

CELL THERAPEUTICS INC

Form 10-Q

April 29, 2014

Table of Contents

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended: March 31, 2014**

**OR**

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number 001-12465**

**CELL THERAPEUTICS, INC.**

**(Exact name of registrant as specified in its charter)**

**Washington**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**3101 Western Avenue, Suite 600**

**Seattle, Washington**  
**(Address of principal executive offices)**

**(206) 282-7100**

**91-1533912**  
**(I.R.S. Employer**  
**Identification No.)**

**98121**  
**(Zip Code)**

**(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  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  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

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

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

<b>Class</b>	<b>Outstanding at April 23, 2014</b>
Common Stock, no par value	149,830,127



**Table of Contents**

**CELL THERAPEUTICS, INC.**

**TABLE OF CONTENTS**

	<b>PAGE</b>
<b>PART I - FINANCIAL INFORMATION</b>	
ITEM 1: Financial Statements	
<u>Condensed Consolidated Balance Sheets at March 31, 2014 (unaudited) and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations Three Months Ended March 31, 2014 and 2013 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss Three Months Ended March 31, 2014 and 2013 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows Three Months Ended March 31, 2014 and 2013 (unaudited)</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>ITEM 3: Quantitative and Qualitative Disclosures about Market Risk</u>	25
<u>ITEM 4: Controls and Procedures</u>	25
<b>PART II - OTHER INFORMATION</b>	
<u>ITEM 1: Legal Proceedings</u>	27
<u>ITEM 1A: Risk Factors</u>	28
<u>ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds</u>	46
<u>ITEM 3: Defaults Upon Senior Securities</u>	46
<u>ITEM 4: Mine Safety Disclosures</u>	46
<u>ITEM 5: Other Information</u>	46
<u>ITEM 6: Exhibits</u>	47
<u>Signatures</u>	52

Table of Contents**CELL THERAPEUTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share amounts)**

	<b>March 31, 2014 (unaudited)</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 50,601	\$ 71,639
Accounts receivable	503	235
Inventory	5,023	5,074
Prepaid expenses and other current assets	3,798	3,567
<b>Total current assets</b>	<b>59,925</b>	<b>80,515</b>
Property and equipment, net	5,148	5,478
Other assets	8,213	7,730
<b>Total assets</b>	<b>\$ 73,286</b>	<b>\$ 93,723</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,604	\$ 5,051
Accrued expenses	9,543	9,469
Warrant liability		991
Current portion of deferred revenue	1,043	1,010
Current portion of long-term debt	2,527	3,155
Other current liabilities	393	393
<b>Total current liabilities</b>	<b>18,110</b>	<b>20,069</b>
Deferred revenue, less current portion	1,450	1,626
Long-term debt, less current portion	10,861	10,152
Other liabilities	6,179	5,657
<b>Total liabilities</b>	<b>36,600</b>	<b>37,504</b>
Commitments and contingencies		
Common stock purchase warrants	13,461	13,461
Shareholders' equity:		
Common stock, no par value:		
Authorized shares 215,000,000		
Issued and outstanding shares 149,838,981 and 145,508,767 at March 31, 2014 and December 31, 2013, respectively	1,942,989	1,933,305
Accumulated other comprehensive loss	(8,450)	(8,429)
Accumulated deficit	(1,908,705)	(1,879,703)

Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

Total CTI shareholders' equity	25,834	45,173
Noncontrolling interest	(2,609)	(2,415)
Total shareholders' equity	23,225	42,758
Total liabilities and shareholders' equity	\$ 73,286	\$ 93,723

See accompanying notes.

Table of Contents

## CELL THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2014	2013
Revenues:		
Product sales, net	\$ 1,268	\$ 1,126
License and contract revenue	143	
Total revenues	1,411	1,126
Operating costs and expenses:		
Cost of product sold	145	55
Research and development	12,179	8,355
Selling, general and administrative	16,750	11,143
Settlement expense		95
Total operating costs and expenses	29,074	19,648
Loss from operations	(27,663)	(18,522)
Other income (expense):		
Interest expense	(464)	(48)
Amortization of debt discount and issuance costs	(178)	(23)
Foreign exchange loss	(5)	(751)
Other expense	(886)	(272)
Total other expense	(1,533)	(1,094)
Net loss before noncontrolling interest	(29,196)	(19,616)
Noncontrolling interest	194	232
Net loss	\$ (29,002)	\$ (19,384)
Basic and diluted net loss per common share	\$ (0.20)	\$ (0.18)
Shares used in calculation of basic and diluted net loss per common share	142,138	106,697

See accompanying notes.





Table of Contents**CELL THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****(In thousands)****(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Net loss before noncontrolling interest	\$(29,196)	\$(19,616)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(29)	339
Net unrealized gain on securities available-for-sale	8	34
Other comprehensive income (loss)	(21)	373
Comprehensive loss	(29,217)	(19,243)
Comprehensive loss attributable to noncontrolling interest	194	232
Comprehensive loss attributable to CTI	\$(29,023)	\$(19,011)

See accompanying notes.

Table of Contents

## CELL THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating activities</b>		
Net loss	\$(29,196)	\$(19,616)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	7,829	2,428
Depreciation and amortization	360	411
Noncash interest expense	178	23
Change in value of warrant liability	886	25
Other	499	251
Changes in operating assets and liabilities:		
Accounts receivable	(267)	(791)
Inventory	50	(750)
Prepaid expenses and other current assets	(139)	3,905
Other assets	(504)	(388)
Accounts payable	(410)	(367)
Accrued expenses	67	(481)
Deferred revenue	(143)	
Other liabilities	1	2
Total adjustments	8,407	4,268
Net cash used in operating activities	(20,789)	(15,348)
<b>Investing activities</b>		
Purchases of property and equipment	(35)	(1,018)
Proceeds from sales of property and equipment		46
Net cash used in investing activities	(35)	(972)
<b>Financing activities</b>		
Issuance of long-term debt, net	(73)	9,764
Other	(133)	(126)

Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

Net cash provided by (used in) financing activities	(206)	9,638
Effect of exchange rate changes on cash and cash equivalents	(8)	560
Net decrease in cash and cash equivalents	(21,038)	(6,122)
Cash and cash equivalents at beginning of period	71,639	50,436
Cash and cash equivalents at end of period	\$ 50,601	\$ 44,314

**Supplemental disclosure of cash flow information**

Cash paid during the period for interest	\$ 439	\$ 5
Cash paid for taxes	\$	\$

**Supplemental disclosure of noncash financing and investing activities**

Issuance of common stock upon exercise of common stock purchase warrants	\$ 1,877	\$
--	----------	----

See accompanying notes.

**Table of Contents**

**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 partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is a high unmet medical need. We are primarily focused on commercializing PIXUVRI® (pixantrone) in the European Union, or the E.U., for adult patients with multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical program of pacritinib for the treatment of myelofibrosis that will support regulatory submission for approval in the United States, or the U.S., and Europe.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration, or FDA, in the U.S., 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 and may take many years and may involve expenditure of substantial resources.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of March 31, 2014 and for the three months ended March 31, 2014 and 2013 has been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial position at such date and the operating results and cash flows for such periods. Operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the entire year or for any other subsequent interim period.

Certain information and footnote disclosure normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or the SEC. These unaudited financial statements and related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2013 included in our Annual Report on Form 10-K filed with the SEC on March 4, 2014, or the 2013 Form 10-K.

The condensed consolidated balance sheet at December 31, 2013 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the U.S. for complete financial statements.

*Principles of Consolidation*

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

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, or CTILS. CTILS 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 consolidated financial statements until dissolution in March 2012.

As of March 31, 2014, we also had a 61% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. The remaining interest in Aequus not held by CTI is reported as *noncontrolling interest* in the consolidated financial statements.

## Table of Contents

All intercompany transactions and balances are eliminated in consolidation.

### *Accounts Receivable*

Our accounts receivable balance includes trade receivables related to PIXUVRI sales. We estimate an allowance for doubtful accounts based upon the age of outstanding receivables and our historical experience of collections, which includes adjustments for risk of loss for specific customer accounts. We periodically review the estimation process and make changes to our assumptions as necessary. When it is deemed probable that a customer account is uncollectible, the account balance is written off against the existing allowance. We also consider the customers country of origin to determine if an allowance is required based on the uncertainty associated with the recent European financial crisis. As of March 31, 2014 and December 31, 2013, our accounts receivable did not include any balance from a customer in a country that has exhibited financial stress that would have had a material impact on our financial results. We did not record an allowance for doubtful accounts as of March 31, 2014 and December 31, 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. The VAT receivable is approximately \$5.8 million and \$5.7 million as of March 31, 2014 and December 31, 2013, of which \$5.6 million and \$5.6 million is included in *other assets* and \$0.2 million and \$0.1 million is included in *prepaid expenses and other current assets* as of March 31, 2014 and December 31, 2013, respectively. The collection period of VAT receivable for our European operations ranges from approximately three months to five years. For our Italian VAT receivable, the collection period is approximately three to five years. As of March 31, 2014, the VAT receivable related to operations in Italy is approximately \$5.6 million. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

### *Inventory*

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

### *Revenue Recognition*

We currently have conditional 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.

### Product Sales

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

## Table of Contents

### Government-mandated discounts and rebates

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

### Product returns and other deductions

At the time of sale, we also record estimates for certain sales deductions such as product returns and distributor discounts and incentives. We offer certain 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 have 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 March 31, 2014 and 2013.

### *Net Loss Per Share*

Basic net income (loss) per share is calculated based on the net income (loss) attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted net income (loss) per common share assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and restricted stock using the treasury stock method. As of March 31, 2014 and 2013, options, warrants and unvested share rights aggregating 16.6 million and 11.5 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.



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

## **Table of Contents**

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. The Company has accounts receivable from the sale of PIXUVRI from a small number of distributors and health care providers. Further, the Company does not require collateral on amounts due from its distributors and is therefore subject to credit risk. The Company has not experienced any significant credit losses to date as a result of credit risk concentration and does not consider an allowance for doubtful accounts to be necessary.

### *Recently Adopted 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, with early adoption permitted. The adoption of this guidance did not have an impact on our consolidated financial statements.

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

### *Reclassifications*

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

**Table of Contents****2. Inventory**

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

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Finished goods	\$ 565	\$ 601
Work-in-process	4,458	4,473
<b>Total inventory</b>	<b>\$ 5,023</b>	<b>\$ 5,074</b>

**3. Long-term Debt**

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

Pursuant to the Amendment, the interest-only period of the Original Loan has been extended by six months such that the 24 equal monthly installments of principal and interest (mortgage style) will now commence on November 1, 2014 (rather than May 1, 2014). In addition, the interest rate on the Original Loan (which is currently 12.25% plus the amount by which the prime rate exceeds 3.25%) will, upon Hercules' receipt of evidence of the achievement of positive Phase III data in connection with our PERSIST-1 clinical trial, be reduced to 11.25% plus the amount by which the prime rate exceeds 3.25%. The modified terms were not considered substantially different pursuant to ASC 470-50, *Modification and Extinguishment*.

If we elect to borrow the funds under the 2014 Term Loan Availability, interest on such portion would float at a rate per annum equal to 10.00% plus the amount by which the prime rate exceeds 3.25%. Any borrowings under the 2014 Term Loan Availability would be repayable in 24 equal monthly installments of principal and interest (mortgage style) commencing on November 1, 2014. As of the time of this filing, we have not borrowed the funds underlying the 2014 Term Loan Availability.

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

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

#### **4. Legal Proceedings**

On December 10, 2009, the Commissione Nazionale per le Società e la Borsa (which is the public authority responsible for regulating the Italian securities markets), or CONSOB, sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations could require us to pay a pecuniary administrative sanction amounting to between \$7,000 and \$684,000 upon conversion from euros as of March 31, 2014. Until CONSOB's right is barred, CONSOB may, at any time, confirm the occurrence of the asserted violation and apply a pecuniary administrative sanction within the foregoing range. To date, we have not received any such notification.

**Table of Contents**

The Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007, or, collectively, the VAT Assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case. We received favorable rulings in 2012, which remain subject to further appeal, and our then remaining deposit for the VAT Assessments was refunded to us in January 2013. Due to the change of the position for the VAT Assessments, 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, and we therefore plan to appeal such decision in front of the Supreme Court both on procedural grounds and on the merits of the case. In January 2014, we were notified that the ITA has requested partial payment of the 2003 VAT assessment in the amount of 430,118. We paid such amount in March 2014.

If the final decisions of the Supreme Court for the VAT Assessments are unfavorable to us, we may incur up to \$12.9 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of March 31, 2014.

**5. Share-based Compensation Expense**

The following table summarizes share-based compensation expense for the three months ended March 31, 2014 and 2013, which was allocated as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Research and development	\$ 782	\$ 403
Selling, general and administrative	7,047	2,025
<b>Total share-based compensation expense</b>	<b>\$ 7,829</b>	<b>\$ 2,428</b>

For the three months ended March 31, 2014 and 2013, we incurred share-based compensation expense due to the following types of awards (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Performance rights	\$ 503	\$ 340
Restricted stock	5,969	1,995
Options	1,357	93

Total share-based compensation expense	\$ 7,829	\$ 2,428
--	----------	----------

**Table of Contents****6. Other Comprehensive Loss**

Total accumulated other comprehensive loss consisted of the following as of March 31, 2014 and December 31, 2013 (in thousands):

	<b>Net Unrealized Gain (Loss) on Securities Available-for- sale</b>	<b>Foreign Currency Translation Adjustments</b>	<b>Accumulated Other Comprehensive Loss</b>
December 31, 2013	\$ (422)	\$ (8,007)	\$ (8,429)
Current period other comprehensive income (loss)	8	(29)	(21)
March 31, 2014	\$ (414)	\$ (8,036)	\$ (8,450)

**7. Leases**

Our deferred rent balance was \$4.7 million as of March 31, 2014, of which \$0.4 million was included in *other current liabilities* and \$4.3 million was included in *other liabilities*. As of December 31, 2013, our deferred rent balance was \$4.8 million, of which \$0.4 million was included in *other current liabilities* and \$4.4 million was included in *other liabilities*.

---

**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*This Quarterly Report on Form 10-Q may contain, in addition to historical information, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on Form 10-Q, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, potential, predicts, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. Such statements, which include statements concerning sufficiency of cash resources and related projections, product sales, research and development expenses, selling, general and administrative expenses, additional financings and additional losses, are subject to known and unknown risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, 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 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), or PIXUVRI, in the European Union, or the E.U., for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial program of pacritinib for the treatment of myelofibrosis that will support regulatory submission for approval in the United States, or the U.S., and Europe.

**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 B-cell NHL. PIXUVRI is the first approved treatment in the E.U. for patients with multiply relapsed or refractory aggressive B-cell NHL who have failed two or three prior lines of therapy. In connection with the conditional marketing authorization, we are conducting the required post-approval commitment trial, which compares pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, Germany, Italy, France, Netherlands, Norway, Sweden and the United Kingdom, or the U.K. 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 U.S. We are pursuing potential partners for commercializing PIXUVRI in other markets, excluding countries in the E.U. where CTI has a commercial presence and the U.S.



Decisions by governmental authorities and healthcare providers will impact the price and market acceptance of PIXUVRI, as pricing and availability of prescription pharmaceuticals are subject to governmental control in almost all European markets. Accordingly, any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by the governmental authorities and healthcare providers in each country where PIXUVRI is available for sale and other factors. In February 2014, PIXUVRI received final guidance for funding and reimbursement from the National Institute for Health and Care Excellence in England/Wales. Previously, in December 2013, we reached agreement for funding and reimbursement with the National Association of Statutory Health Insurance Funds in Germany, and in the third quarter of 2013, PIXUVRI was granted market access in Italy and France.

---

**Table of Contents**

In January 2014, we reached an agreement with Novartis International Pharmaceutical Ltd., or Novartis, to reacquire rights to PIXUVRI and paclitaxel poliglumex (Opaxio<sup>®</sup>), or Opaxio. In exchange for Novartis' agreement to return such rights to us, which we had previously granted to Novartis in September 2006, we are obligated to make payments to Novartis based on net sales of Opaxio and PIXUVRI. For additional information on this agreement, please see the discussion in Part I, Item 2, License Agreements and Additional Milestone Activities - Novartis.

***Pacritinib***

Our lead development candidate, pacritinib, is an oral inhibitor of both Janus Kinase 2, or JAK2, and FMS-like tyrosine kinase (FLT3), which demonstrated meaningful clinical benefit and good tolerability in myelofibrosis patients in Phase 2 clinical trials. Myelofibrosis is a blood-related cancer caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response, scarring the bone marrow and limiting its ability to produce red blood cells prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue, itching and pain. We believe pacritinib may offer an advantage over other JAK inhibitors through effective relief of symptoms with less treatment-emergent thrombocytopenia and anemia.

In collaboration with Baxter International, Inc., or Baxter, pursuant to our worldwide license agreement to develop and commercialize pacritinib, or the Baxter Agreement, we are pursuing a broad approach to advancing pacritinib for patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, which was initiated in January 2013; and the other in patients with low platelet counts, the PERSIST-2 trial, which opened for enrollment in March 2014. In October 2013, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment for PERSIST-2. The trial, together with PERSIST-1, is intended to support registration in the U.S. and the E.U. For additional information on this agreement, please see the discussion in Part I, Item 2, License Agreements and Additional Milestone Activities - Baxter.

***Tosedostat***

Tosedostat is an oral aminopeptidase inhibitor that has demonstrated significant responses in patients with acute myeloid leukemia, or AML. It is currently being evaluated in several Phase 2 trials, which are being conducted as cooperative group sponsored and investigator-sponsored trials, or ISTs. These trials are evaluating tosedostat in combination with hypomethylating agents in AML and myelodysplastic syndrome, which are cancers of the blood and bone marrow. We anticipate that data from these signal-finding trials may be used to determine the appropriate design for a Phase 3 trial.

***Opaxio***

Opaxio is our novel biologically-enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. Taxanes, including paclitaxel (Taxol<sup>®</sup>) and docetaxel (Taxotere<sup>®</sup>), are widely used for the treatment of various solid tumors. Development of Opaxio is currently being conducted through cooperative group trials and ISTs focusing on ovarian cancer, glioblastoma multiforme and head and neck cancers. Opaxio is being evaluated in a Phase 3 trial, GOG-0212, as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This trial is being conducted and managed by the Gynecologic Oncology Group, or the GOG, which is one of the National Cancer Institute's funded cooperative cancer research groups focused on the study of gynecologic malignancies. For purposes of registration, the primary endpoint of this trial is overall survival of patients treated with Opaxio compared to no maintenance therapy. The statistical analysis plan calls for up to four

interim analyses and one final analysis, each with boundaries for early closure for superior efficacy or for futility. The first interim analysis was conducted in January 2013, which passed the futility boundary and continued with no changes. In January 2014, we were informed by the GOG that enrollment in the trial had been completed with 1,150 patients enrolled.

**Table of Contents****Financial summary**

Our product sales are currently generated solely from the sales of PIXUVRI in Europe. We recorded \$1.3 million in total net product sales for the three months ended March 31, 2014. Our product sales may vary significantly from period to period as the commercialization and reimbursement negotiations for PIXUVRI progress. Our loss from operations for the three months ended March 31, 2014 was \$27.7 million, compared to \$18.5 million for the same period in 2013. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

As of March 31, 2014, we had cash and cash equivalents of \$50.6 million and outstanding debt under our senior secured term loan agreement of \$15.0 million (with an option to borrow an additional \$5.0 million through October 31, 2014, subject to certain conditions). Please refer to Note 3, *Long-term Debt*, under Part I, Item 1 in this Quarterly Report on Form 10-Q, which note is incorporated herein by reference, for further information relating to our senior secured term loan agreement, including the amendment thereto that we entered into in March 2014.

**RESULTS OF OPERATIONS****Three months ended March 31, 2014 and 2013**

**Product sales, net.** Net product sales from PIXUVRI for the three months ended March 31, 2014 and 2013 were \$1.3 million and \$1.1 million, respectively. We sell PIXUVRI directly to health care providers and through a limited number of wholesale distributors in the E.U. Of our product sales during the three months ended March 31, 2014, 94 percent were made to a single customer. All sales of PIXUVRI during the periods presented were made in Europe. We generally record product sales upon receipt of the product by the health care provider or distributor at which time title and risk of loss pass. Product sales are recorded net of distributor discounts, estimated government-mandated discounts and rebates, trade discounts and estimated product returns. Any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by governmental authorities in each country where PIXUVRI is available for sale and other factors.

As of March 31, 2014, the balance from activity in returns, discounts and rebates is reflected in *accounts receivable* and *accrued expenses*. Balances and activity for the components of our gross to net sales adjustments for the three months ended March 31, 2014 are as follows (in thousands):

	Product returns	Rebates and other	Total
Balance at December 31, 2013	39	177	216
Provision for current period sales	3		3
Adjustments for prior period sales			
Payments/credits for current period sales			
Payments/credits for prior period sales		(69)	(69)
Balance at March 31, 2014	\$ 42	\$ 108	\$ 150

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

**License and contract revenue.** In connection with the consummation of the Baxter Agreement in 2013, we allocated \$2.7 million of the upfront payment we received under the Baxter Agreement and recorded such \$2.7 million amount as deferred revenue upon such consummation. We recognize *license and contract revenue* based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred. The development services under the Baxter Agreement are expected to be performed through approximately 2018, with the majority of development services expected to be completed by approximately the end of 2015. Of the initial \$2.7 million deferred revenue balance recorded upon consummation of the Baxter Agreement, approximately \$0.1 million was recognized as revenue during the three months ended March 31, 2014 and included in *license and contract revenue*. We had no such revenue during the three months ended March 31, 2013. The following table illustrates such balance of deferred revenue under the Baxter Agreement as of March 31, 2014 and December 31, 2013 (in thousands):

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Current portion of deferred revenue	\$ 1,043	\$ 1,010
Deferred revenue, less current portion	1,450	1,626
<b>Total deferred revenue</b>	<b>\$ 2,493</b>	<b>\$ 2,636</b>

**Table of Contents**

**Cost of product sold.** Cost of product sold for the three months ended March 31, 2014 and 2013 was \$145,000 and \$55,000 for the sales of PIXUVRI, respectively. We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional approval by The Committee for Medicinal Products for Human Use, or the CHMP, which is a committee of the EMA. The manufacturing costs of PIXUVRI product prior to receipt of the CHMP's positive opinion was expensed as research and development as incurred. While we tracked the quantities of individual PIXUVRI product lots, we did not track manufacturing costs in our inventory system prior to capitalization, and therefore the manufacturing cost of PIXUVRI produced prior to capitalization is not reasonably determinable. Most of this reduced-cost inventory is expected to be available for us to use commercially. The timing of the sales of such reduced-cost inventory and its impact on gross margin is dependent on the level of PIXUVRI sales as well as our ability to utilize this inventory prior to its expiration date. We expect that our cost of product sold as a percentage of product revenue will increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold. At this time, we cannot reasonably estimate the timing or rate of consumption of reduced-cost PIXUVRI product manufactured and expensed prior to capitalization.

**Research and development expenses.** Our research and development expenses for compounds under development and preclinical development for the three months ended March 31, 2014 and 2013 were as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Compounds under development:		
PIXUVRI	\$ 1,201	\$ 1,286
Pacritinib	5,964	1,989
Opaxio	107	548
Tosedostat	160	334
Brostallicin	1	2
Operating expenses	4,647	4,153
Research and preclinical development	99	43
<b>Total research and development expenses</b>	<b>\$ 12,179</b>	<b>\$ 8,355</b>

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 New Drug Applications or similar regulatory filings to the FDA, the EMA or other regulatory agencies outside the U.S. and Europe, as well as upfront license fees for acquired technology. Subsequent to receiving a positive opinion for conditional approval of PIXUVRI in the E.U. from the EMA's CHMP, costs associated with commercial batch production, quality control, stability testing, and certain other manufacturing costs of PIXUVRI were capitalized as inventory. Operating expenses include our personnel and an allocation of occupancy, depreciation and amortization expenses associated with developing these compounds. Research and preclinical development costs primarily include costs associated with external laboratory services associated with other compounds. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us as of March 31, 2014 were \$87.4 million for PIXUVRI (excluding costs prior to our merger with Novuspharma S.p.A in January 2004), \$18.7 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S\*BIO Pte Ltd, or S\*BIO, in May 2012 and \$29.1 million of in-process research and development expenses associated with such

acquisition), \$227.1 million for Opaxio, \$10.9 million for tosedostat (excluding costs for tosedostat prior to the effectiveness of the Chroma License Agreement (see License Agreements and Additional Milestone Activities Chroma Therapeutics, Ltd. below)) and \$9.6 million for brostallicin (excluding costs for brostallicin prior to our acquisition of Systems Medicine, LLC in July 2007).

---

**Table of Contents**

Research and development expenses increased to \$12.2 million for the three months ended March 31, 2014 compared to \$8.4 million for the three months ended March 31, 2013. PIXUVRI costs decreased primarily due to a reduction in clinical development costs associated with the PIX306 trial, our on-going confirmatory trial for PIXUVRI in the E.U. This decrease was partially offset by an increase in medical affairs activities in the E.U. Costs for pacritinib increased primarily due to clinical development start-up costs associated with the PERSIST-2 trial, in addition to site initiation, patient enrollment and other clinical development costs associated with the PERSIST-1 trial. Costs associated with pacritinib manufacturing and medical affairs activities also increased between periods. Costs for our Opaxio program decreased primarily due to completion of the required patient enrollment in the GOG-0212 trial during the period ended March 31, 2014, in addition to a reduction in manufacturing costs. Development costs for tosedostat decreased primarily due to a reduction in clinical development activity associated with the Chroma License Agreement. Operating expenses included in research and development expenses increased primarily due to an increase in non-cash share-based compensation and discretionary bonus expense. These increases were partially offset by a decrease in 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 will need to commit significant time and resources to develop our current and any future product candidates. Our drug candidates pacritinib, tosedostat and Opaxio are currently in clinical development, and our product PIXUVRI, which is currently being commercialized in parts of Europe, is undergoing a post-approval commitment study. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. We are unable to provide the nature, timing and estimated costs of the efforts necessary to complete the development of pacritinib, tosedostat and Opaxio, and to complete the post-approval commitment study of PIXUVRI, because, among other reasons, we cannot predict with any certainty the pace of patient enrollment of our clinical trials, which is a function of many factors, including the availability and proximity of patients with the relevant condition. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. Even after a clinical trial is enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Even if our drugs progress successfully through initial human testing in clinical trials, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. For these reasons, among others, we cannot estimate the date on which clinical development of our product candidates will be completed, if ever, or when we will generate material net cash inflows from PIXUVRI or be able to begin commercializing pacritinib, Opaxio or tosedostat to generate material net cash inflows. In order to generate revenue from these products, our product candidates need to be developed to a stage that will enable us to commercialize, sell or license related marketing rights to third parties.

We are also unable to control the amount and timing of resources any of our collaborators devote to product candidates, where applicable, which may result in delays in the development or marketing of products. Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in our risk factors, which begin on page 28 of this Quarterly Report on Form 10-Q and, in particular, in the following risk factors: *If our collaboration with Baxter with respect to pacritinib or any other collaboration for our products or product candidates is not successful, or if we are unable to enter into additional collaborations, we may not be able to effectively develop and/or commercialize the applicable product(s), which could have a material adverse effect on our business.* , Product



*candidates that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all. ; We or our collaboration partners may not obtain or maintain the regulatory approvals required to commercialize some or all of our products. ; Even if our drug candidates are successful in clinical trials and receive regulatory approvals, we or our collaboration partners may not be able to successfully commercialize them. ; and Even if our 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 products, including PIXUVRI.*

## **Table of Contents**

***Selling, general and administrative expenses.*** Selling, general and administrative expenses were \$16.8 million for the three months ended March 31, 2014 as compared to \$11.1 million for the three months ended March 31, 2013. This increase was primarily due to a \$5.0 million increase in non-cash share-based compensation, a \$0.6 million increase related to our provision for value added tax, or VAT, assessments associated with our Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe) branch, and a \$0.5 million increase in compensation and benefits mainly related to an increase in the average number of personnel between comparable periods. These increases were partially offset by a \$0.6 million decrease in advertising and promotional expenses associated with the commercial launch of PIXUVRI in the E.U.

***Settlement expense.*** For the three months ended March 31, 2013, we recorded \$0.1 million in settlement expense related to an agreement entered into with one of our former executive officers for severance payments and related benefits upon such officer's separation from us in the prior year and attorneys' fees in connection with a shareholder lawsuit. There was no settlement expense for the corresponding period in 2014.

***Interest expense.*** Interest expense increased for the three months ended March 31, 2014 as compared to the three months ended March 31, 2013. This increase was primarily due to interest incurred on our senior secured term loan issued in March 2013 and December 2013.

***Amortization of debt discount and issuance costs.*** Amortization of debt discount and issuance costs for the three months ended March 31, 2014 and 2013 is related to the amortization of debt discount and issuance costs incurred on our senior secured term loan originally issued in 2013.

***Foreign exchange loss.*** The foreign exchange losses for the three months ended March 31, 2014 and 2013 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

***Other expense.*** The expense amount for the three months ended March 31, 2014 is primarily related to the change in fair value of the warrant issued to Hercules Technology Growth Capital, Inc. The expense amount for the three months ended March 31, 2013 is primarily related to loss on disposal of property and equipment.

## **LIQUIDITY AND CAPITAL RESOURCES**

### ***Overview***

***Cash and cash equivalents.*** As of March 31, 2014, we had \$50.6 million in cash and cash equivalents.

***Net cash used in operating activities.*** Net cash used in operating activities increased to \$20.8 million during the three months ended March 31, 2014 as compared to \$15.3 million for the same period in 2013. The change is primarily due to an increase in research and development activities related to pacritinib in the first quarter of 2014, an increase in interest paid on our long term debt and a refund of a VAT deposit received during the first quarter of 2013.

***Net cash used in investing activities.*** Net cash used in investing activities decreased to \$35,000 for the three months ended March 31, 2014 compared to \$972,000 for the same period in 2013 due to a decrease in purchases of property and equipment.

***Net cash provided by (used in) financing activities.*** Net cash used in financing activities was \$0.2 million for the three months ended March 31, 2014. Net cash provided by financing activities of \$9.6 million for the three months ended March 31, 2013 was primarily due to the issuance of long-term debt during the period.

In March 2013, we entered into a Loan and Security Agreement, or the Loan and Security Agreement, with Hercules Technology Growth Capital, Inc. for a senior secured term loan of up to \$15.0 million. The first \$10.0 million was funded in March 2013, and we exercised our option to borrow an additional \$5.0 million in December

**Table of Contents**

2013. In March 2014, we entered into a First Amendment, or the Amendment, to Loan and Security Agreement (and as amended by the Amendment, the Loan Agreement) with Hercules Capital Funding Trust 2012-1, which was assigned from the original lender, Hercules Technology Growth Capital, Inc. The Amendment modifies certain terms of the original loan including the grant of an option to borrow an additional \$5.0 million, or the 2014 Term Loan Availability, through October 31, 2014, subject to certain conditions. As of the time of this filing, we have not borrowed the funds underlying the 2014 Term Loan Availability. As used in this Quarterly Report on Form 10-Q, senior secured term loan agreement and senior secured term loan refer to the Loan Agreement and the term loan provided thereunder, respectively. For additional information on the Loan Agreement, please refer to Note 3, *Long-term Debt*, under Part I, Item 1 in this Quarterly Report on Form 10-Q.

***Capital Resources and Requirements***

As of March 31, 2014, our available cash and cash equivalents were \$50.6 million, and we had \$15.0 million in debt outstanding under our senior secured term loan agreement (with an option to borrow an additional \$5.0 million through October 31, 2014, subject to certain conditions). At our currently planned spending rate, we believe that our present financial resources, together with potential pacritinib milestone payments projected to be earned and received over the course of 2014 and 2015 under our collaboration with Baxter, and expected European sales from PIXUVRI, will be sufficient to fund our operations into the third quarter of 2015. However, our future capital requirements will depend on many factors, including:

changes in manufacturing;

results of, and other developments with respect to, our clinical trials (including changes in clinical trial expenses);

acquisitions of compounds or other assets;

any expansion of our sales and marketing organization in Europe;

activities with respect to regulatory approvals;

failure to receive projected milestone payments in connection with our compounds;

failure to achieve projected sales of PIXUVRI; and

other unplanned business developments.

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



**Table of Contents**

We expect that we will need to raise additional funds to develop our business. We may seek to raise such capital through equity or debt financings, partnerships, collaborations, joint ventures, disposition of assets or other sources. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. Additional funding may not be available on favorable terms or at all. If we fail to obtain additional capital when needed, we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses and/or refrain from making our contractually required payments 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 March 31, 2014 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases:					
Facilities	\$ 19,524	\$ 2,516	\$ 4,671	\$ 4,656	\$ 7,681
Long-term debt	15,000	2,831	12,169		
Interest on long-term debt(1)	3,111	1,807	1,304		
Purchase commitments(2)	2,292	2,239	53		
Other obligations(3)	1,335	53	1,282		
	\$ 41,262	\$ 9,446	\$ 19,479	\$ 4,656	\$ 7,681

- (1) The interest rate on our long-term debt currently floats at a rate per annum equal to 12.25% plus the amount by which the prime rate exceeds 3.25%. The amounts presented for interest payments in future periods assume a prime rate of 3.25%.
- (2) Purchase commitments include obligations related to manufacturing supply, insurance and other purchase commitments.
- (3) Other obligations do not include \$4.7 million deferred rent associated with our operating lease for office space. Some of our licensing agreements obligate us to pay a royalty on net sales of products utilizing licensed technology. Such royalties are dependent on future product sales and are not provided for in the table above as they are not estimable. For additional information, please see discussion below in License Agreements and Additional Milestone Activities.

**LICENSE AGREEMENTS AND ADDITIONAL MILESTONE ACTIVITIES***Baxter*

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

Baxter granted to us a non-exclusive license in order for us to perform our rights and obligations under the Baxter Agreement, including our co-promotion rights in the U.S. and manufacturing obligations.

Baxter paid us an upfront payment of \$60 million, which included a \$30 million investment in our equity. We are also eligible to receive potential payments of up to \$302 million upon the successful achievement of certain development and commercialization milestones, comprised of \$112 million of potential clinical, regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to \$190 million. Of such milestones, \$67 million relates to clinical progress milestones. We and Baxter will jointly commercialize and share profits and losses on sales of pacritinib in the U.S.

We were responsible for all development costs incurred prior to January 1, 2014, and will be responsible for approximately \$96 million in U.S. and E.U. development costs incurred on or after January 1, 2014. Of such \$96 million

---

**Table of Contents**

in development costs, we anticipate that up to \$67 million will be offset through the potential receipt from Baxter through 2015 of the aforementioned clinical progress milestones. All development costs exceeding the \$96 million threshold will generally be shared as follows: (i) costs generally applicable worldwide will be shared 75 percent to Baxter and 25 percent to us, (ii) costs applicable to territories exclusive to Baxter will be 100 percent borne by Baxter and (iii) costs applicable exclusively to co-promotion in the U.S. will be shared equally between the parties, subject to certain exceptions.

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

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

The Baxter Agreement also requires Baxter and us to negotiate and enter into a Manufacturing and Supply Agreement, which will provide for the manufacture of the licensed products, with an option for Baxter to finish and package encapsulated bulk product, within 180 days of the effective date of the Baxter Agreement.

*University of Vermont*

We entered into an agreement with the University of Vermont, or UVM, in March 1995, as amended, or the UVM Agreement, which grants us an exclusive license, with the right to sublicense, for the rights to PIXUVRI. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use PIXUVRI, and we are obligated to make royalty payments to UVM ranging from low single-digits to mid single-digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of PIXUVRI, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the first sale of PIXUVRI in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement in the event of an uncured material breach of the UVM Agreement by the other party or in the event of bankruptcy of the other party.



*S\***BIO***

We acquired the compounds SB1518 (which is referred to as pacritinib ) and SB1578, which inhibit JAK2, from S\***BIO** in May 2012. Under our agreement with S\***BIO**, we are required to make milestone payments to S\***BIO** up to an aggregate amount of \$132.5 million if certain U.S., E.U. and Japanese regulatory approvals are

---

**Table of Contents**

obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any compound that we acquired from S\*BIO for use for specific diseases, infections or other conditions. At our election, we may pay up to 50 percent of any milestone payments to S\*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock. In addition, S\*BIO will also be entitled to receive royalty payments from us at incremental rates in the low single-digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis.

*Chroma Therapeutics, Ltd.*

We entered into an agreement, or the Chroma License Agreement, with Chroma Therapeutics, Ltd., or Chroma, 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 collectively, the Licensed Territory. Pursuant to the terms of the Chroma License Agreement, we are required to make a milestone payment to Chroma 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 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. Royalties commence on the first commercial sale of tosedostat in any country in the Licensed Territory and continue with respect to that country until the latest of the expiration date of the last patent claim, 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 are responsible for performing the development operations and commercialization activities in the Licensed Territory, and Chroma will oversee and is responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory. We will be responsible for 75 percent of all development costs, while Chroma will be responsible for 25 percent of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in accordance with the terms of our supply agreement with Chroma. 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. As discussed in Part II, Item 1, Legal Proceedings, the parties have certain disputes arising under the Chroma License Agreement, although no court proceedings have commenced as of the time of this filing.

*Gynecologic Oncology Group*

We entered into an agreement with the GOG in March 2004, as amended, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, which the GOG is conducting. We recorded a \$0.9 million obligation due to the GOG based on the 1,100 patient enrollment milestone achieved in the third quarter of 2013, of which \$0.4 million remained in accounts payable as of March 31, 2014 (and was subsequently paid in April 2014). In the first quarter of 2014, we also recorded a \$0.3 million obligation to the GOG as required under the agreement based on the additional 50 patients enrolled, with such amount being included in accounts payable as of March 31, 2014 (and subsequently paid in April 2014). We may be required to pay up to an additional \$1.0 million upon the attainment of certain other milestones, of which \$0.5 million has been recorded in accrued expenses as of March 31, 2014.

*PG-TXL*

In November 1998, we entered into an agreement, or the PG-TXL Agreement, with PG-TXL Company, L.P., or PG-TXL, as amended, which grants us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL's polymer technology. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we are obligated to make payments to PG-TXL upon the achievement of certain development

---

**Table of Contents**

and regulatory milestones of up to \$14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement is based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we are required to make royalty payments to PG-TXL based on net sales. Our royalty payments range from low to mid single-digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are payable to PG-TXL. We may terminate the PG-TXL Agreement upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans, or for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement upon advance written notice in the event certain license fee payments are not made; in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or in the event of liquidation or bankruptcy of a party.

*Novartis*

In January 2014, we entered into a termination agreement, or the Termination Agreement, with Novartis to reacquire the rights to PIXUVRI and Opaxio, or collectively, the Compounds, previously granted to Novartis under our License and Co-Development Agreement with Novartis entered into in September 2006, as amended, or the Original Agreement. Pursuant to the Termination Agreement, the Original Agreement was terminated in its entirety, except for certain customary provisions, including those pertaining to confidentiality and indemnification, which survive termination.

Under the Termination Agreement, we agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of the Compounds unless the recipient thereof agrees to be bound by the terms of the Termination Agreement. We also agreed to provide potential payments to Novartis, including a percentage ranging from the low double-digits to the mid-teens, of any consideration received by us or our affiliates in connection with any transfer, license, sublicense or other grant of rights with respect to intellectual property of PIXUVRI or Opaxio, respectively; provided that such payments will not exceed certain prescribed ceilings in the low single-digit millions. Novartis is entitled to receive potential payments of up to \$16.6 million upon the successful achievement of certain sales milestones of the Compounds. We are also obligated to pay to Novartis tiered low single-digit percentage royalty payments for the first several hundred million in annual net sales, and ten percent royalty payments thereafter based on annual net sales of each Compound, subject to reduction in the event generic drugs are introduced and sold by a third party, causing the sale of PIXUVRI or Opaxio to fall by a percentage in the high double-digits. To the extent we are required to pay royalties on net sales of Opaxio pursuant to the PG-TXL Agreement, we may credit a percentage of the amount of such royalties paid to those payable to Novartis, subject to certain exceptions. Notwithstanding the foregoing, royalty payments for both PIXUVRI and Opaxio are subject to certain minimum floor percentages in the low single-digits.

*Nerviano Medical Sciences*

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

*Cephalon*

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon. Cephalon was subsequently acquired by Teva Pharmaceutical Industries Ltd., or Teva. Under this agreement, we have the right to receive up to \$100 million in payments upon achievement by Teva of specified sales and development milestones related to TRISENOX. In November 2013, we received a \$5.0 million payment related to achievement of a sales milestone.

---

**Table of Contents****Critical Accounting Estimates**

We make certain judgments and use certain estimates and assumptions when applying accounting principles generally accepted in the U.S. in the preparation of our condensed consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary materially from what we anticipate and different assumptions or estimates about the future could change our reported results. There have been no material changes to our critical accounting estimates discussed in our 2013 Form 10-K. For a discussion of our critical accounting estimates, please see Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of our 2013 Form 10-K.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk***Foreign Exchange Market Risk*

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars for financial reporting purposes. Changes in the value of the U.S. dollar as compared to the euro might have an adverse effect on our reported results of operations and financial condition. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. In addition, the reported carrying value of our euro denominated assets and liabilities held in our European branches and subsidiaries will be affected by fluctuations in the value of the U.S. dollar compared to the euro. As of March 31, 2014, we had a net asset balance, excluding intercompany payables and receivables, in our European branches and subsidiaries denominated in euros. If the euro were to weaken 20 percent against the dollar, our net asset balance would decrease by approximately \$2.4 million as of this date.

*Interest Rate Risk*

As of March 31, 2014, we had an outstanding balance under our senior secured term loan of \$15.0 million, and we have the option to borrow an additional \$5.0 million through October 31, 2014, subject to certain conditions. The senior secured term loan bears interest at variable rates. Based on the outstanding amount under such loan at March 31, 2014 of \$15.0 million (which remains outstanding as of the time of this filing) a 1.0 percent increase in interest rates 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 Part I, Item 1 in this Quarterly Report on Form 10-Q.

**Item 4. Controls and Procedures****(a) Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission, or the SEC, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only

reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our President and Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our President and Chief Executive Officer and EVP of Finance have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

**Table of Contents**

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the first fiscal quarter ended March 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



---

**Table of Contents****PART II OTHER INFORMATION****Item 1. Legal Proceedings**

On December 10, 2009, the Commissione Nazionale per le Società e la Borsa (which is the public authority responsible for regulating the Italian securities markets), or CONSOB, sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanction established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violation could require us to pay a pecuniary administrative sanction amounting to between \$7,000 and \$684,000 upon conversion from euros as of March 31, 2014. Until CONSOB's right is barred, CONSOB may, at any time, confirm the occurrence of the asserted violation and apply a pecuniary administrative sanction within the foregoing range. To date, we have not received any such notification.

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case, although we can make no assurances regarding the ultimate outcome of these cases. If the final decision of the Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to 9.4 million, or approximately \$12.9 million converted using the currency exchange rate as of March 31, 2014, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment.

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. In March 2014, we paid a deposit in respect of the 2003 VAT matter of 0.4 million, or approximately \$0.6 million upon conversion from euros as of the date of payment following the ITA's request for such payment.

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

2006 VAT. In October 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2007 VAT case) in which it (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us

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

---

**Table of Contents**

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 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. The ITA appealed such decision in November 2013.

In July 2012, Chroma sent us a letter claiming that we breached the Chroma License Agreement by allegedly making decisions as to the development of tosedostat without requisite approval, failing to hold certain meetings and not using diligent efforts to develop tosedostat. We dispute the allegations on numerous grounds; in particular, we believe Chroma failed to comply with certain of its antecedent obligations and failed to demonstrate an ability to manufacture tosedostat to requisite standards. A party may terminate the Chroma License Agreement for a material breach only after arbitration. Court proceedings have not been initiated 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.

**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 expect that we will need to raise additional financing to develop our business, 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 the commercialization of PIXUVRI, and we have significant contractual payment obligations. Our available cash and cash equivalents were \$50.6 million as of March 31, 2014. At our currently planned spending rate, we believe that our present financial resources, together with potential pacritinib milestone payments projected to be earned and received over the course of 2014 and 2015 under our collaboration with Baxter and expected European sales from PIXUVRI, will be sufficient to fund our operations into the third quarter of 2015. Cash forecasts and capital requirements are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, clinical trial expenses, acquisitions of compounds or other assets, any expansion of our sales and marketing organization in Europe, activities with respect to regulatory approvals and other unplanned business developments may consume capital resources earlier than planned. Additionally, we may not receive the anticipated pacritinib milestone payments or sales from PIXUVRI. Due to these and other factors, our forecast for the period for which we will have sufficient resources to

fund our operations, as well as any other operational or business projection we have disclosed, or may, from time to time, disclose, may fail.

We have \$15.0 million outstanding under our senior secured term loan agreement and have an option to borrow an additional \$5.0 million through October 31, 2014, subject to certain conditions. Based on the current outstanding balance, we are required to make monthly interest payments of approximately \$158,000, and commencing November 1, 2014 through October 1, 2016, we will be required to make monthly interest plus principal payments in the aggregate amount of approximately \$709,000. The senior secured term loan agreement

**Table of Contents**

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 expect that we will need to acquire additional funds in order to develop our business, including in the event our costs are greater than anticipated or our cash inflow projections fail, or in the event we seek to expand our operations. 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 convertible securities is restricted by the limited number of our residual authorized shares, the difficulty of obtaining shareholder approval to increase authorized shares, and the restrictive covenants of our senior secured term loan agreement;

issuance of equity securities or convertible securities will dilute the proportionate ownership of existing shareholders;

our ability to raise debt capital is limited by our existing senior secured term loan agreement;

some of such arrangements may require us to relinquish rights to certain assets; and

we may be required to meet additional regulatory requirements, and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain funding.

For these and other reasons, additional funding may not be available on favorable terms or at all. If we fail to obtain additional capital when needed, we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses and/or refrain from making our contractually required payments when due, which could harm our business, financial condition, operating results and prospects.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of March 31, 2014, we had an accumulated deficit of \$1.9 billion. We are pursuing regulatory approvals for PIXUVRI, pacritinib, tosedostat and Opaxio. We will need to continue to conduct research, development, testing and regulatory compliance activities and procure manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. There can be no assurances that we will ever achieve profitability.

*If our collaboration with Baxter with respect to pacritinib or any other collaboration for our products or product candidates is not successful, or if we are unable to enter into additional collaborations, we may not be able to effectively develop and/or commercialize the applicable product(s), which could have a material adverse effect on our*

*business.*

Under the Baxter Agreement, we rely heavily on Baxter to collaborate with us in respect of the development and global commercialization of our lead product candidate, pacritinib. As a result of our dependence on our relationship with Baxter, the eventual success or commercial viability of pacritinib is, to a certain extent, beyond our control. We are subject to a number of specific risks associated with our dependence on our collaborative relationship with Baxter, including: possible disagreements between Baxter and us as to the timing, nature and extent of our development plans, including clinical trials or regulatory approval strategy; changes in personnel at Baxter who are key to the collaboration efforts; any changes in Baxter's business strategy adverse to our interests; and possible disagreements with Baxter regarding ownership of proprietary rights. Furthermore, the contingent financial returns under our collaboration with Baxter depend in large part on the achievement of development and commercialization milestones, plus a share of revenues from any sales. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large in part on the performance of both Baxter and us under the Baxter Agreement.

**Table of Contents**

The continued development of our other compounds also depends on our ability to enter into and/or maintain collaborations. We have entered into a third-party service provider agreement with Quintiles Commercial Europe Limited, which provides a variety of services related to the commercialization of PIXUVRI in Europe. We are also pursuing potential partners for commercializing PIXUVRI in other markets, excluding countries in the E.U. where CTI has a commercial presence and the U.S. 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 the GOG, to perform a Phase 3 trial of Opaxio in patients with ovarian cancer.

If we fail to enter into additional collaborative arrangements or 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.

*Product candidates that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all.*

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

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

difficulties in formulating a product candidate, scaling the manufacturing process and obtaining manufacturing approval, pricing, reimbursement issues or other factors that may make the product uneconomical to commercialize;

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

inefficient cost structure of a product candidate compared to alternative treatments;

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

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

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

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

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

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



**Table of Contents**

If the development of our product candidates is delayed or fails, our development costs may increase and the ability to commercialize our product candidates may be harmed, which could harm our business, financial condition, operating results or prospects.

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

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other states and countries, including the EMA in the E.U. Pacritinib and our other product candidates are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the E.U., we have not received marketing approval for our compounds (and we are not currently pursuing FDA marketing approval of PIXUVRI). Information about the status of regulatory approvals of our compounds can be found in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations and is incorporated by reference herein. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other 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 or our collaboration partners may not be able to successfully commercialize them.*

Pacritinib, Opaxio and tosedostat are currently in clinical trials; the development and clinical trials of these products may not be successful and, even if they are, such products may never be successfully developed into commercial products. 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;

**Table of Contents**

they may be difficult to manufacture on a scale necessary for commercialization;

they may be uneconomical to produce;

we may fail to obtain reimbursement amount approvals or pricing that is cost effective for patients as compared to other available forms of treatment;

they may not compete effectively with existing or future alternatives to our products;

we 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. In particular, with respect to the future potential commercialization of pacritinib, we will be heavily dependent on our collaboration partner, Baxter. Under the terms of our agreement, Baxter has exclusive commercialization rights for all indications for pacritinib outside the U.S., while we share commercialization rights with Baxter in the U.S.

The failure of Baxter (or any other applicable collaboration partner) to fulfill its commercialization obligations with respect to a product, or the occurrence of any of the events itemized in the foregoing list, could adversely affect the commercialization of our products. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

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

To the extent our products are successfully introduced 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 payors 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 is and will be determined by national regulatory authorities. 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 in other European markets. The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, 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 on the commercial success in Europe of our only marketed product candidate, PIXUVRI. PIXUVRI is not approved for marketing in the U.S. PIXUVRI is available to healthcare providers in certain countries in Europe. See Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations for a discussion of the reimbursement status in applicable European countries. However, our ability to continue to commercialize PIXUVRI in the E.U. will depend on our ability to obtain an annual renewal of our conditional marketing authorization for PIXUVRI and to timely complete the post-marketing study of PIXUVRI aimed at confirming the clinical benefit previously observed in PIXUVRI. A failure of such study could result in a cessation of commercialization of PIXUVRI in the E.U.

**Table of Contents**

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

increase and maintain demand for and sales of PIXUVRI in Europe and obtain greater acceptance of PIXUVRI by physicians and patients;

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

maintain, and enter into additional, commercial manufacturing arrangements with third-parties, cost-effectively manufacture necessary quantities and build distribution, managerial and other capabilities; and

further develop and maintain a commercial organization to market PIXUVRI.

If we are unable to successfully commercialize PIXUVRI in Europe as planned, 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 develop our business 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 MTA in Italy, or trading on these exchanges may otherwise be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.*

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

If our common stock ceases to be listed for trading on The NASDAQ Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. Our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under our senior secured term loan and any future indebtedness, which would accelerate the maturity date of such debt or trigger other obligations. In addition, certain institutional investors that are not permitted to own securities of non-listed companies may be required to sell their shares adversely affecting the trading price of our common stock. If we are not listed on The NASDAQ Capital Market or if our public float falls below \$75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so

## Table of Contents

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, CONSOB or the Borsa Italiana (which ensures the development of the managed markets in Italy). Any halt or suspension in the trading in our common stock may negatively impact the 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 percent of the total shares of our common stock outstanding before the issuance of such securities sold at a discount to the greater of book or market value in an offering that is not deemed to be a public offering by the NASDAQ Marketplace Rules or NASDAQ as well as under certain other circumstances. We have in the past and may in the future issue additional equity securities that would comprise more than 20 percent of the total shares of our common stock outstanding in order to fund our operations. However, we might not be successful in obtaining the required shareholder approval for any future issuance that requires shareholder approval pursuant to 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.

*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



---

**Table of Contents**

percent of the number of shares of our common stock outstanding at the beginning of that period, subject to certain exceptions. If we are unable to obtain and maintain a registration document, securities note or summary to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. For example, we have 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 percent limitation imposed by E.U. and Italian law. However, any changes to Italian regulatory requirements, exemptions or interpretations may increase compliance costs or limit our ability to issue securities.

*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 in Italy, we are required to also comply with the rules and regulations of CONSOB and the Borsa Italiana, which regulate companies listed on Italy's public markets. Compliance with these regulations and responding to periodic information requests from Borsa Italiana and CONSOB requires us to devote additional time and resources to regulatory compliance matters and to incur additional expenses of engaging additional outside counsel, accountants and other professional advisors. Actual or alleged failure to comply with Italian regulators can also subject us to regulatory investigations. For more information on 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 acquisitions.*

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. Any acquisitions could result in potentially dilutive issuances of equity securities, including common stock and preferred stock, the incurrence of debt, contingent liabilities and/or amortization expenses related to intangible assets, which could harm our business, financial condition, operating results or prospects. In addition, following any acquisition our results of operations and the market price of our common stock may be affected by factors different from those that affected our results of operations and the market price of our common stock prior to such acquisition.

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

Our European operations are subject to the VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was \$5.8 million and \$5.7 million as of March 31, 2014 and December 31, 2013, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the ITA issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million. While we are defending ourselves against the assessments both on procedural grounds and on the merits of the case, there can be no assurances that we will be successful in such defense. Further information pertaining to these cases can be found in Part II, Item 1, Legal Proceedings and is incorporated by reference herein. If the final decision of the Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in

suspending collection efforts, we may be requested to pay to the ITA an amount up to 9.4 million (or approximately \$12.9 million converted using the currency exchange rate as of March 31, 2014) plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment.

---

**Table of Contents**

*Even if our 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 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 E.U. or we are unable to renew our conditional marketing authorization for PIXUVRI in the E.U., our business, financial condition, operating results and prospects would be harmed.

*We cannot predict the outcome of our post-approval commitment trial for PIXUVRI, and any failure thereof, as well as any additional clinical trials or actions we may need to pursue to obtain approval in the E.U. or otherwise, may negatively affect our business, financial condition, operating results or prospects.*

In March 2011, we initiated a randomized pivotal trial of PIXUVRI for the treatment of relapsed or refractory aggressive B-cell NHL. This post-approval commitment trial, referred to as PIX-R, or PIX306, compares 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. 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 trial data from PIX306 by June 2015, it may result in the withdrawal of the conditional marketing authorization for PIXUVRI by the E.U. We may also need to take additional steps to obtain regulatory approval of PIXUVRI. The expense to design and conduct clinical trials are substantial, and any failure of PIX306, as well as any additional clinical trials or actions we may need to pursue to obtain approval of PIXUVRI in the E.U. or otherwise, may negatively affect our business, financial condition, operating results or prospects.

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

Our business and future growth depend on the development, 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 U.S., we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome, generate negative publicity and may result in fines or payments of settlement awards. For example, in April 2007, we paid a civil penalty of \$10.6 million and entered into a settlement agreement with the USAO for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of the Inspector General, Health and Human Services, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities.

## **Table of Contents**

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

In addition, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our drugs. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. Many states have also adopted laws similar to the federal Anti-Kickback Statute and False Claims Act.

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

*We are dependent on third-parties for a number of significant activities including, in particular, for the manufacture, testing and distribution of products and product candidates and associated activities. Any failure or delay in these undertakings by third-parties could harm our business.*

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships, including, in particular, for the manufacture, testing and distribution of products and product candidates and associated activities. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of drug products in compliance with current Good Manufacturing Practices, or cGMPs. As a result, we rely on third party vendors for manufacturing services, as well as for certain warehousing, transportation, order processing and cash collection services. In particular, we are dependent on a single vendor for the manufacturing of each of PIXUVRI, pacritinib and tosedostat. With respect to Opaxio, we are relying on stored inventory of the drug, as we do not presently have a manufacturing agreement in place for this product candidate. Because we do not have a manufacturing infrastructure, we are dependent upon our vendors to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of such regulatory authorities may take action against a contract manufacturer who violates cGMPs. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

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

## Table of Contents

*We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them.*

Competition in the oncology market is intense and is accentuated by the rapid pace of technological and product development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the U.S. and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically:

In Europe, PIXUVRI faces competition from existing treatments for adults with multiply relapsed or refractory aggressive B-cell NHL. For example, patients are currently being treated with bendamustine, oxaliplatin and gemcitabine, although these particular agents do not have regulatory approval in Europe for the foregoing indication. If we were to pursue bringing PIXUVRI to market in the U.S. (which is not currently part of our near-term plan), PIXUVRI would face similar competition. In addition, PIXUVRI may face competition in the E.U. (and, if applicable in the future, the U.S.) if new anti-cancer drugs with reduced toxicity and/or increased efficacy are developed and marketed in the E.U. and/or the U.S.

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

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

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

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 U.S., we are subject to substantial pricing, reimbursement and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Patient Protection and Affordable Care Act (HR 3590) instituted comprehensive health care reform in 2010 and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. These measures 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 could further negatively affect our pricing and reimbursement for, or access to, our products.



**Table of Contents**

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 payors' 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 and patents relating to intellectual property for PIXUVRI, pacritinib and tosedostat. We have also licensed the intellectual property for our drug delivery technology relating to Opaxio, which uses polymers that are linked to drugs known as polymer-drug conjugates. Some of our product development programs depend on our ability to maintain rights under these 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 acquire additional product candidates, our future product portfolio and potential profitability could be harmed.*

One component of our business strategy is the in-licensing and acquisition of drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. PIXUVRI, pacritinib, tosedostat and Opaxio have all been in-licensed or acquired from third-parties. Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing or acquisition opportunities and

enter into arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

*We hold rights under numerous patents that we have acquired or licensed or that protect inventions originating from our research and development, and the expiration of any one or more of these patents may allow our competitors to copy the inventions that are currently protected.*

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research

**Table of Contents**

and development, and we have also obtained rights to various patents and patent applications under licenses with third parties and through acquisitions. Patents have been issued on many of these applications. We have pending patent applications or issued patents in the U.S. and foreign countries directed to PIXUVRI, pacritinib, tosedostat, Opaxio and other product candidates. However, the lives of these patents are limited. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The patent status of our compounds follows:

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

Our U.S. and various foreign pacritinib-directed patents expire from 2026 through 2029.

Our tosedostat-directed U.S. and Canadian patents expire from 2017 to 2018, while our tosedostat-directed patents in Mexico expire in 2020.

Our U.S. and various foreign Opaxio-directed patents expire on various dates ranging from 2017 through 2018.

Our U.S. and various foreign brostallicin-directed patents expire on various dates ranging between 2017 through 2021.

In the absence of a patent, as in the case of PIXUVRI in the U.S., we will, to the extent possible, need to rely on unpatented technology, know-how and confidential information. Ultimately, the lack or expiration at any given time of a patent to protect our compounds may allow our competitors to copy the underlying inventions and better compete with us.

*If we fail to adequately protect our intellectual property, our competitive position could be harmed.*

Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to:

obtain and maintain patent protection for our products or processes both in the U.S. and other countries;

protect trade secrets; and

prevent others from infringing on our proprietary rights.

The patent position of 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 U.S. and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents, and the claims of any

## Table of Contents

issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. Third parties may independently develop such know-how or otherwise obtain access to our technology. While we require our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

*Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business.*

Costly litigation might be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology. With respect to our in-licensed patents, if we attempt to initiate a patent infringement suit against an alleged infringer, it is possible that our applicable licensor will not participate in or assist us with the suit and as a result we may not be able to effectively enforce the applicable patents against the alleged infringers.

*We may be unable to obtain or protect our intellectual property rights and we may be liable for infringing upon the intellectual property rights of others, which may cause us to engage in costly litigation and, if unsuccessful, could cause us to pay substantial damages and prohibit us from selling our products.*

At times, we may monitor patent filings for patents that might be relevant to some of our products and product candidates in an effort to guide the design and development of our products to avoid infringement, but may not have conducted an exhaustive search. We may not be able to successfully challenge the validity of third-party patents and could be required to pay substantial damages, possibly including treble damages, for past infringement and attorneys fees if it is ultimately determined that our products infringe such patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties.

Moreover, third parties may challenge the patents that have been issued or licensed to us. We do not believe that PIXUVRI, pacritinib or any of the other compounds we are currently developing infringe upon the rights of any third parties nor are they infringed upon by third parties; however, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements or redesign our drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from any third parties. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Even if infringement claims against us are without merit, or if we challenge the validity of issued patents, lawsuits take significant time, may, even if resolved in our favor, be expensive and divert management attention from other

business concerns. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

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

## Table of Contents

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, we are currently engaged in a number of pending legal matters. Litigation is subject to inherent uncertainties, and unfavorable rulings could occur. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. It is possible that our financial condition and operating results could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable, and if an unfavorable ruling were to occur in any of the legal proceedings we are or may be subject to, our business, financial condition, operating results and prospects could be harmed. We are subject to a variety of claims and lawsuits from time to time, some of which arise in the ordinary course of our business. The ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future.

Securities class action and shareholder derivative lawsuits are often instituted against issuers, 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. If any raw material required to produce a product or product candidate is insufficient in quantity or quality, if a supplier fails to deliver in a timely fashion or at all or if these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

*Because there is a risk of product liability associated with our products, we face potential difficulties in obtaining insurance, and if product liability lawsuits were to be successfully brought against us, our business may be harmed.*

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products. In particular, as a result of the commercialization of PIXUVRI, our



## **Table of Contents**

risk with respect to potential product liability has increased. If our insurance covering a product or product candidate is not maintained on acceptable terms or at all, we might not have adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim could also exceed our insurance coverage and could harm our financial condition and operating results.

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

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to international, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by the regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

*We depend on sophisticated information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.*

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks could result in the theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. If we fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

## **Risks Related To the Securities Markets**

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended April 23, 2014, our stock price has ranged from a low of \$0.97 to a high of \$4.25. 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 an impact, which, depending on the circumstances, could be significant, on the market price and marketability of our securities include:

announcements by us or others of results of clinical trials and regulatory actions;

**Table of Contents**

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 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 of our securities;

changes in health care policies and practices;

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

halting or suspension of trading in our common stock on The NASDAQ Capital Market by NASDAQ or on the MTA by CONSOB, or the Borsa Italiana; and

general economic and market conditions.

*Shares of common stock are 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.

**Table of Contents**

*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, including in connection with acquisitions we may make from time to time. 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 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 bylaws without shareholder approval; and

the ability of our Board of Directors to issue shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as the Board of Directors may determine. Pursuant to our rights plan, an acquisition of 20 percent or more of our common stock by a person or group, subject to certain exceptions, could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20 percent shareholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. The existence of our rights plan could have the effect of delaying, deterring or preventing a third party from making an acquisition proposal for us and may inhibit a change in control that some, or a majority, of our shareholders might believe to be in their best interest or that could give our shareholders the opportunity to realize a premium over the then-prevailing market prices for their shares. In addition, as a Washington corporation, we are subject to Washington's anti-takeover statute, which imposes restrictions on some transactions between a corporation and certain significant shareholders. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

**Table of Contents****Item 2. Unregistered Sales of Equity Securities and Use of Proceeds***Stock Repurchases in the First Quarter*

The following table sets forth information with respect to purchases of our common stock during the three months ended March 31, 2014:

<b>Period</b>	<b>Total Number of Shares Purchased (1)</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
January 1 - January 31, 2014	500	\$ 2.20		
February 1 - February 28, 2014	8,489	\$ 3.31		
March 1 - March 31, 2014	19,685	\$ 3.88		
Total	28,674	\$ 3.68		

(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.

**Table of Contents****Item 6. Exhibits**

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

Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

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.



**Table of Contents**

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.
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.

**Table of Contents**

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 of Cell Therapeutics, Inc.	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	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 19 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 15, 2013.

**Table of Contents**

3.32	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.
4.1	Shareholder Rights Agreement, dated December 28, 2009, between Cell Therapeutics, Inc. and Computershare Trust Company, N.A.	Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 8-A, filed on December 28, 2009.
4.2	First Amendment to Shareholder Rights Agreement, dated as of August 31, 2012, between Cell Therapeutics, Inc. and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2012.
4.3	Second Amendment to Shareholder Rights Agreement, dated as of December 6, 2012, between Cell Therapeutics, Inc. and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on December 7, 2012.
4.4	Class B Common Stock Purchase Warrant, dated April 13, 2009.	Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed on April 13, 2009.
4.5	Common Stock Purchase Warrant, dated April 13, 2009.	Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2009.
4.6	Common Stock Purchase Warrant, dated May 11, 2009.	Incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2009.
4.7	Form of Common Stock Purchase Warrant, dated April 6, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on April 5, 2010.
4.8	Form of Common Stock Purchase Warrant, dated May 27, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
4.9	Form of Common Stock Purchase Warrant, dated July 27, 2010.	Incorporated by reference to Exhibit 4.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
4.10	Form of Common Stock Purchase Warrant, dated October 22, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
4.11	Form of Common Stock Purchase Warrant, dated May 3, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 2, 2011.

**Table of Contents**

4.12	Form of Common Stock Purchase Warrant, dated July 5, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on July 6, 2011.
4.13	Form of Common Stock Purchase Warrant, dated December 13, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on December 14, 2011.
4.14	Form of Warrant to Purchase Common Stock, dated May 29, 2012.	Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed on May 31, 2012.
4.15	Form of Warrant to Purchase Common Stock, dated July 30, 2012.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.
4.16	Warrant Agreement, dated March 26, 2013, by and between Cell Therapeutics, Inc. and Hercules Technology Growth Capital, Inc.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on March 28, 2013.
10.1	First Amendment to Loan and Security Agreement, dated as of March 25, 2014, by and among Cell Therapeutics, Inc., Systems Medicine LLC and Hercules Capital Funding Trust 2012-1.	Filed herewith.
10.2	Termination Agreement, effective as of January 3, 2014, by and between Novartis International Pharmaceutical Ltd. and Cell Therapeutics, Inc.	Filed herewith.
10.3	Amendment No. 4 to Wholesale Distribution Agreement, effective January 1, 2014, by and between CTI Life Sciences Limited and Max Pharma GmbH.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101. INS	XBRL Instance	Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101. CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101. DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101. LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101. PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

Portions of these exhibits have been omitted pursuant to a request for confidential treatment.

**Table of Contents**

**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: April 29, 2014

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

Dated: April 29, 2014

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