security agreement with Hercules Technology Growth Capital and expected receipts from European PIXUVRI sales, will be sufficient to fund our operations into 2014. See Risk Factors Factors Affecting our Operating Results and Financial Condition *We need to continue to raise additional financing to operate, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could impair our ability to make our contractually obligated payments and harm our liquidity, financial condition, business, operating results and prospects.* and other risk factors relating to our liquidity, capital requirements and expected cash flows.

Capital Requirements

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

- results of our clinical trials;
- regulatory approval of our product candidates;
- the extent to which we acquire, invest or divest products or product candidates, technologies or businesses, or sell or license products or product candidates to others;
- progress in and scope of our research and development activities;
- ability to consummate agreements with appropriate partners for the development of product candidates, and, when applicable, commercialization of products;
- success in our commercialization efforts of PIXUVRI and any future products;
- litigation and other disputes; and
- competitive market developments.

We need to raise additional funds. We may seek to raise such capital through equity or debt financings, partnerships, collaborations, joint ventures or disposition of assets or other sources, but our ability to do so is subject to a number of risks and uncertainties, including that additional funding may not be available on favorable terms or at all. For further discussion of the risks and uncertainties pertaining to our ability to raise capital, see Risk Factors in this report. If we were to successfully pursue the raising of funds through the issuance of equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we will be required to delay, scale back, or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses and/or refrain from making our contractually required payments (including under our senior secured term loan agreement) when due, 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, 2013 (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	$ 20,542	$ 2,513	$ 4,502	$ 4,620	$ 8,907
Long-term debt	10,000	1,457	8,157	386	
Interest on long-term debt(1)	2,408	1,212	1,192	4	
Purchase commitments	2,713	2,188	524	1	
Other obligations	1,720	439	6	1,275	
	$ 37,383	$ 7,809	$ 14,381	$ 6,286	$ 8,907

(1) The interest rate on our long-term debt 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%.

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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. See below License Agreements and Additional Milestone Activities for additional information.

License Agreements and Additional Milestone Activities

Novartis

In September 2006, we entered into an exclusive worldwide licensing agreement, or the Novartis Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of Opaxio. Under the Novartis Agreement, total product and registration milestones to us for Opaxio could potentially amount to $270 million. If Novartis exercises its development rights, royalty payments to us for Opaxio are based on worldwide Opaxio net sales volumes and range from the low- to mid-twenties as a percentage of net sales.

Pursuant to the Novartis Agreement, we are responsible for the development costs of Opaxio and have control over development of Opaxio unless and until Novartis exercises its development rights. We are solely responsible for all costs associated with the development of Opaxio unless and until Novartis exercises its development rights, we will be reimbursed by Novartis for certain pre-exercise costs if Novartis exercises its development rights. If Novartis exercises its development rights, then Novartis will be solely responsible for the development of Opaxio from the date of exercise and we will be required to reimburse Novartis for certain costs pursuant to the Novartis Agreement.

The Novartis Agreement also provides Novartis with an option to develop and commercialize PIXUVRI based on agreed terms. If Novartis exercises its option on PIXUVRI under certain conditions and we are able to negotiate and sign a definitive license agreement with Novartis, Novartis would be required to pay us a $7.5 million license fee, up to $104 million in registration and sales related milestones and a royalty on PIXUVRI worldwide net sales. Royalty payments to us for PIXUVRI are based on worldwide PIXUVRI net sales volumes and range from the low-double digits to the low-thirties as a percentage of net sales.

Specifically, in the event Novartis exercises its applicable options, royalties for Opaxio and PIXUVRI are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its development rights until the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement, or (ii) Novartis determination, in its sole discretion, to terminate its development rights exercise period by written notice to us, the Novartis Agreement will automatically terminate upon expiration of the development rights exercise period. In the event of an uncured material breach of the Novartis Agreement, the non-breaching party may terminate the Novartis Agreement. Either party may terminate the Novartis Agreement without notice upon the bankruptcy of the other party. In addition, Novartis may terminate the Novartis Agreement without cause at any time in its entirety within 30 days written notice prior to the exercise by Novartis of its development rights or on a product-by-product or country-by-country basis on 180 days written notice after the exercise by Novartis of its development rights. If we experience a change of control that involves certain major pharmaceutical companies, Novartis may terminate the Novartis Agreement by written notice within a certain period of time to us or our successor entity.

As of September 30, 2013, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to exercise its option to participate in the development and commercialization of PIXUVRI or exercise its development rights for Opaxio.

University of Vermont

We entered into an agreement with the University of Vermont, or UVM Agreement, in March 1995, as amended in March 2000, 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

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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 Pte Ltd*

We acquired the compounds SB1518 (which is referred to as pacritinib) and SB1578, which inhibit Janus Kinase 2, commonly referred to as JAK2, in April 2012. Under the agreement with S*BIO, we are required to make milestone payments to S*BIO up to an aggregate amount of $132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any compound that we acquired from S*BIO for use for specific diseases, infections or other conditions. At our election, we may pay up to 50% of any milestone payments to S*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock. In addition, S*BIO will also be entitled to receive royalty payments from us at incremental rates in the low-single digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis.

Chroma Therapeutics, Ltd.

We entered into an agreement with Chroma, or the Chroma License Agreement, in March 2011 under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate, tosedostat, in North, Central and South America, or the Licensed Territory. Pursuant to the terms of the Chroma License Agreement, we paid Chroma an upfront fee of $5.0 million upon execution of the agreement and will make a milestone payment of $5.0 million upon the initiation of the first pivotal trial. The Chroma License Agreement also includes additional development- and sales-based milestone payments related to acute myeloid leukemia, or AML, and certain other indications, up to a maximum amount of $209.0 million payable by us to Chroma if all development and sales milestones are achieved.

Under the Chroma License Agreement, we are required to pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the latest of the expiration date of the last patent claim covering tosedostat in that country, the expiration of all regulatory exclusivity periods for tosedostat in that country or ten years after the first commercial sale in that country. Royalty payments to Chroma are based on net sales volumes in any country within the Licensed Territory and range from the low- to mid-teens as a percentage of net sales.

Under the Chroma License Agreement, we are required to oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory, or the ROW Territory. Development costs may not exceed $50.0 million for the first three years of the Chroma License Agreement unless agreed by the parties and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the Chroma Supply Agreement. We have the option of obtaining a commercial supply of

tosedostat from Chroma or from another manufacturer at our sole discretion in the Licensed Territory. The Chroma License Agreement may be terminated by us at our convenience upon 120 days written notice to Chroma. The Chroma License Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

By a letter dated July 18, 2012, Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma s allegations and intend to

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vigorously defend our development activities and judgments. In particular, we dispute Chroma s lack of diligence claim based in part on the appropriateness of completing the ongoing Phase 2 combination trials prior to developing a Phase 3 trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement.

Effective September 25, 2012, we and Chroma entered into a standstill with respect to the parties respective claims under the Chroma License Agreement, but otherwise reserving the parties respective rights as of the commencement of the standstill period. The standstill was extended through June 25, 2013, but has not been renewed by the parties.

Gynecologic Oncology Group

We entered into an agreement with the Gynecologic Oncology Group, or GOG, in March 2004, as amended in August 2008 and August 2013, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, which the GOG is conducting. We recorded a $0.9 million payment due to the GOG based on the 1,100 patient enrollment milestone achieved in the third quarter of 2013, which is included in accounts payable as of September 30, 2013. In addition, we may be required to pay up to $1.0 million upon the attainment of certain milestones, as well as other fees under certain circumstances, of which $0.5 million is included in accrued expenses as of September 30, 2013.

PG-TXL

In November 1998, we entered into an agreement with PG-TXL Company, L.P., or the PG-TXL Agreement (as amended in February 2006), which grants us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL s polymer technology. 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-single digits 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 a party.

Nerviano Medical Sciences

Under a license agreement entered into with Nerviano Medical Sciences for brostallicin, we may be required to pay up to $80.0 million in milestone payments based on the achievement of certain product development results. Due to the early stage of development that brostallicin is in, we are not able to determine whether the clinical trials will be successful and, therefore, cannot make a determination that the milestone payments are reasonably likely to occur at

this time.

Cephalon

Pursuant to an acquisition agreement entered into with Cephalon Inc., or Cephalon, in June 2005, we have the right to receive up to $100.0 million in payments upon achievement by Cephalon of specified sales and development milestones related to TRISENOX. However, the achievement of any such milestones is uncertain at this time.

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Critical Accounting Estimates

We make certain judgments and use certain estimates and assumptions when applying accounting principles generally accepted in the United States 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. As described in Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations,* of our Annual Report on Form 10-K for the year ended December 31, 2012, we consider our estimates for impairment of long-lived assets, contingencies and share-based compensation expense to be the most critical in the preparation of the consolidated financial statements because they involve the most difficult, subjective, or complex judgments about the effect of matters that are inherently uncertain. In addition, we recognized revenue for the three and nine months ended September 30, 2013 on sales of PIXUVRI in the E.U. Information regarding our accounting policies for revenue recognition, cost of product sold, accounts receivable and inventory is included in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q. Revenue from sales of PIXUVRI is recorded net of government-mandated discounts and rebates, product returns and other deductions which involve certain judgments and estimates.

Government-mandated discounts and rebates

Our estimate for government-mandated discounts and rebates is based on actual discounts and rebates healthcare providers and distributors have claimed for reduced pricing as well as statutorily-defined discount rates.

Product returns and other deductions

We offer certain distributors a limited right of return or replacement on product that is damaged in certain instances. Product returned is not resalable given the nature of our product and method of administration. We have developed estimates for product returns based upon historical industry information regarding product return rates for other specialty pharmaceutical products, inventory levels in the distribution channel and other relevant factors. To date, there have been no PIXUVRI product returns. We monitor inventory levels in the distribution channel, as well as sales of PIXUVRI by certain distributors to healthcare providers, using product-specific data provided by those distributors. If necessary, our estimates of product returns or replacements may be adjusted in the future.

For other deductions, we have written contracts with certain distributors that include terms for distribution-related discounts. We record distribution discounts based on the number of units sold to those distributors.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Foreign Exchange Market Risk

Our operations include commercial activity in the E.U. As a result, our operating results are in part dependent on foreign currency denominated activities, which are translated into U.S. dollars based on average exchange rates for the reporting period. Changes in exchange rates between foreign currencies and the U.S. dollar will affect the recorded levels of our operating results, as well as our assets and liabilities as they are translated into U.S. dollars for presentation in our financial statements. The primary foreign currency that we are exposed to is the euro. As of September 30, 2013, we had a net asset balance, excluding intercompany payables and receivables, in our European

branches and subsidiaries denominated in euros. As of September 30, 2013, if the euro had been 20% weaker against the dollar, our net asset balance would have decreased by approximately $1.8 million as of this date.

Interest Rate Risk

Effective in March 2013, and continuing as of September 30, 2013, we had an outstanding balance under our senior secured term loan of $10.0 million, and we have the option to borrow an additional $5.0 million any time from November 30, 2013 through December 15, 2013, subject to satisfaction of certain conditions. The senior secured term loan bears interest at variable rates. Based on the outstanding amount under such loan at September 30, 2013 of $10.0 million, and assuming such amount had been outstanding as of January 1, 2013, a 1.0% increase in the prime rate would result in additional annualized interest expense of $0.1 million. For a detailed discussion of our senior secured term loan, including a discussion of the applicable interest rate, please refer to Note 3, *Long-term Debt*, under Item 1 in this Quarterly Report on Form 10-Q.

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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, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our President and Chief Executive Officer and 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 three months ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

In December 2009, CONSOB sent us a notice claiming, among other now resolved claims, late disclosure of certain information reported in a press release disseminated at CONSOB s request on March 23, 2009, and alleged that the asserted late disclosure violated provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98. CONSOB s claims concerned our 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 is a pecuniary administrative sanction amounting to between 5,000 and 500,000, or approximately $7,000 to $677,000 converted using the currency exchange rate as of September 30, 2013. CONSOB has not yet notified us of a resolution with respect to this claim, but, based on our assessment, we believe the likelihood that a pecuniary administrative sanction will be imposed on us for this asserted violation is probable.

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe), based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million. 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 unfavourable 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 $12.7 million converted using the currency exchange rate as of September 30, 2013, 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.

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

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. As of the date of this filing, the ITA has until the end of November 2013 to appeal the decision.

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 10, 2013, the ITA refunded the VAT deposit including interest and

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collection fees of 0.1 million. 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. As of the date of this filing, the ITA has until the end of November 2013 to appeal the decision.

In August 2009, SICOR Società Italiana Corticosteroidi S.R.L., or Sicor, filed a lawsuit in the Court of Milan to obtain the Court s assessment that we were bound to source the chemical compound, BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma S.p.A, or Novuspharma, a pharmaceutical company located in Italy, on October 4, 2002. We are the successor in interest to such agreement by virtue of our merger with Novuspharma in January 2004. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. At a hearing on June 27, 2013, the Court granted the parties until October 11, 2013 to submit final briefs and until October 31, 2013 to reply. We are unable to estimate the loss, if any, at this time in the event that we do not prevail.

In April 2010, three shareholder derivative complaints were filed against us and certain of our officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to us by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for PIXUVRI. The allegations in the derivative actions are substantially similar to those in the securities action. In May 2010, the Honorable Marsha J. Pechman consolidated the shareholder derivative actions as In re Cell Therapeutics, Inc. Derivative Litigation (Master Docket No. 2:10-cv-00564-MJP). Three more derivative complaints were filed in June, July and October 2010, and they were also consolidated with In re Cell Therapeutics, Inc. Derivative Litigation. On November 6, 2012, co-lead counsel filed an executed Stipulation of Settlement. A settlement hearing occurred on May 31, 2013, and the Court entered a Final Judgment and Order of Dismissal on May 31, 2013, pursuant to which we were required to pay an aggregate of $1.4 million in plaintiffs attorneys fees and reimbursement of expenses, all of which amount was covered by our insurance.

In March 2011, we entered into a license and co-development agreement, or the Chroma License Agreement, with Chroma Therapeutics, Ltd., or Chroma, providing us with exclusive marketing and co-development rights to Chroma s drug candidate, tosedostat, in North, Central and South America. By a letter dated July 18, 2012, Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma s allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma s lack of diligence claim based in part on the appropriateness of completing the ongoing Phase 2 combination trials prior to developing a Phase 3 trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement, there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement. For the period commencing September 25, 2012 through June 25, 2013, a standstill was in effect between the Company and Chroma with respect to the parties respective claims under the Chroma License Agreement, but otherwise reserving the parties respective rights as of the commencement of the standstill period. Although the standstill period has not been renewed, court proceedings have not been initiated by either party as of the time of this filing.

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.

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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 or prospects and the trading price of our common stock. 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 trading price of our common stock.

Factors Affecting Our Operating Results and Financial Condition

We need to continue to raise additional financing to operate, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could impair our ability to make our contractually obligated payments and harm our liquidity, financial condition, business, operating results and prospects.

We have substantial operating expenses associated with the development of our product candidates and have significant contractual payment obligations, including under our senior secured term loan agreement. Our available cash and cash equivalents were $27.2 million as of September 30, 2013. At our currently planned spending rate, we believe that our existing cash and cash equivalents, together with expected availability under our senior secured term loan agreement and expected receipts from European PIXUVRI sales, will be sufficient to fund our operations into 2014. 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, and expansion of our sales and marketing organization in Europe may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for PIXUVRI that we currently assume in planning for 2013 and 2014. 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 or forecast we have disclosed, or may, from time to time disclose, may fail.

We have $10.0 million outstanding under our senior secured term loan agreement, and we have the option to borrow up to $5.0 million at any time from November 30, 2013 through December 15, 2013, subject to the satisfaction of certain conditions. Based on the current outstanding principal amount thereunder of $10.0 million, we must currently make monthly interest payments of approximately $105,000, but commencing May 1, 2014 through October 1, 2016, we will be required to make monthly interest plus principal payments in the aggregate amount of approximately $390,000. The 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 will need to raise additional funds and are currently exploring alternative sources. 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 and uncertainties, including:

- our ability to raise capital through the issuance of additional shares of our common stock or other securities convertible into common stock is restricted by the limited number of authorized shares available for issuance, the difficulty of obtaining shareholder approval to increase the authorized number of shares, and the restrictive covenants of our credit facility;

issuance of equity securities, or securities convertible into our equity 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 and may be further limited by the terms of any future indebtedness, and any such future indebtedness may include (and our existing debt does include) restrictive covenants that limit our operating flexibility;

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- some of such arrangements may require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets; and

- we may be required to meet additional regulatory requirements in the European Union (including Italy) and the United States and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain additional funding.

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 and/or refrain from making our contractually required payments (including under our senior secured term loan agreement) 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, 2013, we had an accumulated deficit of $1.9 billion. We are pursuing regulatory approvals for pacritinib, PIXUVRI, Opaxio, tosedostat and brostallicin. We will need to continue to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. We may never become profitable even with the ongoing commercialization of PIXUVRI or other products currently in development or otherwise.

We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.

Our business is dependent on our ability to successfully undertake extensive clinical testing on humans to demonstrate to the satisfaction of the applicable regulatory authority the safety and efficacy of the product for its intended use. For example, our ability to develop pacritinib depends on our ability to successfully complete two Phase 3 trials, one of which we initiated in January 2013 and the second of which we plan to initiate in the fourth quarter of 2013. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. We forecast the commencement and completion of clinical trials for planning purposes, but actual commencement or completion may take longer than planned or not be completed at all due to a number of reasons, including:

- we may not obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase;

- the FDA, the EMA or other regulatory authority may object to proposed protocols;

- there may be shortages of available product supplies or the materials that are used to manufacture the products or the quality or stability of the product candidates may fall below acceptable standards;

authorized preclinical or clinical testing may require significantly more time, resources or expertise than originally expected to be necessary;

clinical testing may not show potential products to be safe and efficacious for the specific indication for which they are tested and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;

the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials;

inadequate financing to complete a clinical trial;

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- we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons;

- the failure of third parties, such as contract research organizations, academic institutions and/or cooperative groups, to conduct, oversee and monitor clinical trials as well as to process the clinical results and manage test requests, to perform or to meet applicable standards; and

- the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated as a result of factors, such as the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

If we fail to commence or complete, or experience delays in, any of our present or planned clinical trials or need to perform more or larger clinical trials than planned, our development costs may increase, which could harm our ability to commercialize our product candidates, and our business, financial condition, operating results or prospects.

Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market.

The successful development of anti-cancer drugs and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. 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 example, our STELLAR Phase 3 clinical trials for Opaxio for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, in June 2013, the FDA notified us that a partial clinical hold had been placed on tosedostat and as a result new patients may not be entered into any of the ongoing tosedostat protocols until agreement is reached with the FDA**.**

Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market for several reasons, including:

- preclinical or clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;

- failure to receive the necessary U.S. and international regulatory approvals or a delay in receiving such approvals;

- difficulties in formulating the product, scaling the manufacturing process or getting approval for manufacturing;

- manufacturing costs, pricing, reimbursement issues or other factors may make the product uneconomical to commercialize;

any problem in the production of our products, such as the inability of a supplier to provide raw materials or supplies used to manufacture our products, equipment obsolescence, malfunctions or failures, product quality or contamination problems, or changes in regulatory requirements or standards that require modifications to our manufacturing process;

the product candidate may not be cost effective compared to alternative treatments; or

other companies or people have or may have proprietary rights to a product candidate, such as patent rights, and will not let the product candidate be sold on reasonable terms, or at all.

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If the development of our product candidates is delayed, our development costs may increase, the product may not reach later stages of development and/or our ability to commercialize our product candidates may be harmed, which could harm our business, financial condition, operating results or prospects.

We may not obtain or maintain the regulatory approvals required to commercialize some or all of our products.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries, including the EMA in the European Union. Pacritinib and all of our other compounds are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the European Union, we have not received marketing approval for these other compounds or FDA marketing approval of PIXUVRI (and we are not currently pursuing FDA marketing approval of PIXUVRI). Information about the status of the regulatory approval of pacritinib, PIXUVRI, Opaxio, tosedostat, and brostallicin 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 United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate 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;
- a clinical trial results in negative or inconclusive results or adverse medical events 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 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, and operating results will be harmed.

Even if our drug candidates are successful in clinical trials and receive regulatory approvals, we may not be able to successfully commercialize them.

Pacritinib, Opaxio, tosedostat and brostallicin are currently in clinical trials; the development and clinical trials of these products may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. Even if our products are successful in clinical trials or in obtaining other regulatory approvals, our products (even those that have been granted conditional marketing authorization, such as PIXUVRI) may not reach 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;

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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 are 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 by proprietary rights of third parties.

The occurrence of any of these events could adversely affect the commercialization of our products. Products, if introduced, may not be successfully marketed and/or may not achieve customer acceptance. 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.

If users of our products are unable to obtain adequate reimbursement from third party payers, market acceptance of our products may be limited and we may not achieve anticipated revenues.

To the extent we are successful in bringing proposed products to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Governmental and other third-party payors continue to attempt to contain healthcare costs by strictly controlling, directly or indirectly, pricing and reimbursement and we expect pressures on pricing and reimbursement from both governments and private payers inside and outside the U.S. to continue. 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 will be determined by national regulatory authorities, including the pricing of PIXUVRI in Europe. 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. Reimbursement decisions from any of the European markets may impact reimbursement decisions on PIXUVRI in the other European markets. The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital.

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

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend in large part on the commercial success in Europe of our only marketed product candidate, PIXUVRI. PIXUVRI is not approved for marketing in the United States. During the fourth quarter of 2012, we began making PIXUVRI available to healthcare providers in certain countries in the E.U. and initiated our commercial operations on a country-by-country basis. As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland,

Germany, Netherlands, Norway, Sweden and the United Kingdom and had been granted market access in Italy and France (see Management s Discussion and Analysis for a discussion of such reimbursement status). However, even with such availability and market access granted, successful commercialization of PIXUVRI depends heavily on our ability to obtain favorable reimbursement rates for users of PIXUVRI, as discussed below, as well as on several additional factors, including, without limitation, our ability to:

increase and maintain market demand for, and sales of, PIXUVRI in Europe through our sales and marketing efforts and by expanding the sales force;

obtain greater acceptance of PIXUVRI by physicians and patients;

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maintain compliance with regulatory requirements;

obtain a renewal annually of our conditional marketing authorization for PIXUVRI in the European Union and complete a post-marketing study of PIXUVRI aimed at confirming the clinical benefit previously observed in PIXUVRI;

establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;

maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for PIXUVRI, to manufacture commercial quantities at acceptable cost levels and build our distribution, managerial and other non-technical capabilities;

maintain intellectual property protection for PIXUVRI;

compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel; and

develop and maintain our own commercial organization to market PIXUVRI.

If we are unable to successfully commercialize PIXUVRI in Europe as planned, we may be unable to generate sufficient revenues to grow or sustain our business, and our business, financial condition, operating results and prospects could be harmed.

We have in the past received and may in the future receive audit reports with an explanatory paragraph on our consolidated financial statements.

Our independent registered public accounting firm included an explanatory paragraph in its reports on our consolidated financial statements for each of the years ended December 31, 2007 through December 31, 2011 regarding their substantial doubt as to our ability to continue as a going concern. Although our independent registered public accounting firm removed this going concern explanatory paragraph in its report on our December 31, 2012 consolidated financial statements, we expect to continue to need to raise additional financing to fund our operations and satisfy obligations as they become due. The inclusion of a going concern explanatory paragraph in future years may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing, and we cannot guarantee that we will not receive such an explanatory paragraph in the future.

We may not be able to maintain our listings on The NASDAQ Capital Market and the Mercato Telematico Azionario stock market in Italy, or the MTA, 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.

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 loan and security agreement, and any future indebtedness, which would accelerate the maturity date of such debt or trigger other obligations. In addition, certain institutional investors that are not permitted to own securities of non-listed companies may be required to sell their shares adversely affecting the trading price of our common stock. If we are not listed on The NASDAQ Capital

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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. 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, the Commissione Nazionale per le Società e la Borsa, or CONSOB (which is the public authority responsible for regulating the Italian securities markets), 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 trading price of our common stock.

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% 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% 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 the NASDAQ Marketplace Rules, particularly in light of the 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.

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We are subject to limitations on our ability to issue additional shares of our common stock or undertake other business initiatives due to Italian regulatory requirements.

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% 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 in the past issued convertible preferred stock 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% 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.

We are subject to Italian regulatory requirements, which could result in administrative and other challenges and additional expenses.

Because our common stock is traded on the MTA, 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 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 incur additional expense 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 current investigations, see the regulatory investigations that are discussed in more detail in Part II, Item 1 Legal Proceedings.

We will incur a variety of costs for and may never realize the anticipated benefits of any acquisitions we may make.

We evaluate and acquire assets and technologies from time to time. If appropriate opportunities become available, we may attempt to acquire other businesses and assets that we believe are a strategic fit with our business. The process of negotiating an acquisition and integrating an acquired business and assets may result in operating difficulties and expenditures. In addition, our acquisitions 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. Moreover, we may never realize the anticipated benefits of any acquisition, including our acquisition of pacritinib from S*BIO in May 2012. Any acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to intangible assets, which could harm our business, financial condition, operating results or prospects.

We may owe additional amounts for value added taxes related to our operations in Europe.

Our European operations are subject to value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was $5.7 million and $8.1 million as of September 30, 2013 and December 31, 2012, respectively. On April 14, 2009, December 21, 2009 and June 25, 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. 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 unfavourable 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 $12.7 million converted using the currency exchange rate as of September 30, 2013) 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.

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We may not realize any royalties, milestone payments or other benefits under the license and co-development agreement entered into with Novartis.

We have entered into a license and co-development agreement related to Opaxio and PIXUVRI with Novartis pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of Opaxio and an option to enter into an exclusive worldwide license to develop and commercialize PIXUVRI. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to PIXUVRI and we enter into a definitive license agreement with Novartis or Novartis elects to participate in the development and commercialization of Opaxio. Novartis is under no obligation to make such election and enter into a definitive license agreement or exercise such right and may never do so. In addition, even if Novartis exercises such rights, any royalties and milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals and the attainment of certain sales levels. If Novartis does not elect to participate in the development of Opaxio or PIXUVRI, we may not be able to find another suitable partner for the commercialization and development of those products, which may have an adverse effect on our ability to bring Opaxio to market and PIXUVRI to market outside of Europe. In addition, we would need to obtain a release from Novartis prior to entering into any agreement to develop and commercialize PIXUVRI or Opaxio with a third party. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels to generate royalty or milestone payments even if Novartis elects to exercise its option with regard to PIXUVRI and enter into a definitive license agreement or to participate in the development and commercialization of Opaxio. In addition, the agreement imposes restrictions on activities relating to the development and commercialization of PIXUVRI and any actual or alleged failure to comply with the terms of the agreement could result in potential damage claims, legal expenses, loss of rights under the agreement or termination of the agreement. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time upon written notice to us.

Even if our other products receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review by the FDA, the EMA and other foreign regulatory agencies, as applicable, and may be subject to additional post-marketing obligations, all of which may result in significant expense and limit commercialization of our other products, including PIXUVRI.

Even if our other products receive regulatory approvals, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. Regulatory approvals that we receive for our products may be subject to limitations on the indicated uses for which the product may be marketed or require potentially costly post-marketing follow-up studies. Even if a product receives regulatory approval, we may not be able to maintain compliance with regulatory requirements, which could result in the product being withdrawn from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution. In addition, PIXUVRI is subject to extensive regulatory requirements regarding its labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping. If the FDA, the EMA or other foreign regulatory agency approves any of our other products, they will also be subject to similar extensive regulatory requirements. The subsequent discovery of previously unknown problems with PIXUVRI or any of our other products, including adverse events of unanticipated severity or frequency, or the discovery that adverse effects or unknown toxicities observed in preclinical research or clinical trials that were believed to be minor actually constitute more serious problems, may result in restrictions on the marketing of the product or withdrawal of the drug from the market. If we are not granted full approval of PIXUVRI in the European Union or we are unable to renew our conditional marketing authorization for PIXUVRI in the European Union, our business, financial condition, operating results and prospects would be harmed.

We cannot predict the outcome of our clinical trial for PIXUVRI or whether our clinical trial for PIXUVRI will serve as either a post-marketing commitment trial or as a pivotal trial.

In March 2011, we initiated a randomized pivotal trial of PIXUVRI for the treatment of relapsed or refractory aggressive B-cell NHL. This clinical trial, referred to as PIX-R, or PIX306, will compare a combination of PIXUVRI plus rituximab to a combination of gemcitabine plus rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant. We cannot predict the outcome of PIX306 or whether PIX306 will serve as either a post-marketing commitment trial or as a pivotal trial. We may not be able to demonstrate the clinical benefit of PIXUVRI in patients who had previously received rituximab or that PIXUVRI is more clinically effective than treatments currently used in clinical practice. We may not be able to complete the PIX306 clinical trial by June 2015 or at all. If we are unable to submit the clinical trial data from PIX306 by June 2015, it may result in the withdrawal of the conditional marketing authorization by the European Union. We may also need to take additional

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steps to obtain regulatory approval of PIXUVRI. The expense to design and conduct clinical trials are substantial and any additional clinical trials or actions we may need to pursue to obtain approval of PIXUVRI may negatively affect our business, financial condition, operating results or prospects. Failure to meet clinical trial deadlines may also result in the withdrawal of our conditional marketing authorization for PIXUVRI.

We may be delayed, limited or precluded from obtaining regulatory approval of Opaxio as a maintenance therapy for advanced-stage ovarian cancer and as a radiation sensitizer.

Through an investigator-sponsored study, we are currently evaluating Opaxio 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 and as a radiation sensitizer. This Phase 3 clinical trial, or the GOG-0212 trial, is under the control of the Gynecologic Oncology Group, or the GOG, and is expected to enroll 1,150 patients. On January 31, 2013, the Data Safety Monitoring Board recommended continuation of the GOG-0212 trial of Opaxio for maintenance therapy in ovarian cancer with no changes following the first planned interim survival analysis. Three prior pivotal clinical trials for Opaxio have not been successful and failure of the GOG-0212 trial could delay, limit or preclude regulatory approval of Opaxio.

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, use and ultimate sale 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 United States, 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 Inc. 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 Inspector General of the U.S. Department of 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 false claims laws and regulations, could result in substantial penalties and prosecution.

We are subject to risks associated with doing business outside of the United States, 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

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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.

If we fail to establish and maintain collaboration and service-provider relationships with third-parties, we may be unable to develop and commercialize our product candidates.

We currently have limited resources, and the continued development of a commercial organization to market PIXUVRI, as well as the further development and potential future commercialization of pacritinib and our other product candidates, will be expensive and time-consuming. We have entered into a third-party service provider agreement with Quintiles Commercial Europe Limited, or Quintiles, whereby CTILS has engaged Quintiles to provide a variety of services, which may include market access services, promotion and detailing services, strategic planning, project management, pricing and reimbursement support, pharmacovigilance, medical information and other regulatory and consulting services to CTILS and its affiliates related to the commercialization of PIXUVRI in Europe. Because we rely on third parties to manufacture, distribute, and market and sell PIXUVRI, we have limited control over the efforts of these third parties, and we may receive less revenue than if we commercialized PIXUVRI ourselves. We are also a party to other agreements with third parties for our product candidates, including an agreement with GOG to perform a Phase 3 trial of Opaxio in patients with ovarian cancer.

We believe that establishing and maintaining collaborations is necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. We are pursuing potential partners for commercializing PIXUVRI in other markets outside of the United States and our current ten major European Union target markets (Austria, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Sweden and the United Kingdom). We are pursuing potential partners for the development and commercialization of pacritinib, seeking to do so within 2013. We may not be successful in entering into collaborations containing attractive terms for pacritinib or PIXUVRI or other product candidates on a timely basis or at all. The process of negotiating these arrangements may require significant management attention that would otherwise be available for ongoing development of our business and result in additional operating expenses, whether or not any such arrangement is ever consummated. If we fail to enter into additional collaborative arrangements or fail to maintain existing or future arrangements and service provider relationships, we may be unable to further develop and commercialize product candidates, generate revenues to grow, sustain our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

Collaborative arrangements with third parties can subject us to a number of risks that could harm our ability to develop and commercialize products.

Our collaborative arrangements with third parties subject us to a number of risks, including:

disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;

we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;

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partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;

agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;

business combinations or significant changes in a partner s business strategy might adversely affect that partner s willingness or ability to complete its obligations to us; and

the terms and conditions of any collaborative arrangements may not be favorable.

The occurrence of any of these events could harm the development or commercialization of our products.

Our dependence on third-party manufacturers means that we do not always have direct control over the manufacture, testing or distribution of our products and such dependence subjects us to risks, including those associated with any failure by such third-parties to comply with FDA, EMA or other applicable regulations.

We do not currently have internal analytical laboratory or manufacturing facilities to allow the testing or production and distribution of drug products in compliance with cGMPs. We are dependent on a single vendor for manufacturing PIXUVRI and, as such, we do not have direct control over the manufacture, testing or distribution of PIXUVRI. If this vendor is unable to provide us with a sufficient supply of PIXUVRI or we are unable to find an alternative manufacturer of PIXUVRI, we may not be able to fulfill purchase orders for PIXUVRI or meet future demand, which could harm our business, financial condition, operating results and prospects. The active pharmaceutical ingredients and drug products for other products under development, pacritinib, tosedostat and brostallicin, are also manufactured by single vendors. Finished product manufacture and distribution for these products are to be manufactured and distributed by different single vendors. In addition, Opaxio has a complex manufacturing process and supply chain, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it. If our vendors fail to comply with regulatory requirements or we experience a delay in the manufacturing of our finished products, we may experience a delay in the distribution of our products, which may impact the related clinical trials and our commercial activities currently planned or underway.

In addition, we are dependent upon third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by the United States and/or applicable foreign regulatory authorities, and the FDA, EMA and other 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, which would harm our business, financial condition, operating results or prospects.

Our financial condition may be harmed if third parties default in the performance of contractual obligations.

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships. In September 2012, our wholly-owned subsidiary CTILS entered into a Logistics Agreement with Movianto Nederland BV, or Movianto, pursuant to which Movianto agreed to provide certain warehousing, transportation, distribution, order processing and cash collection services and all related activities to CTILS and its affiliates for

PIXUVRI in certain agreed territories in Europe. Movianto provides a variety of services related to our sales of PIXUVRI, including the receipt, unloading and checking, warehousing and inventory control; customer order management; distribution and transportation; lot number and expiry date control; returned goods processing; return and recall; product quality assurance; reporting, credit management and debt collection. If Movianto, or other third parties we may enter into contracts with default on the performance of their contractual obligations, we could suffer significant financial losses and operational problems, which could in turn adversely affect our financial performance, cash flows or operating results and may jeopardize our ability to maintain our operations.

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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 development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically:

- If we are successful in bringing pacritinib to market, pacritinib will face competition from ruxolitinib (Jakafi®) and new drugs targeting similar diseases that may be developed and marketed.

- In Europe, PIXUVRI faces competition with existing treatments, including with anthracyclines, such as mitoxantrone (Novantrone®), for adults with multiply relapsed or refractory aggressive B-cell NHL. If we were to pursue bringing PIXUVRI to market in the United States (which is not currently part of our near-term plan), PIXUVRI would face similar competition. In addition, PIXUVRI may face competition in the European Union (and, if applicable in the future, the United States) if new anti-cancer drugs with reduced toxicity are developed and marketed in the European Union and/or the United States.

- 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. and others, which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which market Tarceva ; Genentech and Roche, which market Avastin ; Eli Lilly, which markets Alimta®; and Celgene, which markets Abraxane . In addition, other companies such as Telik, Inc. are also developing products, which could compete with Opaxio.

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

- If we are successful in bringing brostallicin to market, we will face direct competition from other minor groove binding agents including Yondelis®, which is currently developed by PharmaMar and has received Authorization of Commercialization from the European Commission for soft tissue sarcoma.

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, manufacturing and marketing 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 our current or future products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement, and access to drugs, which could affect our future revenues and profitability if new restrictive legislation is adopted.

Legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing. In the United States, we are subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs and 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), or the PPACA, instituted comprehensive health care reform in 2010 and we believe the U.S. Congress and state legislatures will likely continue to focus on

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health care reform, the cost of healthcare services and products and on the reform of the Medicare and Medicaid systems. The announcement or adoption of these proposals could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, many state legislative proposals would further negatively affect our pricing and reimbursement for, or access to, our products.

Globally, governments are becoming increasingly aggressive in imposing health care cost-containment measures such as:

- adopting more restrictive price controls;
- limiting and reducing both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the FDA or the EMA, but are considered experimental or investigational by third-party payors;
- restricting access to human pharmaceuticals based on the payers assessments of comparative effectiveness and value;
- refusing in some cases to provide coverage when an approved product is used for disease indications in a way that has not received FDA or EMA marketing approval; and
- denying coverage altogether.

If adequate third-party or government coverage is not available, market acceptance of our products may be limited and we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development or achieve anticipated revenues.

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 relating to intellectual property for pacritinib, PIXUVRI, tosedostat, and brostallicin. 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 licenses. 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 enter into new in-licensing arrangements, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Our product candidates Opaxio, tosedostat, and brostallicin, which are in clinical and pre-clinical development, and PIXUVRI, which is in a post-approval commitment study, have been in-licensed from third-parties. Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

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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 United States 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 United States and foreign countries directed to pacritinib, PIXUVRI, Opaxio, tosedostat, brostallicin 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 Opaxio-directed patents will expire on various dates ranging from 2017 through 2018. The pacritinib-directed patents will expire from 2026 through 2029. The PIXUVRI-directed U.S. patents will expire in 2014. The tosedostat-directed U.S. patents will expire in 2017. The brostallicin-directed U.S. patents will expire on various dates ranging between 2017 through 2021. The PIXUVRI-directed patents currently in force in Europe will expire from 2015 through 2023. Although certain PIXUVRI-directed patents may be subject to possible patent-term extensions that could provide extensions through 2019 in the United States and through 2027 in some countries in Europe, there can be no guarantee of extensions of PIXUVRI-directed or other patents in other countries. The expiration of these patents may allow our competitors to copy the inventions that are currently protected and better compete with us.

If we fail to adequately protect our intellectual property, our competitive position 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 patent protection for our products or processes both in the United States and other countries;

protect trade secrets; and

prevent others from infringing on our proprietary rights.

The patent position of biopharmaceutical firms 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 United States 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.

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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 have not conducted an exhaustive search. We may not be able to successfully challenge the validity of third-party patents and could be required to pay substantial damages, possibly including treble damages, for past infringement and attorneys fees if it is ultimately determined that our products infringe such patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties.

Moreover, third parties may challenge the patents that have been issued or licensed to us. We do not believe that pacritinib, PIXUVRI 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 litigation proceedings that could harm our financial condition and operating results.

We may be subject to legal claims or regulatory matters involving shareholder, consumer, regulatory and other issues. As described in Part II, Item 1 Legal Proceedings in this Quarterly Report on Form 10-Q, we are currently engaged in a number of litigation 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. 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.

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.

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. For example, as described in Part II, Item 1 Legal Proceedings of this Quarterly Report on Form 10-Q, CONSOB has not yet notified us of a resolution with respect to its claim that our disclosure related to the contents of the opinion expressed by Stonefield Josephson, Inc.,

an independent public accounting firm, with respect to our 2008 financial statements was late. However, based on our assessment, we believe the likelihood is probable that CONSOB will impose a pecuniary administrative sanction for such asserted violation.

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Securities class action and shareholder derivative lawsuits are often instituted against issuers, and we have been subjected to such actions. For example, on May 31, 2013, we settled a shareholder derivative lawsuit 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 expenses 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.

Our operations in our European branches and subsidiaries make us 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. 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. We purchase paclitaxel and polyglutamic acid (another material used to produce Opaxio) from single sources. If paclitaxel or polyglutamic acid, or any other 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 and marketing 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.

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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.

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 25, 2013, our stock price has ranged from a low of $0.97 to a high of $2.04. Fluctuations in the trading price or liquidity of our common stock may harm the value of your investment in our common stock.

Factors that may have a significant impact on the market price and marketability of our securities include:

- announcements by us or others of results of preclinical testing and 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, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;
- our quarterly operating results;
- developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

our ability to realize the anticipated benefits of pacritinib;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts recommendations;

short selling;

changes in health care policies and practices;

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

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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 equity securities and are subordinate to any preferred stock we may issue and to any existing or 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 our senior secured term loan agreement, or future indebtedness we may incur and 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, dividends are payable only when and if declared by our board of directors or a duly authorized committee of our board of directors, and 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 shareholders generally.

Future sales or other dilution of our equity may harm the market price of shares of our common stock.

We expect to issue additional equity securities to fund our operating expenses as well as for other purposes. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, or the perception that such sales could occur in the future.

Anti-takeover provisions in our charter documents, in our shareholder rights plan, 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 amended and restated articles of incorporation and amended and restated 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:

a classified board of directors so that only approximately one-third of our board of directors is elected each year;

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 amended and restated 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% or more of our common stock by a person or group, subject to certain exceptions, could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20% shareholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common

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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, 2013:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 July 31, 2013	36	$ 1.06		
August 1 August 31, 2013	4,100	$ 1.10		
September 1 September 30, 2013	26,171	$ 1.34		
Total	30,307	$ 1.31		

(1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees granted under our 2007 Equity Incentive Plan, as amended and restated.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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Item 6. Exhibits

(a) Exhibits

3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008).
3.2	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).
3.3	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).
3.4	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).
3.5	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).
3.6	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).
3.7	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).
3.8	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).
3.9	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).
3.10	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).
3.11	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).
3.12	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).
3.13	

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).

3.14 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).

3.15 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).

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3.16	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).
3.17	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).
3.18	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).
3.19	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).
3.20	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).
3.21	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).
3.22	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).
3.23	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).
3.24	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 16 Preferred Stock (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K, filed on June 5, 2012).
3.25	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).
3.26	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).
3.27	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 September 4, 2012).
3.28	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).
3.29	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).
3.30	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).
3.31	

Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K, filed on February 22, 2010).

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4.1	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 March 28, 2013).
4.2	Form of Series 18 Preferred Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K, filed on September 18, 2013).
10.1*	Form of Stock Option Agreement for option grants under the Registrant s 2007 Equity Incentive Plan, as amended (filed herewith).
10.2*	Form of Stock Award Agreement for grants of fully vested shares under the Registrant s 2007 Equity Incentive Plan, as amended (filed herewith).
10.3*	Form of Restricted Stock Award Agreement for grants of restricted shares under the Registrant s 2007 Equity Incentive Plan, as amended (filed herewith).
10.4	Amendment No. 3 to Wholesale Distribution Agreement, effective July 9, 2013, by and between CTI Life Sciences Limited and Max Pharma GmbH (filed herewith).
10.5	Form of Securities Purchase Agreement for Series 18 Preferred Stock (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K, filed on September 18, 2013).
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
101. SCH	XBRL Taxonomy Extension Schema
101. CAL	XBRL Taxonomy Extension Calculation
101. DEF	XBRL Taxonomy Extension Definition
101. LAB	XBRL Taxonomy Extension Labels
101. PRE	XBRL Taxonomy Extension Presentation

* Indicates management contract or compensatory plan or arrangement.

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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:

CELL THERAPEUTICS, INC.
(Registrant)

Dated: October 30, 2013

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

Dated: October 30, 2013

By: /s/ Louis A. Bianco
Louis A. Bianco
Executive Vice President,
Finance and Administration