CELL THERAPEUTICS INC
Form 10-Q
November 01, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended: September 30, 2012

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

(206) 282-7100

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

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

Class	**Outstanding at October 25, 2012**
Common Stock, no par value	96,992,513

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	September 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,289	$ 47,052
Prepaid expenses and other current assets	5,487	4,023
Total current assets	19,776	51,075
Property and equipment, net	7,734	3,604
Other assets	8,665	7,560
Total assets	$ 36,175	$ 62,239
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 11,936	$ 5,750
Accrued expenses	9,067	11,064
Warrant liability	5,445	
Current portion of long-term obligations	393	970
Total current liabilities	26,841	17,784
Long-term obligations, less current portion	5,768	2,985
Total liabilities	32,609	20,769
Commitments and contingencies		
Common stock purchase warrants	13,461	13,461
Shareholders equity (deficit):		
Preferred stock, no par value:		
Authorized shares - 333,333		
Series 14 Preferred Stock, $1,000 stated value, 20,000 shares designated, 0 and 10,000 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively		6,736
Common stock, no par value:		
Authorized shares - 150,000,000 and 76,666,666 at September 30, 2012 and December 31, 2011, respectively		
Issued and outstanding shares - 62,270,179 and 40,613,545 at September 30, 2012 and December 31, 2011, respectively	1,810,035	1,744,801
Accumulated other comprehensive loss	(7,992)	(8,035)
Accumulated deficit	(1,811,030)	(1,714,785)
Total CTI shareholders equity (deficit)	(8,987)	28,717
Noncontrolling interest	(908)	(708)
Total shareholders equity (deficit)	(9,895)	28,009
Total liabilities and shareholders equity (deficit)	$ 36,175	$ 62,239

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Operating expenses:				
Research and development	$ 6,951	$ 7,530	$ 24,080	$ 26,982
Selling, general and administrative	7,763	7,760	29,024	25,297
Acquired in-process research and development			29,108	
Total operating expenses	14,714	15,290	82,212	52,279
Loss from operations	(14,714)	(15,290)	(82,212)	(52,279)
Other income (expense):				
Investment and other income (expense), net	(270)	(14)	(179)	(67)
Interest expense	(43)	(161)	(51)	(734)
Amortization of debt discount and issuance costs		(129)		(436)
Foreign exchange gain (loss)	216	(1,133)	(96)	(56)
Settlement expense	(435)		(435)	
Other income (expense), net	(532)	(1,437)	(761)	(1,293)
Net loss before noncontrolling interest	(15,246)	(16,727)	(82,973)	(53,572)
Noncontrolling interest	57	65	200	179
Net loss attributable to CTI	(15,189)	(16,662)	(82,773)	(53,393)
Dividends and deemed dividends on preferred stock	(5,014)	(13,023)	(13,472)	(49,817)
Net loss attributable to CTI common shareholders	$ (20,203)	$ (29,685)	$ (96,245)	$ (103,210)
Basic and diluted net loss per common share	$ (0.38)	$ (0.80)	$ (2.12)	$ (3.11)
Shares used in calculation of basic and diluted net loss per common share	52,921	36,999	45,442	33,145

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss before noncontrolling interest	$ (15,246)	$ (16,727)	$ (82,973)	$ (53,572)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(121)	703	71	(73)
Net unrealized gain (loss) on securities available-for-sale	48	(107)	(28)	(204)
Other comprehensive income (loss)	(73)	596	43	(277)
Comprehensive loss	(15,319)	(16,131)	(82,930)	(53,849)
Comprehensive loss attributable to noncontrolling interest	57	65	200	179
Comprehensive loss attributable to CTI	$ (15,262)	$ (16,066)	$ (82,730)	$ (53,670)

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2012	**2011**
Operating activities		
Net loss	$ (82,773)	$ (53,393)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	29,108	
Equity-based compensation expense	6,084	2,320
Depreciation and amortization	1,745	1,748
Provision for VAT assessments	(2,118)	
Noncash interest expense		436
Noncontrolling interest	(200)	(179)
Other	(195)	(242)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,308)	(644)
Other assets	(874)	(2,604)
Accounts payable	2,207	(335)
Accrued expenses	(1,895)	(757)
Other liabilities	4,462	(1,140)
Total adjustments	37,016	(1,397)
Net cash used in operating activities	(45,757)	(54,790)
Investing activities		
Cash paid for acquisition of assets of S*BIO Pte Ltd.	(17,764)	
Cash paid for purchases of property and equipment	(1,966)	(1,974)
Proceeds from the sales of property and equipment		27
Net cash used in investing activities	(19,730)	(1,947)
Financing activities		
Proceeds from issuance of Series 8 preferred stock, warrants and additional investment right, net of issuance costs		23,213
Proceeds from issuance of Series 10 preferred stock, warrants and additional investment right, net of issuance costs		23,530
Proceeds from issuance of Series 12 preferred stock and warrants, net of issuance costs		14,962
Proceeds from issuance of Series 13 preferred stock and warrants, net of issuance costs		28,149
Proceeds from issuance of Series 15 preferred stock and warrants, net of issuance costs	32,928	
Cash paid for repayment of 7.5% convertible senior notes		(10,250)
Cash paid for Series 14 preferred stock transaction costs	(170)	
Cash paid for Series 16 preferred stock transaction costs	(47)	
Cash paid for repurchase of shares in connection with taxes on restricted stock vesting	(77)	(342)
Other	(25)	(23)
Net cash provided by financing activities	32,609	79,239

Effect of exchange rate changes on cash and cash equivalents	115	61
Net increase (decrease) in cash and cash equivalents	(32,763)	22,563
Cash and cash equivalents at beginning of period	47,052	22,649
Cash and cash equivalents at end of period	$ 14,289	$ 45,212
Supplemental disclosure of cash flow information		
Cash paid during the period for interest obligations	$ 10	$ 705
Cash paid for taxes	$	$
Supplemental disclosure of noncash financing and investing activities		
Conversion of Series 9 preferred stock to common stock	$	$ 25,000
Conversion of Series 11 preferred stock to common stock	$	$ 24,957
Conversion of Series 12 preferred stock to common stock	$	$ 10,647
Conversion of Series 13 preferred stock to common stock	$	$ 19,077
Conversion of Series 14 preferred stock to common stock	$ 6,736	$
Conversion of Series 15 preferred stock to common stock	$ 15,442	$
Conversion of Series 16 preferred stock to common stock	$ 11,240	$
Issuance of common stock upon exercise or exchange of common stock purchase warrants	$ 12,351	$ 17,485
Issuance of Series 9 preferred stock	$	$ 25,000
Issuance of Series 11 preferred stock	$	$ 24,957
Issuance of Series 16 preferred stock for acquisition of assets of S*BIO Pte Ltd.	$ 11,344	$
Redemption of Series 8 and 10 preferred stock	$	$ 36,638

See accompanying notes.

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CELL THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Description of Business and Summary of Significant Accounting Policies

Description of Business

Cell Therapeutics, Inc., also referred to in this Quarterly Report on Form 10-Q as CTI, the Company, we, us or our, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer, an area with significant market opportunity that we believe is not adequately served by existing therapies. All of our current product candidates, including Pixuvri (pixantrone dimaleate), or Pixuvri, pacritinib, OPAXIO (paclitaxel poliglumex), or OPAXIO, tosedostat and brostallicin are under development.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to ongoing oversight by, the Food and Drug Administration, or the FDA, in the United States, by the European Medicines Agency, or EMA, in the European Union, or EU, and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is uncertain, may take many years and may involve the expenditure of substantial resources.

Basis of Presentation

The accompanying unaudited financial information of CTI as of September 30, 2012 and for the three and nine months ended September 30, 2012 and 2011 has been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial position at such date and the operating results and cash flows for such periods. Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the entire year.

Certain information and footnote disclosure normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or the SEC. These unaudited financial statements and related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K filed with the SEC on March 8, 2012.

The condensed consolidated balance sheet at December 31, 2011 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of CTI and its wholly-owned subsidiaries, which include Systems Medicine LLC, or SM, and CTI Life Sciences Limited. CTI Life Sciences Limited opened a branch in Italy in December 2009. We also retain ownership of our branch, Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe); however, we ceased operations related to this branch in September 2009. In addition, CTI Commercial LLC, a wholly-owned subsidiary, was included in the condensed consolidated financial statements until dissolution in March 2012.

As of September 30, 2012, we also had a 67% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. In accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 810, *Consolidation*, the noncontrolling interest in Aequus is reported below net loss in *noncontrolling interest* in the condensed consolidated statement of operations and condensed consolidated statements of comprehensive loss and shown as a component of equity in the condensed consolidated balance sheet.

All intercompany transactions and balances are eliminated in consolidation.

Reverse Stock Splits

On May 15, 2011 and September 2, 2012, we effected a one-for-six and one-for-five reverse stock split, respectively, or the May Split and September Split, respectively. Unless otherwise noted, all impacted amounts included in the condensed

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consolidated financial statements and notes thereto have been retroactively adjusted for the May Split and September Split. Unless otherwise noted, impacted amounts include shares of common stock authorized and outstanding, share issuances, shares underlying preferred stock, convertible notes, warrants and stock options, shares reserved and loss per share. Additionally, the May Split and September Split impacted preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the applicable reverse stock split).

Liquidity

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date of these condensed consolidated financial statements. However, we have incurred net losses since inception and expect to generate losses for the next few years primarily due to research and development costs for Pixuvri, pacritinib, OPAXIO, tosedostat and brostallicin.

Our available cash and cash equivalents were $14.3 million as of September 30, 2012. Subsequent to period end, we received $60.0 million in gross proceeds, before deducting underwriting discounts and commissions and other offering costs, from the issuance of our Series 17 convertible preferred stock, or Series 17 Preferred Stock. See Note 9, *Subsequent Events* for additional information. At our currently planned spending rate, we believe that our financial resources, in addition to the expected receipts from European Pixuvri sales, will be sufficient to fund our operations for the next fifteen (15) months. Changes in manufacturing, clinical trial expenses, and expansion of our sales and marketing organization in Europe, may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for Pixuvri that we currently assume in planning for 2013.

We expect we will need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. Our board of directors may issue shares depending on our financial needs and market opportunities, if deemed to be in the best interest of the shareholders. However, additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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 $5.0 million as of September 30, 2012 and December 31, 2011, respectively, of which $4.8 million and $4.7 million is included in *other assets* and $0.2 million and $0.3 million is included in *prepaid expenses and other current assets* as of September 30, 2012 and December 31, 2011, respectively. This receivable balance primarily relates to our Italian operations and typically has a three-year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

Acquired in-process research and development

Costs to acquire in-process research and development, projects and technologies which had no alternative future use and which had not reached technological feasibility are expensed as incurred.

Net Loss per Share

Basic net income (loss) per common share is calculated based on the net income (loss) attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted net income (loss) per common

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share assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and share awards using the treasury stock method. As of September 30, 2012 and 2011, options, warrants, unvested share awards, unvested share rights and convertible debt securities aggregating 9.6 million and 5.7 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.

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.

Recently Adopted Accounting Standards

In May 2011, the FASB issued guidance to enhance fair value measurement and disclosure requirements and provide a common framework between U.S. GAAP and IFRS. This guidance was effective for interim and annual periods beginning on or after December 15, 2011, with early adoption prohibited. The adoption of this guidance on January 1, 2012 did not have a material impact on our condensed consolidated financial statements.

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance was effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. Subsequently, in December 2011, the FASB deferred the effective date of the portion of the June 2011 accounting standards update requiring separate presentation of reclassifications out of accumulated other comprehensive income. Upon adoption on January 1, 2012, we had the option to report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. We elected to present comprehensive income in two separate but consecutive statements as part of the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Reclassifications

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

2. Other Comprehensive Income (Loss)

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

	Net Unrealized Loss on Securities Available-for-sale	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Income (Loss)

December 31, 2011	$ (165)	$ (7,870)	$ (8,035)
Current period other comprehensive income (loss)	(28)	71	43
September 30, 2012	$ (193)	$ (7,799)	$ (7,992)

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3. Lease Agreements

During 2005, we reduced our workforce in the United States and Europe. In conjunction with this reduction in force, we vacated a portion of our laboratory and office facilities and recorded excess facilities charges. Charges for excess facilities relate to our lease obligation for excess laboratory and office space in the United States that we vacated as a result of the restructuring plan. We recorded these restructuring charges when we ceased using this space. During 2010, we recorded an additional liability of $1.5 million for excess facilities under an operating lease upon vacating a portion of our corporate office space.

The following table summarizes the changes in the liability for excess facilities during the period ended September 30, 2012 (in thousands):

	2005 Activities	2010 Activities	Total Excess Facilities Liability
Balance at December 31, 2011	$ 215	$ 530	$ 745
Adjustments	(32)	(62)	(94)
Payments	(183)	(468)	(651)
Balance at September 30, 2012	$	$	$

As of September 30, 2012, we have a $1.9 million receivable balance included in *prepaid expenses and other current assets* related to incentives for leasehold improvements and rent reimbursement under the terms of our operating lease for office space entered into January 2012. In addition, we have approximately $5.0 million in deferred rent recorded as of September 30, 2012, of which $0.4 million is included in *current portion of long-term obligations* and $4.6 million is included in *long-term obligations, less current portion*.

4. Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three and nine months ended September 30, 2012 and 2011, which was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	$ 363	$ 206	$ 1,379	$ 839
Selling, general and administrative	653	574	4,705	1,481
Total share-based compensation expense	$ 1,016	$ 780	$ 6,084	$ 2,320

For the three and nine months ended September 30, 2012 and 2011, we incurred share-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
2012-2014 performance awards	$ (111)	$	$ 2,158	$
Restricted stock	996	753	3,635	2,243
Options	131	27	291	77
Total share-based compensation expense	$ 1,016	$ 780	$ 6,084	$ 2,320

5. Commitments and Contingencies

On August 3, 2009, Sicor Società Corticosteroidi S.r.l., or Sicor, filed a lawsuit in the Court of Milan to obtain the Court s assessment that we were bound to source a chemical compound, whose chemical name is BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma on October 4,

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2002. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. At the hearing of October 11, 2012, the parties informed the court about the ongoing negotiations pending between them and asked to postpone the case. Sicor alleges that the agreement was not terminated according to its terms. At the request of the parties, the court extended the final hearing until March 21, 2013. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On December 10, 2009, CONSOB sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations could require us to pay a pecuniary administrative sanction amounting to between $6,000 and $643,000 upon conversion from euros on September 30, 2012.

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). We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. We have a reserve in the amount of $1.3 million upon conversion from euros as of September 30, 2012, of which $1.1 million is included in *long-term obligations, less current portion* and $0.2 million of the reserve is accounted for as an offset to our VAT receivable included in *other assets*. If the final decision of the lower tax courts (i.e. the Provincial Tax Court or the Regional Tax Court) or of the Supreme Court is unfavorable to us, we may incur approximately $10.8 million upon conversion from euros on September 30, 2012 in additional losses for VAT assessed, penalties and interest, 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.

On June 16, 2012, Craig W. Philips, then President of Cell Therapeutics, Inc., delivered notice of his intention to resign as President of the Company, effective July 16, 2012. Mr. Philips departure was the result of a perceived diminution of responsibilities. The parties finalized a settlement agreement in October 2012, and the Company has accrued approximately $0.4 million as of September 30, 2012.

In addition to the contingencies discussed above, we are from time to time subject to legal proceedings and claims arising in the ordinary course of business, some of which may be covered in whole or in part by insurance.

6. Reverse Stock Split

In August 2012, our Board of Directors approved a one-for-five reverse stock split and, on September 2, 2012, the reverse stock split became effective, which we refer to as the September Split. As a result of the September Split, every five shares of our authorized and outstanding common stock were converted into one authorized and outstanding share of common stock and every five shares of our authorized preferred stock were converted into one authorized share of preferred stock; there were no shares of preferred stock outstanding so there was no impact. No fractional shares were issued in the September Split. In lieu of fractional shares, shareholders received cash at a rate of approximately $0.435 per whole pre-split share. The September Split affected all of the holders of our common stock pro rata and did not materially affect any shareholder s percentage of ownership interest. Any shares of our common stock or shares underlying options and warrants were proportionately reduced and the exercise price of any warrants or options were proportionately increased in accordance with the terms of the related agreements. Unless otherwise noted, all impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the September Split.

7. Preferred Stock

Prior to the effective date of the September Split (see Note 6, *Reverse Stock Splits*), we completed the preferred stock transactions described in this Note 7, *Preferred Stock*. All of the outstanding shares of the preferred stock issued in these transactions converted to common stock prior to the effective date of the September Split. Accordingly, for purposes of the

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descriptions of these transactions included in this Note 7, *Preferred Stock*, the number of shares of preferred stock issued and the initial stated value of shares of preferred stock issued are not adjusted to reflect the September Split. However, the number of shares of common stock issued upon conversion of the preferred stock, the conversion price of common stock issued upon conversion, the exercise prices of warrants issued and the number of shares of common stock issued or issuable upon exercise of the warrants in these transactions are adjusted to reflect the September Split.

Series 14 Preferred Stock

In December 2011, we issued 20,000 shares of our Series 14 convertible preferred stock, or Series 14 Preferred Stock. As of December 31, 2011, 10,000 shares of Series 14 Preferred Stock remained outstanding. In January 2012, the remaining 10,000 shares of Series 14 Preferred Stock automatically converted into 1.7 million shares of our common stock pursuant to the terms of the Series 14 Preferred Stock.

Series 15-1 Preferred Stock

In May 2012, we issued 20,000 shares of our Series 15 convertible preferred stock, or Series 15-1 Preferred Stock, and a warrant to purchase up to 2.7 million shares of our common stock, or Series 15-1 Warrant, for gross proceeds of $20.0 million. Issuance costs related to this transaction were approximately $1.3 million.

Each share of our Series 15-1 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of $1,000 per share of Series 15-1 Preferred Stock, plus any accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 15-1 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any *pari passu* or junior securities. The Series 15-1 Preferred Stock was converted into our common stock, at the option of the holder, at a conversion price of $5.00 per share, subject to a 9.99% blocker provision. The Series 15-1 Preferred Stock had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law. For the nine months ended September 30, 2012, we recognized $8.5 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 15-1 Preferred Stock. In May 2012, all 20,000 shares of our Series 15-1 Preferred Stock were converted into 4.0 million shares of our common stock.

The Series 15-1 Warrant has an exercise price of $5.46 per share of our common stock, was exercisable immediately on the date of issuance and expires five years from the date of issuance. If the price per share of our common stock is less than the exercise price of the warrant at any time while the warrant is outstanding, the warrant may be exchanged for shares of our common stock based on an exchange value, or the Exchange Value, derived from a specified Black-Scholes value formula, subject to certain limitations. We may elect to pay all or some of such Exchange Value in cash upon exchange by the holder. Since the warrant did not meet the additional considerations necessary for equity classification in the applicable authoritative guidance, we determined the warrant is a liability instrument that is marked to fair value with changes in fair value recognized through earnings at each reporting period. Upon issuance, we estimated the fair value of the Series 15-1 Warrant to be approximately $10.3 million. In September 2012, the holder elected to exchange a portion of the Series 15-1 Warrant to purchase 1.3 million shares with an Exchange Value of $5.0 million. The Company elected to issue 2.8 million shares as payment for the Exchange Value.

The fair value of the remaining portion of the Series 15-1 Warrant was approximately $5.4 million as of September 30, 2012. We classified the Series 15-1 Warrant as Level 2 in the fair value hierarchy as the significant inputs used in determining fair value are considered observable market data. Since the exercise price exceeded the market price of our common stock on September 30, 2012, the remaining portion of the Series 15-1 Warrant outstanding was exchangeable for an amount equal to the Exchange Value. The fair value of the Series 15-1 Warrant approximated the Exchange Value, which applied the following assumptions: (i) market price of our common stock of $4.55, (ii) an expected term of 5 years, (iii) volatility of 135%, (iv) no dividend yield, and (v) a risk-free rate of 0.6%. Assumptions (i) through (iv) are specified in the terms of the warrant agreement. The risk-free interest rate used in the Black-Scholes formula is based on the implied yield currently available for U.S. Treasury securities at maturity with an equivalent term.

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Series 15-2 Preferred Stock

In July 2012, we issued 15,000 shares of our Series 15 convertible preferred stock, or Series 15-2 Preferred Stock, and a warrant to purchase up to 3.4 million shares of our common stock, or Series 15-2 Warrant, for gross proceeds of $15.0 million. Issuance costs related to this transaction were approximately $0.8 million. For the three and nine months ended September 30, 2012, we recognized $5.0 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 15-2 Preferred Stock.

Each share of our Series 15-2 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of $1,000 per share of Series 15-2 Preferred Stock, plus any accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 15-2 Preferred Stock was converted into 5.0 million shares of our common stock, at the option of the holder, at a conversion price of $2.97475 per share, subject to a 9.99% blocker provision.

The Series 15-2 Warrant had substantially the same features as the Series 15-1 Warrant described above, with the exception of the exercise price of $3.0672 per share of common stock and expires five years from the date of issuance. Upon issuance, we estimated the fair value of the warrant to be approximately $7.2 million. In September 2012, the holder elected to exchange the Series 15-2 Warrant for shares of our common stock with an Exchange Value of $7.4 million. We elected to issue 2.9 million shares of common stock to the holder as payment for the Exchange Value of the Series 15-2 Warrant.

8. Acquisitions

In April 2012, we entered into an asset purchase agreement with S*BIO Pte Ltd., or S*BIO, to acquire all right, title and interest in, and assume certain liabilities relating to, certain intellectual property and other assets related to compounds SB1518 (also referred to as pacritinib) and SB1578, or the Seller Compounds, which inhibit Janus Kinase 2, commonly referred to as JAK2. In consideration of the assets and rights acquired under the agreement, we made a payment of $15.0 million in cash and issued 15,000 shares of Series 16 convertible preferred stock, or Series 16 Preferred Stock, to S*BIO at the closing in May 2012. Each share of Series 16 preferred stock had a stated value of $1,000 per share and was convertible into shares of our common stock at an initial conversion price of $5.95 per share, subject to certain adjustments and a 19.99% blocker provision. All outstanding shares of Series 16 Preferred Stock were automatically converted into 2.5 million shares of our common stock in June 2012.

The total initial purchase consideration was as follows (in thousands):

Cash	$ 15,000
Fair value of Series 16 Preferred Stock	11,344
Transaction costs	2,764
Total initial purchase consideration	$ 29,108

The transaction was treated as an asset acquisition as it was determined that the assets acquired did not meet the definition of a business. We determined that the acquired assets can only be economically used for the specific and intended purpose and have no alternative future use after taking into consideration further research and development, regulatory and marketing approval efforts required in order to reach technological feasibility. Accordingly, the entire initial purchase consideration of $29.1 million was immediately expensed to *acquired in-process research and development* for the nine months ended September 30, 2012. The contingent consideration arrangement as discussed below will be recognized when the contingency is resolved and the consideration is paid or becomes payable.

As part of the consideration, S*BIO also has a contingent right to certain milestone payments from us up to an aggregate amount of $132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any Seller Compound for use for specific diseases, infections or other conditions. 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.

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9. Subsequent Events

In October 2012, we entered into an underwriting agreement relating to the issuance and sale of 60,000 shares of our Series 17 Preferred Stock for gross proceeds of $60.0 million, before deducting underwriting commissions and discounts and other offering costs. Each share of Series 17 Preferred Stock is entitled to a liquidation preference equal to the stated value of $1,000 per share plus any accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The holders of the Series 17 Preferred Stock are entitled to receive dividends equal to and in the same form as dividends actually paid on shares of common stock or other junior securities, as and if such dividends are paid. The Series 17 Preferred Stock is convertible into common stock, at the option of the holder, at an initial conversion price of $1.40 per share. The Series 17 Preferred Stock is subject to a 9.99% blocker provision; provided, however, that in the event of an automatic conversion, the maximum conversion threshold will increase to 19.99% effective from the 90th day after the original issuance date of the Series 17 Preferred Stock, without any further action on the part of a holder. The Series 17 Preferred Stock has no voting rights on general corporate matters. As of October 25, 2012, 48,325 shares of the Series 17 preferred stock have been converted into 34.5 million shares of our common stock.

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

This Quarterly Report on Form 10-Q, including the following discussion, contains forward-looking statements, which involve risks and uncertainties and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item I of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on Form 10-Q, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, potential, predicts, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. Such statements, which include statements concerning product sales, research and development expenses, selling, general and administrative expenses, additional financings and additional losses, are subject to known and unknown risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, particularly in Factors Affecting Our Operating Results and Financial Condition, that could cause actual results, levels of activity, performance or achievement 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 develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary oncology drugs. Our development, acquisition and in-licensing activities concentrate on identifying and developing new, less toxic and more effective ways to treat cancer. We are currently focusing our efforts on the European launch of Pixuvri™ (pixantrone dimaleate), or Pixuvri, an ongoing Phase III trial of Pixuvri and the development of pacritinib and tosedostat. We continue work with OPAXIO (paclitaxel poliglumex), or OPAXIO, and brostallicin through cooperative group and investigator initiated studies. We seek to continue to evaluate additional novel clinical stage compounds to expand our hematologic cancer product pipeline. We are interested in compounds or products that are complementary to our existing pipeline.

As of September 30, 2012, we had incurred aggregate net losses of approximately $1.8 billion since inception. We expect to continue to incur operating losses for at least the next couple of years.

Pixuvri

We are developing Pixuvri, a novel aza-anthracenedione, for the treatment of non-Hodgkin s lymphoma, or NHL, and various other hematologic malignancies, and solid tumors. Pixuvri was studied in our EXTEND, or PIX301, clinical trial, which was a phase III single-agent trial of Pixuvri for patients with relapsed, refractory aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In November 2008, we announced that this trial achieved the primary efficacy endpoint. We began a rolling NDA submission to the FDA in April 2009 and completed the submission in June 2009.

In 2010, the FDA completed its inspection of the facilities at NerPharMa DS, S.r.l. and NerPharMa, S.r.l. (two independent pharmaceutical manufacturing companies belonging to Nerviano Medical Sciences S.r.l., in Nerviano, Italy). The FDA found both manufacturing sites in compliance and acceptable for continued manufacturing of the drug in early March 2010. NerPharMa, S.r.l. agreed to manufacture our drug product, Pixuvri, which will be used for clinical and commercial supplies.

On March 22, 2010, the FDA s ODAC panel voted unanimously that the clinical trial data was not adequate to support approval of Pixuvri for this patient population. In early April 2010, we received a complete response letter from the FDA regarding our NDA for Pixuvri recommending that we design and conduct an additional trial to demonstrate the safety and efficacy of Pixuvri and other items. We met with the FDA in August 2010 at an end of review meeting at which time the FDA informed us that the Pixuvri Investigational New Drug application, or IND, and NDA were being transferred to the newly-formed Division of Hematology Drug Products, or the DHP. We filed an appeal in December 2010 with the FDA s Center for Drug Evaluation and Research regarding the FDA s decision in April 2010 to not approve Pixuvri for relapsed/refractory aggressive NHL and to ask the Office of New Drugs, or the OND, to conclude that PIX301 demonstrated efficacy. In March 2011, we met with officials of the OND and presented our arguments supporting our belief that the data contained in the NDA are consistent with the conclusion that Pixuvri is effective for its planned use. At the meeting, the OND requested additional analyses related to the EXTEND clinical study, which we submitted.

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In April 2011, the OND responded to our December 2010 appeal of the FDA s April 2010 decision to not approve Pixuvri for relapsed or refractory aggressive NHL. In its response, the OND indicated that after considering the data available in the appeal, it does not believe that accelerated approval of our NDA is necessarily out of reach based on a single controlled clinical trial, provided that two key matters can be resolved satisfactorily. First, the circumstances of stopping the PIX301 trial early must be resolved to assure that ongoing results assessment were not dictating the decision to stop. Second, ascertainment of the primary endpoint in the PIX301 study must be determined to have been sound and not subject to bias.

The OND also indicated that our request that the OND find that the data in our NDA demonstrate efficacy and return the NDA to the Office of Oncology Drug Products for consideration of safety and other issues was denied because the OND was not able to conclude that efficacy had been demonstrated. However, the OND also did not find that it could be concluded that PIX301 was a failed study, which warranted application of interim analysis statistical thresholds.

In June 2011, we met with the FDA s Division of Oncology Drug Products, or DODP, in a meeting that focused on the documents we proposed to provide regarding the circumstances of stopping the enrollment of PIX301 prior to achieving the original planned patient accrual and the make-up of the new radiology expert panel, as well as our plan to address the items noted in the FDA s complete response letter. The DODP confirmed that our NDA would be reviewed within six months from the resubmission of our NDA. Subsequently, a second independent radiology assessment of response and progression endpoint data from our PIX301 clinical trial of Pixuvri was achieved with statistical significance. We believe this assessment confirmed the statistical robustness of the PIX301 efficacy data that was previously submitted by us to the FDA in our NDA for Pixuvri.

In October 2011, we resubmitted the NDA to the FDA s Division of Oncology Products 1, or DOP1, for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. In December 2011, the DOP1 notified us that our resubmitted NDA is considered a complete, Class 2 response to the FDA s April 2010 complete response letter. The FDA set a PDUFA goal date of April 24, 2012 for a decision on our resubmitted NDA.

ODAC was scheduled to review our resubmitted NDA for Pixuvri on February 9, 2012. In January 2012, we voluntarily withdrew our resubmitted NDA for Pixuvri. The NDA was withdrawn because, after communications with the FDA, we needed additional time to prepare for the review of the NDA by ODAC at its February 9, 2012 meeting. Prior to withdrawing the NDA, we requested that the FDA consider rescheduling the review of the NDA to the ODAC meeting to be held in late March. The FDA was unable to accommodate our request to reschedule, and given the April 24, 2012 PDUFA date, the only way to have Pixuvri possibly considered at a later ODAC meeting was to withdraw and later resubmit the NDA. We are planning to meet with regulatory authorities in 2013 to discuss our resubmission strategy, which we would like to include data generated from our ongoing PIX-R® phase III study, or PIX306, and therefore the resubmission of the NDA would occur beyond year-end 2012.

We believe the results of the EXTEND trial met its primary endpoint and showed that patients randomized to treatment with Pixuvri achieved a significantly higher rate of confirmed and unconfirmed complete response compared to patients treated with standard chemotherapy had a significantly increased overall response rate and experienced a statistically significant improvement in median progression free survival. Pixuvri had predictable and manageable toxicities when administered at the proposed dose and schedule in the EXTEND clinical trial in heavily pre-treated patients. The most common (incidence greater than or equal to 10%) grade 3/4 adverse events reported for Pixuvri-treated subjects across studies were neutropenia and leukopenia. Other common adverse events (any grade) included infection, anemia, thrombocytopenia, asthenia, pyrexia and cough. Overall, the incidence of grade 3 or greater cardiac adverse events was 7% (five patients) on the Pixuvri arm and 2% (one patient) on the comparator arm. There were an equal number of deaths due to an adverse event in both the Pixuvri and comparator arm.

In March 2011, we initiated the PIX-R® trial, or PIX306, to study Pixuvri in combination with rituximab in patients with relapsed or refractory aggressive B-cell NHL. The trial will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant. The PIX-R trial

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utilizes overall survival, or OS, as the primary endpoint of the study, with a secondary endpoint of progression free survival, or PFS. The PIX-R trial is targeting to enroll approximately 350 patients and will include patients who have failed at least one line of previous therapy and patients who are not candidates for myeloablative chemotherapy and stem cell transplant. We had discussions with the DHP relating to a Special Protocol Assessment, or SPA, and following these discussions we determined that we would not pursue a SPA. The DHP noted that we could conduct a study utilizing PFS along with OS as co-primary endpoints which would be an acceptable design outside of the formal SPA process. At the initiation of the study, co-primary endpoints of OS and PFS were used. Subsequently, an amendment was made to the study protocol in January 2012, to make OS the sole primary endpoint, and PFS a secondary endpoint. As this study is being conducted without a SPA, regulatory acceptability will depend on the magnitude of the difference between the trial study arms as well as a risk and benefit analysis.

In Europe in July 2009, we were notified by the EMA that Pixuvri was eligible to be submitted for an MAA through the EMA s centralized procedure. The centralized review process provides for a single coordinated review for approval of pharmaceutical products that is conducted by the EMA on behalf of all EU member states. The EMA also designated Pixuvri as a New Active Substance, or NAS; if approved by the EMA, compounds designated as an NAS are eligible to receive a 10-year market exclusivity period in EU member states. In September 2009, we applied to the EMA for orphan drug designation for Pixuvri, which was granted in December 2009. In September 2009, we also submitted a Pediatric Investigation Plan, or PIP, to the EMA as part of the required filing process for approval of Pixuvri for treating relapsed, refractory aggressive NHL in Europe. In April 2010, the EMA recommended that we submit an updated PIP for Pixuvri following discussions with us about the preclinical and clinical Pixuvri data, including EXTEND, and the desire to explore the potential benefits Pixuvri may offer to children with lymphoid malignancies and solid tumors. We submitted an expanded PIP to the Pediatric Committee of the EMA, or PDCO, in July 2010. The expanded PIP was accepted for review by the PDCO in August 2010. In October 2010, we announced that the PDCO adopted an opinion agreeing to our PIP. The PDCO also recommended deferral of the initiation of the clinical studies until after Pixuvri receives EMA approval. In November 2010, the MAA seeking approval for Pixuvri for the treatment of adult patients with multiple relapsed or refractory aggressive NHL was validated and accepted for review by the EMA. Since Pixuvri was initially granted orphan drug status by the EMA for the treatment of DLBCL, we agreed to withdraw the orphan designation from the EU register in November 2010 based on the expansion of the MAA to the broader aggressive NHL population.

In June 2010, the Italian Medicines Agency, or AIFA, the national authority responsible for drug regulation in Italy, approved the facility at NerPharMa DS, S.r.l. for the production of Pixuvri drug substance. In July 2010, we signed a supply agreement with NerPharMa, S.r.l. for Pixuvri drug product manufacturing. The five-year contract provides for both the commercial and clinical supply of Pixuvri drug product.

After we completed the EMA s Committee for Medicinal Products for Human Use s, or CHMP, review of our MAA for Pixuvri, on February 17, 2012, Pixuvri was granted a positive opinion for conditional approval from CHMP. On May 10, 2012, Pixuvri received conditional marketing authorization in the EU from the European Commission as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive NHL. The decision allows us to market Pixuvri in the 27 Member States of the EU as well as in Iceland, Liechtenstein and Norway. Pixuvri is currently available in the EU and Turkey, through a named patient program.

Similar to accelerated approval regulations in the US, conditional marketing authorizations are granted in the EU to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. A conditional marketing authorization is renewable annually. Under the provisions of the conditional marketing authorization for Pixuvri, we will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed.

The EMA s CHMP accepted PIX306, our ongoing randomized controlled phase III clinical trial, which compares Pixuvri-rituximab to gemcitabine-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. As a condition of approval, we have agreed to have the PIX306 clinical trial results available by June 2015.

We initiated EU commercialization making Pixuvri available in Sweden, Denmark and Finland in September 2012 and Austria in October 2012. We expect to make Pixuvri available in Germany, the United Kingdom and the Netherlands in November 2012 and Norway in December 2012. We plan to expand availability of Pixuvri to France, Italy and Spain as well as other European countries in 2013.

We have entered into an agreement with Quintiles Commercial Europe Limited, or Quintiles, under which we will interview, approve for hire, train and manage a sales force for Pixuvri in the EU. While the sales force would be dedicated to Pixuvri, they are not our employees, but Quintiles employees. We believe this is a cost effective way to launch Pixuvri in the EU. We have also entered into a third-party logistics agreement with Movianto Nederland BV to provide us with warehousing, transportation and distribution services for Pixuvri. Lastly, we have entered into an agreement with LogixX Pharma Solutions, Ltd to act as our interim wholesaler dealers license holder while we apply for our own license.

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Pacritinib

In April 2012, we entered into an asset purchase agreement with S*BIO, or the S*BIO Agreement, to acquire all right, title and interest in, and assume certain liabilities relating to, certain intellectual property and other assets related to compounds SB1518 (also referred to as pacritinib) and SB1578, or the Seller Compounds, which inhibit Janus kinase 2, commonly referred to as JAK2. Under the terms of the S*BIO Agreement, we made an initial payment of $2 million in cash at signing. In consideration of the assets and rights acquired under the agreement, we made an additional payment of $13 million in cash and issued 15,000 shares of Series 16 Preferred Stock, convertible into common stock, to S*BIO at the closing in May 2012. The shares of preferred stock were automatically converted into 2.5 million shares of our common stock in June 2012. The S*BIO Agreement also includes regulatory success- and sales-based milestone payments, as well as single digit royalties on net sales. Under the S*BIO Agreement, we are solely responsible for development and commercialization activities of pacritinib worldwide.

Pacritinib is an oral, once a day, tyrosine kinase inhibitor, or TKI, with dual activity against JAK2 and FMS-like tyrosine kinase 3, or FLT3. Mutations in these kinases have been shown to be directly related to the development of a variety of blood related cancers including myeloproliferative neoplasms, leukemia, and lymphoma. Pacritinib has been studied in two phase II trials in a total of 65 myelofibrosis patients. In these trials, 30-74% improvement in the seven of the myelofibrosis symptom assessment form (MF-SAF) scores was observed relative to baseline at cycle 4, 7 or 10 (28 day cycles). Pacritinib does not appear to be myelosuppressive as no grade 3/4 hematological toxicities were observed in either phase II trials. Among evaluable patients, 31% achieved 35% or greater reduction in spleen volume by MRI. Significantly, these effects appear to be independent of patient platelet count. We expect the first of two phase III studies in patients with myelofibrosis to initiate in the fourth quarter of 2012 and the second phase III study to initiate in the second quarter of 2013.

OPAXIO

OPAXIO, which we have previously referred to as XYOTAX, is our novel biologically-enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. We are currently focusing our development of OPAXIO on ovarian, brain (glioblastoma), and locally advanced head and neck cancer.

OPAXIO for ovarian cancer

We are currently focusing our development of OPAXIO as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. In March 2004, we entered into a clinical trial agreement with the Gynecologic Oncology Group, or GOG, to perform a phase III trial, or the GOG0212 trial. As such, the GOG0212 trial is conducted and managed by the GOG. The trial is expected to enroll 1,100 patients with 946 patients enrolled as of September 30, 2012. On February 21, 2012, we were informed that the Data Monitoring Committee for GOG0212 adopted an amendment to the study s statistical analysis plan, or SAP, to perform four interim analyses instead of the previously-planned single interim analysis allowing for an earlier analysis of survival results than previously noted. The first interim analysis is expected to take place when 109, versus the previously-planned 138, events occur in the control arm. There are early stopping criteria for either success or futility. The final fifth analysis would be conducted when 301, versus the previously-planned 277, events have occurred in the control arm. Based on feedback from the GOG, the GOG Data Monitoring Committee currently plans to conduct its first interim analysis of overall survival in 2013.

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OPAXIO for brain (glioblastoma) cancer

In November 2010, results were presented by the Brown University Oncology Group from a phase II trial of OPAXIO combined with temozolomide, or TMZ, and radiotherapy in patients with newly-diagnosed, high-grade gliomas, a type of brain cancer. The trial demonstrated a high rate of complete and partial responses and an encouragingly high rate of six month PFS. Based on these results, the Brown University Oncology Group has initiated a randomized, multicenter, phase II study of OPAXIO and standard radiotherapy versus TMZ and radiotherapy for newly diagnosed patients with glioblastoma with an active gene termed MGMT that reduces responsiveness to TMZ. The trial goals are to estimate disease free and overall survival for the two study arms. Preliminary results are expected to be available in the second half of 2013. In September 2012, OPAXIO was granted orphan-drug designation by the FDA for the treatment of glioblastoma multiforme.

OPAXIO for locally advanced head and neck cancer

A phase I/II study of OPAXIO combined with radiotherapy and cisplatin was initiated by SUNY Upstate Medical University, in patients with locally advanced head and neck cancer. Preliminary results are expected to be presented mid-2013.

Tosedostat

In March 2011, we entered into a co-development and license agreement with Chroma, or the Chroma License Agreement, providing us with exclusive marketing and co-development rights to Chroma s drug candidate, tosedostat, in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. Final results from the phase II OPAL study of tosedostat in elderly patients with relapsed or refractory AML were presented in December 2011 at the 2011 American Society of Hematology Annual Meeting. These results showed that once-daily, oral doses of tosedostat had predictable and manageable toxicities and results demonstrated encouraging response rates including a high-response rate among patients who received prior hypomethylating agents, which are used to treat myelodysplastic syndrome, or MDS, a precursor of AML. There are two ongoing phase II investigator-sponsored trials examining the activity of combining tosedostat with hypomethylating agents (HMAs). We expect that data from these trials may be used to determine the appropriate design for a phase III trial.

By a letter dated July 18, 2012, Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma s allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma s lack of diligence claim based in part on the appropriateness of completing the ongoing phase II combination trials prior to developing a phase III trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement.

Effective September 25, 2012, we and Chroma entered into a three month standstill with respect to the parties respective claims under the Chroma License Agreement, but otherwise reserving the parties respective rights as of the commencement of the standstill period. The standstill is terminable by either party on one month s notice.

Brostallicin

We are developing brostallicin through our worldwide rights to use, develop, import and export brostallicin. Brostallicin is a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity and a favorable safety profile in clinical trials in which more than 230 patients have been treated to date. We use a genomic-based platform to guide the development of brostallicin.

In the second quarter of 2010, the NCCTG opened for enrollment a phase II study of brostallicin in combination with cisplatin in patients with metastatic triple-negative breast cancer, or mTNBC. mTNBC is defined by tumors lacking expression of estrogen, progesterone receptors and without over-expression of HER2. Women with mTNBC have very limited effective treatments and, based on the novel mechanism of action of brostallicin and the recognized activity of cisplatin in this disease, the combination of the two agents will be explored by the NCCTG. In addition to standard clinical efficacy measures, biological endpoints will also be evaluated to assist in understanding the specific activity of brostallicin in this disease. This study completed planned enrollment and results are expected during the fourth quarter of 2012.

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Research and Preclinical Development

Platinates are an important class of chemotherapy agents used to treat a wide variety of cancers. There are three platinates currently commercially available (cisplatin, carboplatin, and oxaliplatin), which are first-line agents in ovarian cancer, lung cancer, testicular cancer, and colorectal cancer, as well as a broad variety of other diseases. We are developing the dinuclear-platinum complex CT-47463. CT-47463 has a different mechanism of action than the commercially available platinum compounds and is substantially more active on many preclinical models including those with resistance to monoplatinates. We initiated active pharmaceutical ingredient and formulation development as prerequisites to IND enabling activities for bisplatinates. Depending on our resources and priorities, we may choose to resume additional pre-IND work or seek to out-license the product to another third party.

Critical Accounting Policies and Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States in the preparation of our condensed consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. As described in Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations,* of our Annual Report on Form 10-K for the year ended December 31, 2011, we consider our policies for impairment of long-lived assets, valuation of goodwill, derivatives embedded in certain debt securities, restructuring charges and share-based compensation expense to be the most critical in the preparation of the condensed consolidated financial statements because they involve the most difficult, subjective, or complex judgments about the effect of matters that are inherently uncertain. There have been no material changes to our application of critical accounting policies and significant judgments and estimates since December 31, 2011.

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RESULTS OF OPERATIONS

Three months ended September 30, 2012 and 2011

***Research and development expenses*.** Research and development costs are expensed as incurred in accordance with ASC 730, *Research and Development*. In instances where we enter into agreements with third parties for research and development activities, we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon completion of milestones or receipt of deliverables. In instances where we enter into cost-sharing arrangements, all research and development costs reimbursed by the collaborator are a reduction to research and development expense while research and development costs paid to the collaborator are an addition to research and development expense. We expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative future use.

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

	Three Months Ended September 30,	
	2012	2011
Compounds under development:		
Pixuvri	$ 1,319	$ 2,942
Pacritinib	349	
OPAXIO	444	255
Tosedostat	884	567
Brostallicin	(17)	13
Operating expenses	3,967	3,702
Research and preclinical development	5	51
Total research and development expenses	$ 6,951	$ 7,530

Costs for compounds under development include external direct expenses such as principal investigator fees, clinical research organization charges and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, EMA or other regulatory agencies outside the United States and Europe, as well as upfront license fees for acquired technology. Operating expenses include our personnel and an allocation of occupancy expenses associated with developing these compounds. Research and preclinical development costs primarily include costs associated with bisplatinates development as well as external laboratory services associated with other compounds. We do not allocate operating costs to the individual compounds under development as our accounting system does not track these costs by individual compound. As a result, we are not able to capture the total cost of each compound. Direct external costs incurred to date for Pixuvri, pacritinib, OPAXIO, tosedostat and brostallicin are $80.6 million, $0.4 million (excluding in-process research and development associated with the acquisition of S*BIO assets), $225.8 million, $9.4 million and $9.5 million, respectively. Costs for Pixuvri prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, or CTI (Europe), in January 2004 are excluded from this amount. Costs for pacritinib prior to our acquisition of S*BIO assets in May 2012 are also excluded from this amount. Costs for tosedostat prior to our co-development and license agreement with Chroma are also excluded from this amount. Costs for brostallicin prior to our acquisition of SM in July 2007 are also excluded from this amount.

Research and development expenses decreased to approximately $7.0 million for the three months ended September 30, 2012 from approximately $7.5 million for the three months ended September 30, 2011. Pixuvri costs decreased primarily due to a decrease in consulting costs within our regulatory group, in addition to decreases in clinical activity associated with the wind-down of the PIX203 trial, consulting and lab analysis costs associated with the PIX301 independent assessment and a reduction in costs associated with the PIX306 trial. Costs for pacritinib relate primarily to clinical development and manufacturing activities incurred subsequent to the acquisition of

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related assets from S*BIO. Costs for our OPAXIO program increased primarily due to an increase in clinical development activity associated with investigator initiated studies. Costs for tosedostat increased primarily due to an increase in manufacturing activity. Costs for brostallicin relate primarily to clinical development activities associated with phase I and phase II studies. Our operating expenses increased primarily due to costs associated with an increase in average number of personnel between comparable periods in addition to an increase in non-cash share-based compensation expense. These increases in operating expenses were partially offset by a decrease in discretionary bonus expense.

Our drug candidates Pixuvri, pacritinib, OPAXIO, tosedostat and brostallicin are currently in clinical development. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, 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. 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 or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, 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. We have drug candidates that are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates.

Our products will be successful and we will be able to generate revenues only if:

- our product candidates are developed to a stage that will enable us to commercialize, sell, or license related marketing rights to third parties; and

- our product candidates, if developed, are approved.

Failure to generate such revenues may preclude us from continuing our research, development and commercial activities for these and other product candidates. We also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products. Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost. Specific comments for individual product candidates are below.

Pixuvri. Pixuvri is an aza-anthracenedione that has distinct structural and physiochemical properties that make its anti-tumor unique in this class of agents. The novel pharmacologic differences between Pixuvri and the other agents in the class may allow re-introduction of anthracycline-like potency in the treatment of patients who are otherwise at their lifetime recommended doxorubicin exposure. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of Pixuvri because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. 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. For these reasons, among others, we cannot estimate the date on which clinical development of Pixuvri will be completed or when we will be able to generate material net cash inflows.

Pacritinib. Pacritinib is an oral, once a day, TKI with dual activity against JAK2 and FLT3. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of pacritinib because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. 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. For these reasons, among others, we cannot estimate the date on which clinical development of pacritinib will be completed or when we will be able to begin commercializing pacritinib to generate material net cash inflows.

OPAXIO. OPAXIO is our novel biologically enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. We are currently focusing our development of OPAXIO on ovarian, brain (glioblastoma), and locally advanced head and neck cancer. We are

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unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of OPAXIO because, among other reasons, a third party is conducting the key clinical trial of OPAXIO and even after a clinical trial has been 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. For these reasons, among others, we cannot estimate the date on which clinical development of OPAXIO will be completed or when we will be able to begin commercializing OPAXIO to generate material net cash inflows.

Tosedostat. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of tosedostat because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. 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. For these reasons, among others, we cannot estimate the date on which clinical development of tosedostat will be completed or when we will be able to begin commercializing tosedostat to generate material net cash inflows.

Brostallicin. Brostallicin is a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity. The NCCTG is conducting a phase II study of brostallicin in combination with cisplatin in patients with mTNBC. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of brostallicin because, among other reasons, a third party is conducting the clinical trial of brostallicin and even after a clinical trial has been 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. For these reasons, among others, we cannot estimate the date on which clinical development of brostallicin will be completed or when we will be able to begin commercializing brostallicin to generate material net cash inflows.

Bisplatinates (CT-47463). Cisplatin is a platinum-based chemotherapy drug used to treat a wide variety of cancers. We are developing new analogues of the dinuclear-platinum complex, or CT-47463, that is more potent than cisplatin. CT-47463 is endowed with a unique mechanism of action, active in preclinical studies on a large panel of tumor models, sensitive and refractory to cisplatin, and has a safety profile comparable to that of cisplatin. The novel bisplatinum analogues are rationally designed and synthesized to have improved biopharmaceutical properties that reduce the intrinsic reactivity of the molecule and that demonstrate preclinical anti-tumor efficacy in solid tumor models. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of CT-47463 because, among other reasons, no clinical trial design for CT-47463 has been developed yet and 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. For these reasons, among others, we cannot estimate the date on which clinical development of CT-47463 will be completed or when we will be able to begin commercializing CT-47463 to generate material net cash inflows.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in the following risk factors, which begin on page 35 of this Form 10-Q: *Our financial condition may be harmed if third parties default in the performance of contractual obligations.* ; *We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO as a maintenance therapy for advanced stage ovarian cancer and as a radiation sensitizer.* ; *We are subject to extensive government regulation.* ; *Even if our drug candidates are successful in clinical trials, we may not be able to successfully commercialize them.* ; *If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.* ; and *We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.*

Selling, general and administrative expenses. Selling, general and administrative expenses were approximately $7.8 million for the three months ended September 30, 2012 and approximately $7.8 million for the three months ended September 30, 2011. During the three months ended September 30, 2012, there was a $1.3 million decrease related to the VAT assessment reserve associated with our CTI (Europe) operations and a $0.7 million decrease in discretionary bonus as compared to the same period in 2011. These decreases were offset by a $1.2 million increase in consulting and other professional services mainly associated with the commercial launch of Pixuvri in the EU and a $0.7 million increase in legal and patent services.

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Foreign exchange gain (loss). The foreign exchange gain for the three months ended September 30, 2012 and foreign exchange loss for the three months ended September 30, 2011 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.

Settlement expense. Settlement expense of $0.4 million for the three months ended September 30, 2012 relates to the accrual for the cost of benefits to be provided to Craig W. Philips, former President of the Company, as discussed in Note 5, *Commitments and Contingencies* in the Notes to Condensed Consolidated Financial Statements included in Item 1, Part I of this Quarterly Report on Form 10-Q.

Dividends and deemed dividends on preferred stock. Dividends and deemed dividends on preferred stock were approximately $5.0 million for the three months ended September 30, 2012 related to the issuance of our Series 15-2 Preferred Stock. Dividends and deemed dividends on preferred stock were approximately $13.0 million for the three months ended September 30, 2011 related to the issuance of our Series 13 preferred stock.

Nine months ended September 30, 2012 and 2011

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

	Nine Months Ended September 30,	
	2012	2011
Compounds under development:		
Pixuvri	$ 7,088	$ 8,975
Pacritinib	363	
OPAXIO	1,314	1,235
Tosedostat	2,435	6,183
Brostallicin	107	53
Operating expenses	12,623	10,426
Research and preclinical development	150	110
Total research and development expenses	$ 24,080	$ 26,982

Research and development expenses decreased to approximately $24.1 million for the nine months ended September 30, 2012 from approximately $27.0 million for the nine months ended September 30, 2011. Pixuvri costs decreased primarily due to a decrease in clinical activity associated with the wind-down of the PIX203 study, a reduction in consulting and lab analysis costs associated with PIX301 independent assessment and a reduction in costs associated with the PIX306 trial. Manufacturing activities also decreased between periods. These decreases were partially offset by an increase in costs associated with regulatory activities. Costs for pacritinib relate primarily to clinical development and manufacturing activities incurred subsequent to the acquisition of related assets from S*BIO. Costs for our OPAXIO program increased primarily due to an increase in clinical development activity associated with investigator initiated studies. Costs for tosedostat decreased primarily due to the $5.0 million upfront license fee upon execution of the co-development and license agreement with Chroma incurred during the nine months ended September 30, 2011. This decrease was partially offset by increases in clinical development and manufacturing activities. Costs for brostallicin increased primarily due to an increase in costs associated with clinical development activities related to phase I and phase II studies, in addition to an increase in costs associated with manufacturing activities. Our operating expenses increased primarily due to increases in noncash share-based compensation expense, occupancy costs associated with our new office lease and increases in recruiting and consulting activities associated with our clinical development group. Additional increases consisted of costs associated with an increase in average number of personnel between comparable periods.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $29.0 million for the nine months ended September 30, 2012 from approximately $25.3 million for the nine months ended September 30, 2011. This increase was related to a $3.4 million increase in consulting and other professional services mainly associated with the commercial launch of Pixuvri in the EU, a $3.2 million increase in noncash share-based compensation and a $0.8 million increase in salaries and benefits related to an increase in personnel. These increases were partially offset by a $1.2 million decrease in discretionary bonus, a $1.0 million decrease in legal services and a $2.1 million decrease related to the VAT assessment reserve associated with our CTI (Europe) operations.

Acquired in-process research and development. Acquired in-process research and development for the nine months ended September 30, 2012 relates to charges of $29.1 million recorded in connection with our acquisition of assets of S*BIO.

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Interest expense. Interest expense decreased to approximately $51,000 for the nine months ended September 30, 2012 from approximately $0.7 million for the nine months ended September 30, 2011. Upon maturity, we retired the remaining $10.3 million outstanding principal balance of our 7.5% convertible senior notes in April 2011 and the remaining $10.9 million outstanding principal balance of our 5.75% convertible senior notes in December 2011.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs for the nine months ended September 30, 2011 is primarily related to the amortization of debt discount and issuance costs incurred on our 5.75% and 7.5% convertible senior notes.

Foreign exchange gain (loss). The foreign exchange loss for the nine months ended September 30, 2012 and 2011 is due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches denominated in foreign currencies.

Settlement expense. Settlement expense of $0.4 million for the nine months ended September 30, 2012 relates to the accrual for the cost of benefits to be provided to Craig W. Philips, former President of the Company, as discussed in Note 5, *Commitments and Contingencies* in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Dividends and deemed dividends on preferred stock. Dividends and deemed dividends on preferred stock were approximately $13.5 million for the nine months ended September 30, 2012 related to the issuances of our Series 15-1 and 15-2 Preferred Stock. Dividends and deemed dividends on preferred stock were approximately $49.8 million for the nine months ended September 30, 2011 primarily related to the redemptions of our Series 8 and 10 preferred stock in addition to the issuances of our Series 12 and 13 preferred stock.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents. As of September 30, 2012, we had approximately $14.3 million in *cash and cash equivalents*. Subsequent to period end, we received $60.0 million in gross proceeds, before deducting underwriting discounts and commissions and other offering costs, from the issuance of our Series 17 Preferred Stock. See Note 9, *Subsequent Events* in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Net cash used in operating activities. Net cash used in operating activities decreased to approximately $45.8 million during the nine months ended September 30, 2012 compared to approximately $54.8 million for the same period during 2011 primarily due to a one-time upfront payment of $5.0 million in March 2011 related to the licensing of tosedostat, which is included in *research and development* expense, a decrease in cash paid for interest on our convertible notes, and an increase in *accounts payable* during the nine months ended September 30, 2012.

Net cash used in investing activities. Net cash used in investing activities increased to approximately $19.7 million for the nine months ended September 30, 2012 compared to $1.9 million for the nine months ended September 30, 2011 as a result of $17.8 million paid for the acquisition of assets of S*BIO. See Note 8, *Acquisitions* in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 included in this Quarterly Report on Form 10-Q for additional information.

Net cash provided by financing activities. Net cash provided by financing activities was approximately $32.6 million for the nine months ended September 30, 2012. We received approximately $32.9 million in net proceeds from the issuance of our Series 15 preferred stock and warrants to purchase common stock in May 2012 and July 2012. These proceeds were offset by $0.2 million cash paid in 2012 for transaction costs associated with the issuance of Series 14 preferred stock and $0.1 million cash paid for the repurchase of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees. Net cash provided by financing activities of approximately $79.2 million for the nine months ended September 30, 2011 was primarily due to issuances of our preferred stock. We received approximately $23.2 million in net proceeds from the issuance of our Series 8 Preferred Stock, warrants to purchase common stock and an additional investment right to purchase shares of our Series 9 Preferred Stock in January 2011. We received approximately $23.5 million in net proceeds from the issuance of our Series 10 preferred stock, warrants to purchase common stock and an additional investment right to purchase shares of our Series 11 Preferred Stock in February 2011. We received approximately $15.0 million in net proceeds from the issuance of our Series 12 preferred stock and warrants to purchase common stock in May 2011. We received approximately $28.1 million in net proceeds from the issuance of our Series 13 preferred stock and warrants to purchase common stock in July 2011. These proceeds were offset by a $10.3 million payment to fully retire the outstanding principal balance on our 7.5% convertible senior notes in April 2011 and $0.3 million cash paid for the repurchase of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees.

Capital Requirements and Resources

We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. At our currently planned spending rate, we believe that our financial resources, in

addition to the expected receipts from European Pixuvri sales, will be sufficient to fund our operations for the next fifteen (15) months. Changes in manufacturing,

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clinical trial expenses, and expansion of our sales and marketing organization in Europe, may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for Pixuvri that we currently assume in planning for 2013.

Capital Resources

We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources. However, our ability to issue equity securities may be limited by the number of shares we may issue under our amended and restated articles of incorporation unless we get shareholder approval to increase authorized shares.

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

- results of our clinical trials;
- regulatory approval of our products;
- success in acquiring or divesting products, technologies or businesses;
- progress in and scope of our research and development activities;
- finding appropriate partners for the development and commercialization of our products if they are approved for marketing;
- success in commercializing our products;
- litigation and other disputes; and
- competitive market developments.

Capital Requirements

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies or sell or license our products to others. We will require additional financing and such financing may not be available when needed or, if available, we may not be able to obtain it on terms favorable to us or to our shareholders. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs, which may adversely affect our ability to operate as a going concern and we may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, or may harm our ability to operate as a going concern.

The following table includes information relating to our contractual obligations as of September 30, 2012 (in thousands):

Contractual Obligations	**Payments Due by Period**				
	Total	**1 Year**	**2-3 Years**	**4-5 Years**	**After 5 Years**
Operating leases:					

Facilities	$ 22,413	$ 2,320	$ 4,561	$ 4,441	$ 11,091
Long-term obligations (1)	28		28		
Purchase commitments	5,354	4,368	535	451	
	$ 27,795	$ 6,688	$ 5,124	$ 4,892	$ 11,091

(1) This amount does not include long-term obligations of $5.0 million related to deferred rent and $1.1 million related to the reserve for VAT assessments.

Manufacturing Supply Agreements

We signed a manufacturing supply agreement, or the NerPharMa Agreement, with NerPharMa, S.r.l., or NerPharMa (a pharmaceutical manufacturing company belonging to Nerviano Medical Sciences, S.r.l., in Nerviano, Italy), for our drug candidate Pixuvri. The NerPharMa Agreement is a five year non-exclusive agreement and provides for both the commercial and clinical supply of Pixuvri. The NerPharMa Agreement commenced on July 9, 2010 and expires on the fifth anniversary date of the first government approval obtained either in the United States or Europe. The NerPharMa Agreement may be terminated for an uncured material breach, insolvency or the filing of

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bankruptcy, or by mutual agreement. We may also terminate the NerPharMa Agreement (i) upon prior written notice in the event of failure of three or more of seven consecutive lots of product or (ii) in the event NerPharMa is acquired or a substantial portion of NerPharMa s assets related to the NerPharMa Agreement are sold to another entity.

We signed a manufacturing and supply agreement, or the Chroma Supply Agreement, with Chroma for our drug candidate tosedostat. The Chroma Supply Agreement is a non-exclusive agreement and provides for both the clinical and commercial drug supply of tosedostat. The Chroma Supply Agreement commenced on June 8, 2011 and expires two years from the date when tosedostat is granted first approval for commercial distribution by the applicable regulatory authority in the licensed territory. Upon expiration of the initial term, we have a one year renewal option. We have the right to terminate the Chroma Supply Agreement without cause with 90 days written notice to Chroma. Both parties have the right to terminate for breach, bankruptcy, mutual agreement, or termination of the development agreement.

Additional Milestone Activities

Chroma Therapeutics, Ltd.

We have an agreement with Chroma, the Chroma License Agreement, under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate, tosedostat, in North, Central and South America, or the Licensed Territory. Pursuant to the terms of the Chroma License Agreement, we paid Chroma an upfront fee of $5.0 million upon execution of the agreement and will make a milestone payment of $5.0 million upon the initiation of the first pivotal trial, which is expected to commence in 2013. 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.

We will also pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the later of (a) the expiration date of the last patent claim covering tosedostat in that country, (b) the expiration of all regulatory exclusivity periods for tosedostat in that country or (c) 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.

We will oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory, or the ROW Territory. Development costs may not exceed $50.0 million for the first three years of the Chroma License Agreement unless agreed by the parties and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the Chroma Supply Agreement. We have the option of obtaining a commercial supply of tosedostat from Chroma or from another manufacturer at our sole discretion in the Licensed Territory. The Chroma License Agreement may be terminated by us at our convenience upon 120 days written notice to Chroma. The Chroma License Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

By a letter dated July 18, 2012, Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma s allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma s lack of diligence claim based in part on the appropriateness of completing the ongoing phase II combination trials prior to developing a phase III trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement.

Effective September 25, 2012, we and Chroma entered into a three month standstill with respect to the parties respective claims under the Chroma License Agreement, but otherwise reserving the parties respective rights as of the commencement of the standstill period. The standstill is terminable by either party on one month s notice.

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*S*BIO Pte Ltd*

Pursuant to the S*BIO Agreement, we acquired the Seller Compounds, which inhibit Janus Kinase 2, commonly referred to as JAK2, and we made an initial payment of $2 million in cash at signing. In consideration of the assets and rights acquired under the S*BIO Agreement, we made an additional payment of $13 million in cash and issued 15,000 shares of our Series 16 Preferred Stock, which were automatically converted into 2.5 million shares of our common stock, to S*BIO. The S*BIO Agreement also provides S*BIO with a contingent right to certain milestone payments from us up to an aggregate amount of $132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any Seller Compound for use for specific diseases, infections or other conditions. 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.

At our election, we may pay up to 50% of any milestone payments to S*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock, provided that in no event will the issuances of our common stock or preferred stock in connection with the asset purchase, in the aggregate, equal or exceed 20% of our common stock or voting power outstanding as of the date of the S*BIO Agreement, except with the prior approval of our shareholders. At our annual meeting of shareholders on August 31, 2012, our shareholders approved the proposal to issue shares to S*BIO in connection with, or to finance, the acquisition of the Seller Compounds and approval to, at our option, issue shares of our common stock or shares of our preferred stock in lieu of cash for up to 50% of the milestone payments that may be made to S*BIO.

University of Vermont

We have an agreement with the University of Vermont, or UVM, which grants us an exclusive license, with the right to sublicense, for the rights to Pixuvri, or the UVM Agreement. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use Pixuvri. Pursuant to the UVM Agreement, we are obligated to make payments to UVM based on net sales. Our royalty payments range 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 (a) in the event of an uncured material breach of the UVM Agreement by the other party; or (b) in the event of bankruptcy of the other party.

PG-TXL

We have an agreement, or the PG-TXL Agreement, with PG-TXL Company, L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL s polymer technology. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we are obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to $14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement is based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we are required to make royalty payments to PG-TXL based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are payable to PG-TXL. We may terminate the PG-TXL Agreement (i) upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans or (ii) for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement (a) upon advance written notice in the event certain license fee payments are not made; (b) in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or (c) in the event of liquidation or bankruptcy of a party.

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Gynecologic Oncology Group

We have an agreement with the GOG related to the GOG0212 trial, which the GOG is conducting. We recorded a $1.7 million payment due to the GOG based on the 800 patient enrollment milestone achieved in the second quarter of 2011, of which $0.9 million is outstanding and included in *accounts payable* as of September 30, 2012. Under this agreement, we are required to pay up to $1.8 million in additional milestone payments related to the trial, of which $0.5 million will become due upon receipt of the interim analysis and data transfer which may occur in 2013. There were 946 patients enrolled as of September 30, 2012.

Nerviano Medical Sciences

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

Cephalon

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

Novartis

In September 2006, we entered into an exclusive worldwide licensing agreement, or the Novartis Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of OPAXIO. Total product and registration milestones to us for OPAXIO under the Novartis Agreement could reach up to $270 million. Royalty payments to us for OPAXIO are based on worldwide OPAXIO net sales volumes and range from the low-twenties to mid-twenties as a percentage of net sales.

Pursuant to the Novartis Agreement, we are responsible for the development costs of OPAXIO and have control over development of OPAXIO unless and until Novartis exercises its development rights, or the Development Rights. In the event that Novartis exercises the Development Rights, then from and after the date of such exercise, or the Novartis Development Commencement Date, Novartis will be solely responsible for the development of OPAXIO. Prior to the Novartis Development Commencement Date, we are solely responsible for all costs associated with the development of OPAXIO, but will be reimbursed by Novartis for certain costs after the Novartis Development Commencement Date. After the Novartis Development Commencement Date, Novartis will be responsible for costs associated with the development of OPAXIO, subject to certain limitations; however, we are also responsible for reimbursing Novartis for certain costs pursuant to the Novartis Agreement.

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

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the United States and sales volumes in other countries.

Royalties for OPAXIO and Pixuvri are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and

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country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its Development Rights until the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement or (ii) Novartis determination, in its sole discretion, to terminate the Development Rights exercise period by written notice to us (events (i) and (ii) collectively being referred to as the Development Rights Exercise Period), the Novartis Agreement will automatically terminate upon expiration of the Development Rights Exercise Period. In the event of an uncured material breach of the Novartis Agreement, the non-breaching party may terminate the Novartis Agreement. Either party may terminate the Novartis Agreement without notice upon the bankruptcy of the other party. In addition, Novartis may terminate the Novartis Agreement without cause at any time (a) in its entirety within 30 days written notice prior to the exercise by Novartis of its Development Rights or (b) on a product-by-product or country-by-country basis on 180 days written notice after the exercise by Novartis of its Development Rights. If we experience a change of control that involves certain major pharmaceutical companies, Novartis may terminate the Novartis Agreement by written notice within a certain period of time to us or our successor entity.

As of September 30, 2012, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to exercise its option to participate in the development and commercialization of Pixuvri or exercise its Development Rights for OPAXIO.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Foreign Exchange Market Risk

We are exposed to risks associated with foreign currency transactions insofar as we use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. As of September 30, 2012, our foreign currency transactions were minimal and changes to the exchange rate between the U.S. dollar and foreign currencies would have an immaterial affect on our earnings. In addition, the reported carrying value of our euro-denominated assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. As of September 30, 2012, we had a net asset balance excluding intercompany payables and receivables in our European branches and subsidiaries denominated in euros. As of September 30, 2012, if the euro had been 20% weaker against the dollar, our net asset balance would have decreased by approximately $1.3 million as of this date.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

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

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

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB s request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) 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 are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately $6,000 to $643,000 converted using the currency exchange rate as of September 30, 2012, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB had to evaluate before imposing any possible administrative sanctions. In a letter dated March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of 40,000, or approximately $55,000 converted using the currency exchange rate as of March 10, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment we believe the likelihood that a pecuniary administrative sanction will be imposed on us for the violation asserted in clause (ii) is probable.

On April 14, 2009, December 21, 2009 and June 25, 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003, 2005 and 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, or approximately $0.7 million, $7.1 million, $3.2 million and $1.1 million converted using the currency exchange rate as of September 30, 2012, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the final decision of the lower tax courts (i.e. the Provincial Tax Court or the Regional Tax Court) or of the Supreme Court is unfavourable to us, we may be requested to pay to the ITA an amount ranging from 2.9 million to 9.4 million, or approximately $3.7 million to $12.1 million converted using the currency exchange rate as of September 30, 2012, 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. On September 13, 2011, the Provincial Tax Court issued decision no. 229/3/2011 with which it (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, or approximately $13,000 converted using the currency exchange rate as of September 30, 2012, as partial refund of the legal expenses we incurred for our appeal. On October 16, 2012, ITA appealed against this decision. We will defend ourselves in front of the Regional Tax Court both on procedural grounds and on the merits of the case.

2005 VAT. On January 13, 2011, the Provincial Tax Court issued decision No. 4/2010 in which it (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. As a result of this decision, our exposure for 2005 VAT assessment is currently reduced by the waiver of penalties of 2.6 million, or approximately $3.4 million converted using the currency exchange rate as of September 30, 2012.

On February 2, 2011, we paid the required VAT deposit of 1.5 million, or approximately $2.1 million converted using the currency exchange rate as of February 2, 2011 (including 50% of the assessed VAT, interest and collection fees). On March 25, 2011, we paid to the Italian collection agent an additional amount of 0.1 million, or

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approximately $0.1 million converted using the currency exchange rate as of March 25, 2011. The additional payment was for interest and collection fees during the suspension period. We do not believe this additional payment was due and we intend to pursue recovery of such payment through litigation. At the end of the first quarter of 2012, the ITA issued an additional notice of deposit payment for an amount of 0.5 million, or approximately $0.7 million converted using the currency exchange rate as of September 30, 2012 (including approximately 16.7% of the assessed VAT, interest and collection fees). Such amount has been partially offset with the refund of the deposit payment made for 2006 VAT (please refer to 2006 VAT below). On April 10, 2012, an additional deposit payment of 0.1 million, or approximately $0.1 million converted using the exchange rate as of April 10, 2012, was made to the ITA.

The ITA has appealed to the higher court against the decision that no penalties could be imposed on us. We do not believe that the Provincial Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and presented during the hearing, including an appraisal from an independent expert. Accordingly, we also filed an appeal against the Provincial Tax Court s decision. On October 15, 2012, the Regional Tax Court issued decision no. 127/31/2012 with which it (i) fully accepted the merits of our appeal and (ii) confirmed that no penalties can be imposed against us. The ITA is entitled to appeal such decision to the Italian Supreme Court within six months.

2006 VAT. On October 18, 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2007 VAT case) with which it (i) fully accepted the merits of our appeal (ii) declared that no penalties can be imposed against us, and (iii) found for 2006 and 2007 VAT cases the ITA liable to pay us 10,000, or approximately $13,000 converted using the currency exchange rate as of September 30, 2012, as partial refund of the legal expenses incurred for the appeal.

On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT for an amount of 0.4 million, or approximately $0.6 million converted using the currency exchange as of March 4, 2011 (including 50% of the assessed VAT, interest and collection fees). After the Provincial Tax Court s decision at the end of the first quarter 2012, the ITA issued an order of refund of the deposit amount. Such refund was offset with the additional deposit payment made on April 10, 2012 for 2005 VAT (please refer to 2005 VAT above).

The ITA has appealed to the higher court against this decision. We will defend against the ITA s appeal before the higher Regional Tax Court. The Regional Tax Court has scheduled the first hearing for November 6, 2012.

2007 VAT. On October 18, 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2006 VAT case) 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 for 2006 and 2007 VAT cases the ITA liable to pay us 10,000, or approximately $13,000 converted using the currency exchange rate as of September 30, 2012, as partial refund of the legal expenses incurred for the appeal.

On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million, or approximately $0.1 million converted using the currency exchange rate as of September 26, 2011 (including 50% of the assessed VAT, interest and collection fees). After the Provincial Tax Court s decision at the end of the first quarter 2012, the ITA issued an order of refund of the deposit amount. Such refund has been suspended by the collection agent because of the assessment of social contribution due for an amount equal to 0.1 million, or approximately $0.1 million converted using the currency exchange rate as of September 30, 2012. We do not believe this social contribution was due and we are in the process of resolving the issue with the social contribution authorities.

The ITA has appealed to the higher court against this decision. We will defend against the ITA s appeal before the higher Regional Tax Court. The Regional Tax Court has scheduled the first hearing for November 6, 2012.

Due to the change of the position for the VAT assessment cases, we have reduced the reserve for VAT assessed by 1.7 million, or approximately $2.1 million converted using the currency exchange rate as of September 30, 2012. Therefore, we have a reserve for VAT assessed, interest and collection fees totalling 1.0 million as of September 30, 2012, or approximately $1.3 million converted using the currency exchange rate as of September 30, 2012, of which $1.1 million included in *long-term obligations, less current portion* and $0.2 million of the reserve is accounted for as an offset to VAT receivable included in *other assets*.

On August 3, 2009, Sicor - Società Cortisteroisi S.r.l., or Sicor, filed a lawsuit in the Court of Milan to obtain the Court s assessment that we were bound to source a chemical compound, whose chemical name is BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma on October 4, 2002. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply

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agreement in question was properly terminated and that we have no further obligation to comply with its terms. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. The parties filed the authorized pleadings and submitted to the Court their requests for evidence. On November 11, 2010, a hearing was held to examine and discuss the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing held on November 11, 2010, the judge declared that the case does not require any discovery or evidentiary phase, and may be decided on the basis of the documents and pleadings already filed by the parties. At the hearing held on October 11, 2012 the parties informed the Court about the ongoing negotiations pending between the parties and asked the Court, accordingly, to postpone the case. At the request of the parties, the Court extended the final hearing until March 21, 2013. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

In March 2010, three purported securities class action complaints were filed against the Company and certain of our officers and directors in the United States District Court for the Western District of Washington. On August 2, 2010, Judge Marsha Pechman consolidated the actions, appointed lead plaintiffs, and approved lead plaintiffs counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint, captioned Sabbagh v. Cell Therapeutics, Inc. (Case No. 2:10-cv-00414-MJP), naming the Company, Dr. James A. Bianco, Louis A. Bianco, and Craig W. Philips as defendants. The amended consolidated complaint alleges that defendants violated the federal securities laws by making certain alleged false and misleading statements related to the FDA approval process for Pixuvri. The action seeks damages on behalf of purchasers of our stock during a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, defendants moved to dismiss the amended consolidated complaint. On February 4, 2011, the Court denied in large part the defendants motion. Defendants answered the amended consolidated complaint on March 28, 2011, and discovery commenced, with trial set for June 25, 2012. On December 14, 2011, the parties filed a letter with the Court indicating they had agreed to the general terms of a settlement, and asking the Court to remove the case deadlines from the Court calendar. On February 14, 2012, plaintiffs filed a motion for preliminary approval of the settlement, along with related documents. On March 16, 2012, the Court granted preliminary approval of the settlement, granted conditional certification to the proposed class, and approved the proposed forms of notice to the class. A settlement hearing occurred on July 20, 2012. The Court entered a Final Judgment and Order of Dismissal with Prejudice on July 25, 2012. The negotiated terms of the settlement include a $19.0 million dollar settlement fund, which was paid by our insurance carriers. As a result, there is no estimated loss to us.

In April 2010, three shareholder derivative complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to the Company by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for Pixuvri. The allegations in the derivative actions are substantially similar to those in the securities action. On May 10, 2010, Judge Marsha Pechman consolidated the shareholder derivative actions under the caption Shackleton v. Bauer (Case No. 2:10-cv-00414-MJP), and appointed the law firms of Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs. Three more derivative complaints were filed in June, July and October 2010, and they have also been consolidated with Shackleton v. Bauer. The court has set a trial date of December 3, 2012 for the shareholder derivative action. At this stage of the litigation no probability of loss can be predicted in the event we do not prevail.

In December 2011, we were informed of a decree by the Italian Ministry for Education, University and Research, or the Ministry, dated July 7, 2011 revoking a financial support granted to Novuspharma S.p.A. (now the Company, following the merger of Novuspharma into the Company in January 2004) in July 2002, or the Financial Support, and requesting the repayment of the amount paid to Novuspharma as grant for the expenses (i.e. 0.5 million, plus interest for an additional amount of 0.1 million) by January 15, 2012, or the January Decree. The Financial Support was granted (following a proper application by Novuspharma) for a research project about new compounds for the treatment of tumors of the gastrointestinal area, or the Project. The initial amount of the Financial Support was (i) up to 2.3 million as a subsidized loan, and (ii) up to 2.5 million as a grant for expenses (a portion of which, corresponding to 0.5 million, was effectively paid to Novuspharma). Following the interruption of the Project in June 2004, due to unforeseeable technical reasons not ascribable to the beneficiary company, the Financial Support was reduced (i) to 0.6 million for the subsidized loan, and (ii) to 0.6 million for the grant for expenses. In 2005, we requested the Ministry to authorize the joint ownership of the Project by both Cell Therapeutics Europe S.r.l., or CTE, and our Italian branch. In May 2007, the Ministry accepted such joint ownership of the Project subject to the issuance of a guarantee, or the Guarantee, for the portion corresponding to the subsidized loan, but we never issued such Guarantee. In 2009, our Italian branch s research activities were terminated. Since we assert that the January Decree is unlawful and that the relevant issuance represents a breach of the Ministry s duty of good faith and an abuse of right, on February 13, 2012, we served a writ of summons upon the Ministry, suing it in the civil Court of Rome in order to have the January Decree declared ineffective. However, if we are unable to successfully defend ourselves against the January Decree issued by the Ministry, we may be requested to pay 0.6 million (i.e. the amount paid to Novuspharma as grant for the expenses plus interest, as described above), or approximately $0.8 million converted using the currency exchange rate as of September 30, 2012, plus counterparty s attorney s fees, litigation costs and additional default interest for the period lapsed between January 16, 2012 and the date of the effective payment. While the parties were engaged in pending settlement negotiations, (i) the Ministry interrupted the recovery process of the relevant financial support, and (ii) at the first hearing before the Court of Rome that took place on July 20, 2012, the Ministry failed to appear at the hearing, with the consequence that the Judge declared it in default of

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appearance, and we requested a postponement to continue the negotiations with the Ministry; the judge granted the postponement and the next hearing is now scheduled for April 5, 2013. On September 17, 2012, we were informed of a decree, dated August 27, 2012, issued by the General Director of the Ministry, or the August Decree, that is aimed at rectifying the January Decree and according to which the revocation will apply to only the portion of the relevant financial support that had never been requested by or granted to the Company (i.e., 0.2 million as subsidized loan and 0.1 million as grant for expenses, that we never received and therefore not obliged to return). We believe that the August Decree is still subject to the approval by the Italian Court of Auditors (Corte dei Conti). We expect to be informed by the Ministry of this approval once it is granted by the Italian Court of Auditors. At this time, considering the contents of the August Decree, the likelihood of an unfavorable outcome of these legal proceedings is remote.

In July 2012, a complaint was filed against us in the Superior Court of Washington for King County captioned GLY Construction Inc. v. Cell Therapeutics, Inc. and Selig Holdings Company (Case No. 12-2-22742-0 SEA), naming the Company and Selig Holdings Company as defendants. The complaint asserts claims for breach of contract, unjust enrichment/quantum meruit and lien foreclosure, and alleges that we failed to pay certain amounts to plaintiffs for work performed for construction improvements totaling approximately $4.0 million. We contend that these amounts should be offset by amounts owed under the lease agreement with Selig Holdings Company. We asserted cross-claims for breach of contract and business devastation against Selig in the above-referenced lawsuit. These cross-claims were based on Selig s refusal to pay amounts owed under the lease agreement, including amounts owed to GLY and other expenses incurred. GLY, Selig and the Company reached a settlement on all of GLY s claims on or around September 4, 2012. The settlement included a partial lump sum payment with subsequent monthly payments from both Selig and us. We still have claims against Selig for amounts owed under the lease agreement, including portions of the settlement amount paid by us to GLY. The remaining litigation between Selig and us is in the early stages and, as such, no probability of success can be predicted at this time.

In March 2011, we entered into a license and co-development agreement, or the Chroma License Agreement, with Chroma Therapeutics, Ltd., or Chroma, providing us with exclusive marketing and co-development rights to Chroma s drug candidate, tosedostat, in North, Central and South America. By a letter dated July 18, 2012 Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma s allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma s lack of diligence claim based in part on the appropriateness of completing the ongoing phase II combination trials prior to developing a phase III trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement.

Effective September 25, 2012, we and Chroma entered into a three month standstill with respect to the parties respective claims under the Chroma License Agreement, but otherwise reserving the parties respective rights as of the commencement of the standstill period. The standstill is terminable by either party on one month s notice.

On June 16, 2012, Craig W. Philips, then President of Cell Therapeutics, Inc., delivered notice of his intention to resign as President of the Company, effective July 16, 2012. Mr. Philips departure was the result of a perceived diminution of responsibilities. The parties finalized a settlement agreement in October 2012, and the Company has accrued approximately $0.4 million as of September 30, 2012.

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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, some of which may be covered in whole or in part by insurance.

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

Factors Affecting Our Operating Results and Financial Condition

We are largely dependent on the commercial success of Pixuvri and although we anticipate generating revenue from sales of Pixuvri, we may never significantly increase these sales or become profitable.

We are at an early stage of commercialization and we anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only marketed product candidate, Pixuvri, which in turn, will depend on several factors, including our ability to:

- successfully maintain and increase market demand for, and sales of, Pixuvri in Europe through our sales and marketing efforts by expanding our sales force;
- obtain greater acceptance of Pixuvri by physicians and patients;
- maintain compliance with regulatory requirements;
- obtain a renewal annually of our conditional marketing authorization for Pixuvri in the E.U. and complete a post-marketing study of Pixuvri aimed at confirming the clinical benefit previously observed in Pixuvri;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for Pixuvri and continue to manufacture commercial quantities at acceptable cost levels; and
- successfully maintain intellectual property protection for Pixuvri.

We cannot be certain that our marketing of Pixuvri in Europe will result in increased demand for, and sales of, the product. Further, if we are unsuccessful in expanding our sales force in Europe, we may be unable to successfully sell Pixuvri in Europe. If we fail to successfully sell Pixuvri in Europe, or our sales are lower than expected, we may be unable to generate sufficient revenues to grow or sustain our business and we may never become profitable, and our business, financial condition, operating results and prospects and the trading price of our securities could be harmed.

Our current business strategy is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of Pixuvri. If we are unable to successfully execute on our sales and marketing strategy, we may not be able to generate significant product revenues or execute on our business strategy.

One of the priorities of our business strategy is to successfully execute the commercial launch of Pixuvri in Europe. We may not be able to successfully commercialize Pixuvri in Europe as planned. In order to commercialize Pixuvri in Europe, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. We currently have limited resources and the continued development of our own commercial organization to market Pixuvri and any additional product candidates we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. To the extent we rely on additional third parties to commercialize Pixuvri or any other product candidates that may be approved in the future, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop our own commercial organization or collaborate with a third-party sales and marketing organization, we may not be able to commercialize our product candidates, including Pixuvri, and execute on our business strategy. If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of Pixuvri, or any other product candidates that may be approved in the future, marketing and commercialization efforts, then we will not be able to generate sustainable revenues from product sales, which could harm our business, financial condition, operating results and prospects and the trading price of our securities.

We need to raise additional funds and expect that we will need to continue to raise funds in the future, and additional funds may not be available on acceptable terms, or at all; failure to raise significant additional funds may cause us to cease development of our products and operations.

We have substantial operating expenses associated with the development of our product candidates and as of September 30, 2012, we had *cash and cash equivalents* of $14.3 million. Subsequent to period end, we received approximately $60.0 million in gross proceeds from the issuance of preferred stock (before deducting underwriting discounts and commissions and offering expenses), see Note 9, *Subsequent Events* in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information. At our currently planned spending rate, we believe that our financial resources, in addition to the expected receipts from European Pixuvri sales, will be sufficient to fund our operations for the next fifteen (15) months. Changes in manufacturing, clinical trial expenses, and expansion of our sales and marketing organization in Europe, may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for Pixuvri that we currently assume in planning for 2013. There can be no assurance that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations.

Raising additional capital will likely require that we issue additional shares of our common stock. Because of the number of shares reserved for, and to be reserved for, issuance under various convertible securities, derivative securities and otherwise, we have a limited amount of authorized shares of common stock available for issuance and it can be difficult for us to obtain an increase in our authorized shares. If we do not have enough shares authorized to effect an equity financing, our ability to raise capital through equity financings may be harmed. To the extent that we raise additional capital through the sale of equity securities, or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us.

We may not be able to raise such capital or, if we can, it may not be on favorable terms. We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. In addition, some financing alternatives may require us to meet additional regulatory requirements in the European Union (including Italy) and the United States and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain additional funding. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to Pixuvri, pacritinib, OPAXIO, tosedostat and brostallicin 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, including the rights to Pixuvri, pacritinib, OPAXIO, tosedostat, brostallicin and bisplatinates.

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We need to implement a reduction in expenses across our operations if we are unable to secure additional financing.

We may need substantial additional capital to fund our current operations, particularly in light of the cash needed to fund development of our drug candidates. If we are unable to secure additional financing on acceptable terms in the near future, we will need to implement additional cost reduction initiatives, such as further reductions in the cost of our workforce and the discontinuation of a number of business initiatives to further reduce our rate of cash utilization and extend our existing cash balances. We believe that these additional cost reduction initiatives, if undertaken, could provide us with additional time to continue our pursuit of additional funding sources and also strategic alternatives. In the event that we are unable to obtain financing on acceptable terms and reduce our expenses, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects.

Our common stock is listed on The NASDAQ Capital Market and the Mercato Telematico Azionario stock market in Italy, or the MTA, and we may not be able to maintain those listings or trading on these exchanges may be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.

The closing bid price of our common stock has been below the minimum $1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2). On June 29, 2012, we received a notification from The NASDAQ Stock Market LLC, or NASDAQ, indicating non-compliance with this requirement and providing a grace period of 180 calendar days to regain compliance with this requirement or be delisted if we do not regain compliance. On August 7, 2012, in an effort to regain compliance with the NASDAQ listing requirements and increase the per-share trading price of our common stock, our board of directors approved the September Split. The September Split became effective on September 2, 2012. On September 19, 2012, we announced that we received a letter from NASDAQ indicating that as of that date we had regained compliance with NASDAQ Marketplace Rule 5550(a)(2). As a result, our common stock will continue to be listed and traded on The NASDAQ Capital Market. However, notwithstanding our current compliance with NASDAQ listing standards, there can be no assurance that we will be able to maintain our continued listing on The NASDAQ Capital Market in the future.

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. Furthermore, our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under any future indebtedness which would accelerate the maturity date of such future debt or trigger other obligations. Delisting from NASDAQ could also affect our ability to maintain our listing on the Borsa Italiana. Trading in our common stock has been halted or suspended in the past and may also be halted or suspended due to market or trading conditions at the discretion of NASDAQ, the Commissione Nazionale per le Società e la Borsa, or CONSOB (which is the public authority responsible for regulating the Italian securities markets), or the Borsa Italiana (which ensures the development of the managed markets in Italy). In addition, if we are not listed on The NASDAQ Capital Market or if our public float falls below $75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations may harm our ability to raise the capital we need.

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.

At our annual meeting of shareholders held on August 31, 2012, or the Annual Meeting, our shareholders approved an amendment to our amended and restated articles of incorporation, as amended, or our articles of incorporation, to increase the total number of authorized shares and authorized shares of common stock available for issuance. However, in the future, if we are unable to obtain a quorum at our shareholder meetings and/or fail to obtain shareholder approval of corporation actions, such failure could harm us. 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. As a result, there is a risk that we may not get shareholder approval for amendments to our articles of incorporation, including an amendment to increase the number of authorized shares of common stock at a time when we need those shares to effect a future equity financing. If we do not receive shareholder approval for such increase in authorized shares, our ability to raise capital through equity financings will be significantly harmed.

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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, when a quorum required a majority of the outstanding shares of our voting stock be represented in person or by proxy, we scheduled two annual meetings of shareholders, but were unable to obtain quorum at either meeting. 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. We were able to obtain a quorum to hold special meetings of the shareholders in April 2007, January 2008, March 2009 and June 2011 and annual meetings of the shareholders in September 2007, June 2008, October 2009, September 2010, November 2011 and August 2012. Nevertheless, obtaining a quorum at future meetings even at the lower thresholds established by certain provisions of the Washington Business Corporation Act enacted in April 2011, and obtaining necessary shareholder approvals 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. We are continuing to explore other alternatives to achieve a quorum for and shareholder representation at our meetings; however, we cannot be certain that we will find an alternate method if we are unable to continue to use the custody transfer arrangements. As a result, we may be unable to obtain a quorum at future annual or special meetings of shareholders or obtain shareholder approval of proposals when needed.

Even if we obtain a quorum at our shareholder meetings, we may not obtain enough votes to approve matters to be resolved upon at those meetings. Under Rule 452 of the New York Stock Exchange, or Rule 452, the U.S. broker-dealer may only vote shares absent direction from the beneficial owner on certain specified routine matters, such as certain amendments to our articles of incorporation to increase authorized shares that are to be used for general corporate purposes and the ratification of our auditors. If our shareholders do not instruct their brokers on how to vote their shares on non-routine matters, then we may not obtain the necessary number of votes for approval. Non-routine matters include, for example, proposals that relate to the authorization or creation of indebtedness or preferred stock. Revisions to Rule 452 that further limit matters for which broker discretionary voting is allowed, such as the revisions imposed by the Dodd-Frank Act to prohibit broker discretionary voting on matters related to executive compensation and in the election of directors, may further harm our ability to obtain a quorum and shareholder approval of certain matters. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, including if a proposal is submitted to our shareholders to increase the number of authorized shares of common stock, such failure could harm us. For example, a proposal to approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of September 30, 2012, we had an accumulated deficit of $1.8 billion. We are pursuing regulatory approval for Pixuvri, pacritinib, OPAXIO, tosedostat and brostallicin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. We may never become profitable even if we are able to commercialize Pixuvri as planned, commercialize other products currently in development or otherwise.

We may be unable to use our net operating losses to reduce future income tax liability.

We have substantial tax loss carryforwards for U.S. federal income tax purposes. As a result of prior changes in the stock ownership of the Company, our ability to use such carryforwards to offset future income or tax liability is

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limited under section 382 of the Internal Revenue Code of 1986, as amended. 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.

We have received audit reports with a going concern disclosure on our consolidated financial statements.

As we may need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their reports on our December 31, 2011, 2010 and 2009 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our common stock and we may have a more difficult time obtaining necessary financing.

We will incur a variety of costs and may never realize the anticipated benefits of any acquisitions we may make, including our acquisition of pacritinib.

In May 2012, we completed our acquisition of pacritinib from S*BIO. 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, including the acquisition of pacritinib, may result in operating difficulties and expenditures. In addition, our acquisitions may require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we may never realize the anticipated benefits of any acquisition, including the acquisition of pacritinib. Any additional acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to intangible assets, which could harm our business, financial condition, operating results and prospects and the trading prices of our securities.

The global financial crisis may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.

The ongoing credit crisis and related turmoil in the global financial system has had and may continue to have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve or continue to worsen. In particular, our ability to access the capital markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so, which could have an adverse effect on our ability to meet our current and future funding requirements and on our flexibility to react to changing economic and business conditions.

We are required to comply with the regulatory structure of Italy because our stock is traded on the MTA, which could result in administrative and other challenges and additional expenses.

Our common stock is traded on the MTA and we are required to also comply with the rules and regulations of CONSOB and the Borsa Italiana, which ensures the development of the managed markets in Italy. Collectively, these entities regulate companies listed on Italy s public markets. Conducting our operations in a manner that complies with all of the applicable laws and rules requires us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all of the applicable regulatory regimes. In addition, the Borsa Italiana and CONSOB have made several requests for information asking us to provide additional clarifications about our business operations and financial condition, and we have complied with such requests and have met with CONSOB on several occasions to answer questions. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

In addition, under Italian law, we must publish a registration document, securities note and summary that have to be approved by CONSOB prior to issuing common stock that exceeds, in any twelve-month period, 10% of the number of shares of our common stock outstanding at the beginning of that period (except for certain applicable exceptions).

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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 may need to use convertible preferred stock and convertible debt since the common stock resulting from the conversion of such securities, subject to the current provisions of European Directive No. 71/2003 and, according to the current interpretations of the Committee of European Securities Regulators, is not subject to the 10% limitation imposed by E.U. and Italian law. However, there can be no assurance that these exceptions to the registration document requirement are not changed from time to time.

Moreover, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB s request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) 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 are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately $6,000 to $643,000 converted using the currency exchange rate as of September 30, 2012, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB would have to evaluate before imposing any possible administrative sanctions. In a letter dated March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of 40,000, or approximately $55,000 converted using the foreign currency exchange rate as of March 10, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment, we believe the likelihood that a pecuniary administrative sanction will be imposed on us for such asserted violation (ii) is probable.

Our assets and liabilities that remain 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. As long as we continue to have assets and liabilities held in our European branches and subsidiaries, the carrying value of these assets and liabilities 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 results of operations and financial condition.

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

Our European operations are subject to value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was $5.0 million as of September 30, 2012 and December 31, 2011, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003, 2005 and 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, or approximately $0.7 million, $7.1 million, $3.2 million and $1.1 million converted using the currency exchange rate as of September 30, 2012, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally

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filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the final decision of lower tax courts (i.e. the Provincial Tax Court or the Regional Tax Court) or of the Supreme Court was unfavourable to us, we may be requested to pay to the ITA an amount ranging from 2.9 million to 9.4 million, or approximately $3.7 million to $12.1 million converted using the currency exchange rate as of September 30, 2012, 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. Further information pertaining to these cases can be found in this Quarterly Report on Form 10-Q under Part II, Item 1 Legal Proceedings and is incorporated by reference herein.

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

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships and if third parties default on their performance of their contractual obligations, we could suffer significant financial losses and operational problems, which could in turn adversely affect our financial performance, cash flows or results of operations and may jeopardize our ability to maintain our operations.

We may not realize any royalties, milestone payments or other benefits under the License and Co-Development Agreement entered into with Novartis Pharmaceutical Company Ltd.

We have entered into a license and co-development agreement related to OPAXIO and Pixuvri with Novartis pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize Pixuvri. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to Pixuvri and we are able to reach a definitive agreement or Novartis elects to participate in the development and commercialization of OPAXIO. Novartis is under no obligation to make such election and enter into a definitive license agreement or exercise such right and may never do so. In addition, even if Novartis exercises such rights, any royalties and milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals and the attainment of certain sales levels. In the event Novartis does not elect to participate in the development of OPAXIO or Pixuvri, we may not be able to find another suitable partner for the commercialization and development of those products, which may have an adverse effect on our ability to bring those drugs to market. In addition, we would need to obtain a release from Novartis prior to entering into any agreement to develop and commercialize Pixuvri or OPAXIO with a third party. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels to generate royalty or milestone payments even if Novartis elects to exercise its option with regard to Pixuvri and enter into a definitive license agreement or to participate in the development and commercialization of OPAXIO. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time upon written notice to us. Further information about the status of the regulatory approval for Pixuvri can be found in Risk Factors Factors Affecting Our Operating Results and Financial Condition *We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.*

We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.

Obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

Information about the status of the regulatory approval of Pixuvri can be found in this Quarterly Report on Form 10-Q under Part I, Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations and is incorporated by reference herein.

In March 2011, we initiated a randomized pivotal trial of Pixuvri for the treatment of relapsed or refractory aggressive B-cell NHL. This clinical trial, referred to as PIX306 or PIX-R, is now open to patient enrollment. PIX-R will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant. We cannot predict the outcome of PIX-R or whether PIX-R will serve as either a

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post-marketing commitment trial or as a pivotal trial. Moreover, the FDA may request that we conduct more clinical trials in addition to PIX-R to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or how long it would take to execute this study and provide additional information to the FDA. 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 additional clinical trials or actions we may need to pursue to obtain approval of Pixuvri may negatively affect our business, financial condition and results of operations.

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

Our future financial success depends in part on obtaining regulatory approval of OPAXIO. We are currently focusing our development of OPAXIO as a potential maintenance therapy for women with advanced-stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin and as a radiation sensitizer. This study, the GOG0212 trial, is under the control of the GOG and is expected to enroll 1,100 patients with 946 patients enrolled as of September 30, 2012. The GOG Data Monitoring Committee plans to conduct the first interim analysis of overall survival and, based on feedback provided by the GOG, that interim analysis is currently expected in 2013. If successful, we could utilize those results to form the basis of an NDA for OPAXIO. However, prior clinical trials for OPAXIO have not been successful. In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of OPAXIO in non-small cell lung cancer, or NSCLC. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC. Accordingly, there can be no assurance that the GOG0212 will provide compelling evidence or any positive results, which would preclude any submission of an NDA to the FDA. In addition, we cannot predict the outcome of the GOG0212 study and that study may not demonstrate or be adequate to support regulatory approval of OPAXIO by the FDA.

In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced NSCLC who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the EMA s Scientific Advice Working Party; the EMA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMA of our decision to withdraw the MAA and we refocused our resources on the approval of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

We are subject to extensive government regulation.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries, including the EMA in the European Union. Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product, withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. Except for conditional approval of Pixuvri in Europe, none of our current product candidates have received approval for marketing in any country.

Information about the status of the regulatory approval of Pixuvri can be found in this Quarterly Report on Form 10-Q under Part I, Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations and is incorporated by reference herein. Except for conditional approval of Pixuvri in the European Union, none of our current product candidates have received approval for marketing in any country.

In March 2011, we initiated a randomized pivotal trial of Pixuvri for the treatment of relapsed or refractory aggressive B-cell NHL. This clinical trial, referred to as PIX306 or PIX-R, is now open to patient enrollment. PIX-R will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant. We cannot predict the outcome of PIX-R or whether PIX-R will serve as either a post-marketing commitment trial or as a pivotal trial. Moreover, the FDA may request that we conduct more clinical

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trials in addition to PIX-R to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or how long it would take to execute this study and provide additional information to the FDA. 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 additional clinical trials or actions we may need to pursue to obtain approval of Pixuvri may negatively affect our business, financial condition and results of operations.

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. In addition, data obtained from preclinical and clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our operating expenses, our business, financial condition and results of operations will be harmed.

In the event that we receive marketing approval for any of our product candidates, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. For example, federal statutes generally prohibit providing certain discounts and payments to physicians to encourage them to prescribe our product. Violations of such regulations or statutes may result in treble damages, criminal or civil penalties, fines or exclusion of us or our employees from participation in federal and state health care programs. Although we have policies prohibiting violations of relevant regulations and statutes, unauthorized actions of our employees or consultants, or unfavorable interpretations of such regulations or statutes may result in third parties or regulatory agencies bringing legal proceedings or enforcement actions against us. Because we will likely need to develop a new sales force for any future marketed products, we may have a greater risk of such violations from lack of adequate training or experience. The expense to retain and pay legal counsel and consultants to defend against any such proceedings would be substantial, and together with the diversion of management s time and attention to assist in any such defense, may negatively affect our business, financial condition and results of operations.

In addition, both before and after approval, our contract manufacturers and our products are subject to numerous regulatory requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA, EMA and other regulatory authorities periodically inspect manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort to maintain compliance. Failure 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.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of $10.6 million and entered into a settlement agreement with the United States Attorney s Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct.

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

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

If we are successful in bringing Pixuvri to market in the United States, Pixuvri will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®). In addition, Pixuvri may face competition in the United States and the European Union if new anti-cancer drugs with reduced toxicity are developed and marketed in the United States and/or the European Union.

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

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

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

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

Many of our competitors, particularly the multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial resources and substantially larger development and marketing teams than us. In addition, many of our competitors, either alone or together with their collaborators, have significantly greater experience than we do in developing, manufacturing and marketing products. As a result, these companies products 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.

Uncertainty regarding third-party reimbursement and healthcare cost containment initiatives may limit our returns.

The ongoing efforts of governmental and third-party payors to contain or reduce the cost of healthcare may affect our ability to commercialize our products successfully. Governmental and other third-party payors continue to attempt to contain healthcare costs by:

challenging the prices charged for health care products and services;

limiting 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;

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.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the

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availability of capital. In the United States, given the comprehensive health care reform legislation that the President signed into law on March 23, 2010, under the Patient Protection and Affordable Care Act (HR 3590), or the PPACA, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of healthcare services and products and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities.

Even if we succeed in bringing any of our proposed products to the market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. If adequate third-party or government coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, 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.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products if approved for commercialization. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to sell our products at a profit.

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

The successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market for several reasons, including:

- clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;
- preclinical tests may show the product to be toxic or lack efficacy in animal models;
- failure to receive the necessary U.S. and international regulatory approvals or a delay in receiving such approvals;
- difficulties in formulating the product, scaling the manufacturing process or getting approval for manufacturing;
- manufacturing costs, pricing, reimbursement issues or other factors may make the product uneconomical to commercialize;
- other companies or people have or may have proprietary rights to a product candidate, such as patent rights, and will not let the product candidate be sold on reasonable terms, or at all; or

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the product candidate is not cost effective in light of existing therapeutics.

Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. In addition, any significant problem in the production of our products, such as the inability of a supplier to provide raw materials or supplies used to manufacture our products, equipment obsolescence, malfunctions or failures, product quality or contamination problems, or changes in regulatory requirements or standards that require modifications to our manufacturing process could delay, limit or prevent regulatory approval which could harm our business, financial condition and results or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for our products.

If any of our license agreements for intellectual property underlying Pixuvri, pacritinib, OPAXIO, tosedostat, brostallicin, bisplatinates or any other products are terminated, we may lose the right to develop or market that product.

We have licensed intellectual property, including patent applications relating to intellectual property for Pixuvri, pacritinib, tosedostat, brostallicin and bisplatinates. We have also in-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.

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

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the United States and various other countries seeking protection of inventions originating from our research and development and we have also obtained rights to various patents and patent applications under licenses with third parties and through acquisitions. Patents have been issued on many of these applications. We have pending patent applications or issued patents in the United States and foreign countries directed to Pixuvri, pacritinib, OPAXIO, tosedostat, brostallicin and other product candidates. However, the lives of these patents are limited. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The OPAXIO-directed patents will expire on various dates ranging from 2017 through 2018. The pacritinib-directed patent will expire from 2026 through 2029. The Pixuvri-directed patents will expire in 2014. The tosedostat-directed patents will expire in 2017. The brostallicin-directed patents will expire on various dates ranging between 2017 through 2021. The patent expiration ranges given above are only for U.S. issued patents. The Pixuvri-directed patents in Europe will expire from 2012 through 2015. Although such patent expirations do not account for potential extensions that may be available in certain countries (for example, certain Pixuvri-directed patents may be subject to possible patent-term extensions that could provide extensions through 2019 in the United States and 2021 in Europe), there can be no assurance that such extensions will be obtained. The expiration of these patents may allow our competitors to copy the inventions that are currently protected and better compete with us**.**

If there is an adverse outcome in the securities class actions and shareholder derivative litigation that have been filed against us, our business may be harmed.

Cyril Sabbagh (Securities Class Action):

In March 2010, three purported securities class action complaints were filed against us and certain of our officers and directors in the United States District Court for the Western District of Washington. On August 2, 2010, Judge Marsha Pechman consolidated the actions, appointed lead plaintiffs, and approved lead plaintiffs counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint, captioned Sabbagh v. Cell Therapeutics, Inc. (Case No. 2:10-cv-00414-MJP), naming us, Dr. James A. Bianco, Louis A. Bianco, and Craig W. Philips as defendants. The amended consolidated complaint alleges that defendants violated the federal securities

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laws by making certain alleged false and misleading statements related to the FDA approval process for Pixuvri. The action seeks damages on behalf of purchasers of our stock during a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, defendants moved to dismiss the amended consolidated complaint. On February 4, 2011, the Court denied in large part the defendants motion. Defendants answered the amended consolidated complaint on March 28, 2011, and discovery commenced, with trial set for June 25, 2012. On December 14, 2011, the parties filed a letter with the Court indicating they had agreed to the general terms of a settlement, and asking the Court to remove the case deadlines from the Court calendar. On February 14, 2012, plaintiffs filed a motion for preliminary approval of the settlement, along with related documents. On March 16, 2012, the Court granted preliminary approval of the settlement, granted conditional certification to the proposed class, and approved the proposed forms of notice to the class. A settlement hearing occurred on July 20, 2012. The Court entered a Final Judgment and Order of Dismissal with Prejudice on July 25, 2012. The negotiated terms of the settlement include a $19.0 million dollar settlement fund, which was paid by our insurance carriers. As a result, there is no estimated loss to the Company.

Joseph Shackleton (Derivative Action):

In April 2010, three shareholder derivative complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to the Company by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for Pixuvri. The allegations in the derivative actions are substantially similar to those in the securities action. On May 10, 2010, Judge Marsha Pechman consolidated the shareholder derivative actions under the caption Shackleton v. Bauer (Case No. 2:10-cv-00414-MJP), and appointed the law firms of Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs. Three more derivative complaints were filed in June, July and October 2010, and they have also been consolidated with Shackleton v. Bauer. The court has set a trial date of December 3, 2012 for the shareholder derivative action. At this stage of the litigation no probability of loss can be predicted in the event we do not prevail.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits. In the event of an adverse outcome, our business could be materially harmed.

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

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

- obtain patent protection for our products or processes both in the United States and other countries;
- protect trade secrets; and
- prevent others from infringing on our proprietary rights.

The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. 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

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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 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.

Our products could infringe upon the intellectual property rights of others, which may cause us to engage in costly litigation and, if unsuccessful, could cause us to pay substantial damages and prohibit us from selling our products.

At times, we may monitor patent filings for patents that might be relevant to some of our products and product candidates in an effort to guide the design and development of our products to avoid infringement, but have not conducted an exhaustive search. We may not be able to successfully challenge the validity of third-party patents and could be required to pay substantial damages, possibly including treble damages, for past infringement and attorneys fees if it is ultimately determined that our products infringe such patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties. Moreover, third parties may challenge the patents that have been issued or licensed to us. Even if infringement claims against us are without merit, or if we challenge the validity of issued patents, lawsuits take significant time, may be expensive and may divert management attention from other business concerns**.**

We could fail in financing efforts or be delisted from NASDAQ if we fail to receive shareholder approval when needed.

We are required under the NASDAQ Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding before the issuance of such securities sold at a discount to the greater of book or market value in an offering that is not deemed to be a public offering by the NASDAQ Marketplace Rules or NASDAQ. NASDAQ Marketplace Rules also require shareholder approval if an issuance would result in a change of control as defined under the NASDAQ Marketplace Rules and other circumstances. Funding of our operations in the future may require issuance of additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding. 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 as outlined above. If we are unable to in the future, obtain financing due to shareholder approval difficulties, such failure may harm our ability to continue operations.

We may be unable to obtain the raw materials necessary to produce our OPAXIO product candidate in sufficient quantity to meet demand when and if such product is approved.

We may not be able to continue to purchase the materials necessary to produce OPAXIO, including paclitaxel, in adequate volume and quality. Paclitaxel is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. We purchase the raw materials paclitaxel and polyglutamic acid from single sources. Should the paclitaxel or polyglutamic acid purchased from our sources prove to be insufficient in quantity or quality, should a supplier fail to deliver in a timely fashion or at all, or should these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

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Our dependence on third-party manufacturers means that we do not always have direct control over the manufacture, testing or distribution of our products.

We do not currently have internal analytical laboratory or manufacturing facilities to allow the testing or production and distribution of drug products in compliance with cGMPs. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it.

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by United States and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA, EMA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers and contract service providers may at times violate cGMPs. The FDA, EMA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Failure 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.

In addition, one of our other products under development, OPAXIO, has a complex manufacturing process and supply chain, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredients and drug products for Pixuvri, pacritinib, tosedostat and brostallicin are manufactured by single vendors. Finished product manufacture and distribution for Pixuvri, pacritinib, and brostallicin are to be manufactured and distributed by different single vendors. We are currently disputing our right to cancel the exclusive manufacturing contract between us and the former manufacturer of Pixuvri. We assert multiple grounds for terminating this exclusive manufacturing agreement, which the former manufacturer disputes. The former manufacturer has asserted that we do not have the right to terminate the manufacturing contracts and has filed a lawsuit in the Court of Milan to compel us to source Pixuvri from that manufacturer. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. On November 11, 2010, a hearing was held aimed at examining and discussing the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing on November 11 2010, the judge declared that the case does not require any discovery or evidentiary phase, as it may be decided on the basis of the documents and pleadings filed by the parties. At the hearing on October 11, 2012, the parties informed the court about the ongoing negotiations pending between them and asked the court, accordingly, to postpone the case. At the request of the parties, the court extended the final hearing until March 21, 2013.

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

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. We have been granted conditional marketing authorization for Pixuvri in the European Union, and all of our other compounds are currently in research or development and have not received marketing approval for these other compounds or FDA marketing approval of Pixuvri.

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of anti-cancer drugs, including those we are currently developing, is unpredictable and subject to numerous risks. Potential products that appear to be promising at early stages of development and even products that have been granted conditional marketing authorization, such as Pixuvri, may not reach the market for a number of reasons including that they may:

- be found ineffective or cause harmful side effects during preclinical testing or clinical trials;
- fail to receive necessary regulatory approvals;
- be difficult to manufacture on a scale necessary for commercialization;
- be uneconomical to produce;

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fail to achieve market acceptance; or

be precluded from commercialization by proprietary rights of third parties.

The occurrence of any of these events could adversely affect the commercialization of our products. Products, if introduced, may not be successfully marketed and/or may not achieve customer acceptance. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.

We divested our commercial product, TRISENOX, in July 2005 and fully divested our commercial product, Zevalin, in March 2009. Currently only our product Pixuvri is approved for marketing in the European Union. Pacritinib, OPAXIO, tosedostat and brostallicin are currently in clinical trials; the development and clinical trials of these products may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, 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. We will need to commit significant time and resources to develop these and any additional product candidates. Even if our trials are viewed as successful, we may not get regulatory approval. Our product candidates will be successful only if:

our product candidates are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;

we are able to commercialize product candidates in clinical development or sell the marketing rights to third parties; and

our product candidates, if developed, are approved by the regulatory authorities.

We are dependent on the successful completion of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing our research and development of these and other product candidates.

If we are unable to enter into new in-licensing arrangements, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Our product candidates Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates are in clinical and pre-clinical development and are in-licensed from a third-party.

Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

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

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product. For example, as a condition of the approval of the MAA for Pixuvri, we have agreed to have available the trial results of our ongoing randomized controlled phase III clinical trial, PIX306, by June 2015. The PIX306 clinical trial 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. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors. For example:

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

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- the FDA or the EMA may object to proposed protocols;
- there may be shortages of available product supplies or the materials that are used to manufacture the products;
- the quality or stability of the product candidates may fall below acceptable standards;
- authorized preclinical or clinical testing may require significantly more time, resources or expertise than originally expected to be necessary;
- clinical testing may not show potential products to be safe and efficacious and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;
- clinical testing may show that potential products are not appropriate for the specific indication for which they are being tested;
- the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials;
- we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons; and
- the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

We may not be able to complete the PIX306 clinical trial by June 2015 or at all. If we are unable to submit the clinical trial data from the PIX306 clinical study by June 2015 it may result in the withdrawal of the conditional marketing authorization by the EU. We expect to continue to rely on third parties, such as contract research organizations, academic institutions and/or cooperative groups, to conduct, oversee and monitor clinical trials as well as to process the clinical results and manage test requests, which may result in delays or failure to complete trials if the third parties fail to perform or to meet the applicable standards.

If we fail to commence, complete, experience delays in any of our present or planned clinical trials or need to perform more or larger clinical trials than planned, our development costs may increase and/or our ability to commercialize our product candidates may be harmed. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be harmed.

If we fail to establish and maintain collaborations or if our partners do not perform, we may be unable to develop and commercialize our product candidates.

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the GOG to perform a phase III trial of OPAXIO in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing

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collaborative arrangements, the number of product candidates from which we could receive future revenues would decline. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX; however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

Our dependence on collaborative arrangements with third parties will subject us to a number of risks that could harm our ability to develop and commercialize products, including that:

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;
- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;
- partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;
- business combinations or significant changes in a partner s business strategy might adversely affect that partner s willingness or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

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

Because we base several of our drug candidates on unproven technologies, we may never develop them into commercial products.

We base several of our product candidates upon novel technologies that we are using to develop drugs for the treatment of cancer. These technologies have not been proven. Furthermore, preclinical results in animal studies may not predict outcomes in human clinical trials. Our product candidates may not be proven safe or effective. If these technologies do not work, our drug candidates will not develop into commercial products.

Because there is a risk of product liability associated with our products, we face potential difficulties in obtaining insurance.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering the product use in our clinical trials for our product candidates, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will not provide 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 in excess of our insurance coverage could exceed our net worth.

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

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

We may not be able to conduct animal testing in the future, which could harm our research and development activities.

Certain of our research and development activities involve animal testing. Such activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting activities through protests and other means. To the extent the activities of these groups are successful, our business could be materially harmed by delaying or interrupting our research and development activities.

The unfavorable outcome of litigation and other claims against us could harm our financial condition and results of operations.

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. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. While we currently believe that resolution of these matters, individually or in the aggregate, will not have a material adverse impact on our financial position, results of operations or trading price of our securities, the ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future. It is possible that our financial condition and results of operations could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable.

Our financial condition and results of operations could be harmed by public health issues, wars and other military action, as well as terrorist attacks and threats and government responses thereto, especially if any such actions were directed at us or our facilities or customers.

Public health issues, terrorist attacks in the United States and elsewhere, government responses thereto, and military actions in Afghanistan and elsewhere, may disrupt our operations or those of our customers and suppliers and may affect the availability of materials needed to manufacture our products or the means to transport those materials to manufacturing facilities and finished products to customers. A health pandemic could cause damage or disruption to international commerce by creating economic and political uncertainties that may have a strong negative impact on the global economy, us, and our customers or suppliers. Should a severe public health issues arise, we could be negatively impacted by the need for more stringent employee travel restrictions, additional limitations in the availability of freight services, governmental actions limiting the movement of products between various regions and disruptions in the operations of our customers or suppliers. The long-term effects public health issues, the terrorist attacks, and the ongoing war on terrorism on our business and on the global economy remain unknown. In addition, any of these events could increase volatility in the United States and world financial markets which may depress the price of our common stock and may limit the capital resources available to us or our customers or suppliers, which could result in decreased orders from customers, less favorable financing terms from suppliers, and scarcity or increased costs of materials and components of our products. Additionally, terrorist attacks directly upon us may significantly disrupt our ability to conduct our business. Any of these occurrences could have a significant impact on our operating results, revenues and costs and may result in increased volatility of the trading price of our securities.

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Higher health care costs could harm our business.

We will be impacted by the PPACA. Under the PPACA, we may be required to amend our health care plans to, among other things, provide affordable coverage, as defined in the PPACA, to all employees, or otherwise be subject to a payment per employee based on the affordability criteria in the Act: cover adult children of our employees to age 26; delete lifetime limits; and delete pre-existing condition limitations. Many of these requirements will be phased in over a period of time. Additionally, some states and localities have passed state and local laws mandating the provision of certain levels of health benefits by some employers. Increased health care costs could harm our business, financial condition and results of operations.

Risks Related To the Securities Markets

The market price 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 twelve month period ended October 25, 2012, our stock price has ranged from a low of $1.37 to a high of $8.25 (as adjusted to reflect the one-for-five reverse stock split effective September 2, 2012). Fluctuations in the trading price or liquidity of our common stock may harm the value of your investment in our common stock.

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

- announcements by us or others of results of preclinical testing and clinical trials and regulatory actions;
- announcements by us or others of serious adverse events that have occurred during treatment of patients following the grant of conditional marketing authorization for Pixuvri in the European Union;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;
- our quarterly operating results;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- acquisitions or divestitures;
- litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts recommendations;

short selling;

changes in health care policies and practices;

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halting or suspension of trading in our common stock by NASDAQ, CONSOB or the Borsa Italiana;

economic and other external factors; and

general market conditions.

In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. For example, in the case of our company, we and certain of our officers and directors were named as defendants in purported securities class action and shareholder derivative lawsuits brought on behalf of a putative class of purchasers of our securities from March 25, 2008 through March 22, 2010. These lawsuits seek unspecified damages and, as with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits and our management s attention and resources could be diverted from operating our business as we respond to the litigation. We maintain significant insurance to cover these risks for us and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, 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.

Shares of common stock are equity securities and are subordinate to any future indebtedness.

Shares of our common stock are common equity interests. This means that our common stock will rank junior to any outstanding shares of our preferred stock that we may issue in the future to any 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. Any future indebtedness and preferred stock may restrict payment of dividends on our common stock.

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

The market price of our common stock may be harmed by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market.

The market price of our common stock may be harmed by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market. These conditions may result in (i) volatility in the level of, and fluctuations in, the market prices of stocks generally and, in turn, our shares of common stock, and (ii) sales of substantial amounts of our common stock in the market, in each case that could be unrelated or disproportionate to changes in our operating performance.

There may be future sales or other dilution of our equity, which may harm the market price of shares of our common stock.

We expect to issue additional shares of our common stock upon the conversion of our outstanding shares of Series 17 preferred stock. We expect to issue additional equity securities to fund our operating expenses as well as for other purposes. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, or the perception that such sales could occur in the future.

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Anti-takeover provisions in our charter documents, in our shareholder rights plan, or rights plan, and under Washington law could make removal of incumbent management or an acquisition of us, which may be beneficial to our shareholders, more difficult.

Provisions of our amended and restated articles of incorporation and amended and restated bylaws may have the effect of deterring or delaying attempts by our shareholders to remove or replace management, to commence proxy contests, or to effect changes in control. These provisions include:

- a classified board of directors so that only approximately one-third of our board of directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our board of directors to amend our amended and restated bylaws without shareholder approval; and
- the ability of our board of directors to issue shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as the board of directors may determine.

Pursuant to our rights plan, an acquisition of 20% or more of our common stock could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20% shareholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. The existence of our rights plan could have the effect of delaying, deferring 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 law which imposes restrictions on some transactions between a corporation and certain significant shareholders. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

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

Stock Repurchases in the Third Quarter

The following table sets forth information with respect to purchases of our common stock during the three months ended September 30, 2012 (as adjusted to reflect the one-for-five reverse stock split effective September 2, 2012):

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 July 31, 2012	105	$ 3.02		

August 1	August 31, 2012	751	$ 2.01
September 1	September 30, 2012	293	$ 2.42
Total		1,149	$ 2.21

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

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Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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Item 6. Exhibits

(a) Exhibits

3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008).
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series F Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on February 9, 2009).
3.3	Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on March 27, 2009).
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 1 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on April 13, 2009).
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 2 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on August 21, 2009).
3.6	Articles of Amendment to Amended and Restated Articles of Incorporation; Certificate of Designation, Preferences and Rights of Series ZZ Junior Participating Cumulative Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Registration Statement on Form 8-A, filed on December 28, 2009).
3.7	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 3 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on January 19, 2010).
3.8	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 4 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on April 5, 2010).
3.9	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 5 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on May 27, 2010).
3.10	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 6 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on July 27, 2010).

3.11	Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on September 17, 2010).
3.12	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 7 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on October 22, 2010).
3.13	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 8 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on January 18, 2011).
3.14	Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 9 Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K, filed on January 18, 2011).
3.15	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 10 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on February 24, 2011).
3.16	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 11 Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K, filed on February 24, 2011).
3.17	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 12 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on May 2, 2011).
3.18	Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on May 18, 2011).
3.19	Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed on June 17, 2011).
3.20	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 13 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed on July 6, 2011).
3.21	Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on November 15, 2011).

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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	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	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K, filed on August 1, 2012).
4.2	First Amendment to Shareholder Rights Agreement, dated as of August 31, 2012, between the Registrant and Computershare Trust Company, N.A., as Rights Agent (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K, filed on September 4, 2012).
4.3	Form of Series 17 Preferred Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K, filed on October 11, 2012).
10.1	Master Services Agreement, dated July 9, 2012, between Quintiles Commercial Europe Limited and CTI Life Sciences Ltd. (incorporated by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q, filed on August 2, 2012).

10.2	Letter of Guarantee, dated July 1, 2012, between the Registrant and Quintiles Commercial Europe Limited (incorporated by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q, filed on August 2, 2012).
10.3	2007 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K, filed on September 4, 2012).
10.4	Logistics Agreement, dated September 1, 2012, between Movianto Nederland BV and CTI Life Sciences Limited.*
10.5	Settlement Agreement and Full and Final Release of Claims, dated as of October 25, 2012, by and between the Registrant and Craig W. Philips (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K, filed on October 31, 2012).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101. INS	XBRL Instance
101. SCH	XBRL Taxonomy Extension Schema
101. CAL	XBRL Taxonomy Extension Calculation
101. DEF	XBRL Taxonomy Extension Definition
101. LAB	XBRL Taxonomy Extension Labels
101. PRE	XBRL Taxonomy Extension Presentation

Portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC.

* Filed herewith.

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SIGNATURES

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

CELL THERAPEUTICS, INC.
(Registrant)

Dated: November 1, 2012

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

Dated: November 1, 2012

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