CELL THERAPEUTICS INC
Form 10-Q
October 28, 2010
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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, 2010

OR

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

For the transition period from _____ to _____

Commission File Number 001-12465

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington	91-1533912
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
501 Elliott Avenue West, Suite 400 Seattle, Washington (Address of principal executive offices)	98119 (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 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 x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No 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 22, 2010
Common Stock, no par value	814,781,932

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	September 30, 2010 (unaudited)	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,268	$ 37,811
Prepaid expenses and other current assets	2,813	4,354
Total current assets	20,081	42,165
Property and equipment, net	3,114	3,430
Goodwill	17,064	17,064
Other assets	6,354	6,936
Total assets	$ 46,613	$ 69,595
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 6,506	$ 7,297
Accrued expenses	8,368	14,807
Current portion of deferred revenue		80
Current portion of long-term obligations	812	1,312
7.5% convertible senior notes	10,187	
4% convertible senior subordinated notes		40,363
Total current liabilities	25,873	63,859
Deferred revenue, less current portion		239
Long-term obligations, less current portion	1,010	1,861
7.5% convertible senior notes		10,102
5.75% convertible senior notes	11,985	11,677
Total liabilities	38,868	87,738
Commitments and contingencies		
Common stock purchase warrants	13,461	626
Shareholders deficit:		
Common stock, no par value:		
Authorized shares - 1,200,000,000 and 800,000,000 at September 30, 2010 and December 31, 2009, respectively		
Issued and outstanding shares - 758,453,915 (unaudited) and 590,282,575 at September 30, 2010 and December 31, 2009, respectively	1,545,324	1,418,931
Accumulated other comprehensive loss	(8,159)	(8,412)
Accumulated deficit	(1,542,526)	(1,429,083)

Total CTI shareholders deficit	(5,361)	(18,564)
Noncontrolling interest	(355)	(205)
Total shareholders deficit	(5,716)	(18,769)
Total liabilities and shareholders deficit	$ 46,613	$ 69,595

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,	
	2010	2009	2010	2009
Revenues:				
License and contract revenue	$	$ 20	$ 319	$ 60
Total revenues		20	319	60
Operating expenses, net:				
Research and development	5,101	7,602	19,375	22,878
Selling, general and administrative	7,893	19,667	39,378	38,997
Restructuring charges and related gain on sale of assets, net		(178)		3,766
Gain on sale of investment in joint venture				(10,244)
Total operating expenses, net	12,994	27,091	58,753	55,397
Loss from operations	(12,994)	(27,071)	(58,434)	(55,337)
Other income (expense):				
Investment and other income (expense), net	(23)	26	240	97
Interest expense	(385)	(826)	(1,948)	(4,026)
Amortization of debt discount and issuance costs	(166)	(227)	(600)	(5,575)
Foreign exchange gain (loss)	1,000	183	(300)	278
Debt conversion expense			(2,031)	
Make-whole interest expense				(6,345)
Gain on derivative liabilities, net				7,218
Gain on exchange of convertible notes		180		7,381
Equity loss from investment in joint venture				(1,204)
Milestone modification expense		(6,000)		(6,000)
Settlement expense, net		(1,342)		(4,710)
Other income (expense), net	426	(8,006)	(4,639)	(12,886)
Net loss before noncontrolling interest	(12,568)	(35,077)	(63,073)	(68,223)
Noncontrolling interest	46	53	149	205
Net loss attributable to CTI	(12,522)	(35,024)	(62,924)	(68,018)
Gain on restructuring of preferred stock				2,116
Preferred stock dividends				(24)
Deemed dividends on preferred stock	(3,085)	(13,812)	(50,519)	(23,460)
Net loss attributable to CTI common shareholders	$ (15,607)	$ (48,836)	$ (113,443)	$ (89,386)

Basic and diluted net loss per common share	$ (0.02)	$ (0.09)	$ (0.17)	$ (0.21)
Shares used in calculation of basic and diluted net loss per common share	711,549	527,204	659,244	420,520

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2010	**2009**
Operating activities		
Net loss	$ (62,924)	$ (68,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	16,260	13,283
Gain on sale of investment in joint venture		(10,244)
Non-cash interest expense	600	5,575
Depreciation and amortization	1,413	1,424
Debt conversion expense	2,031	
Non-cash gain on derivative liabilities, net		(7,218)
Gain on exchange of convertible notes		(7,381)
Equity loss from investment in joint venture		1,204
Noncontrolling interest	(149)	(205)
Other	(217)	(457)
Changes in operating assets and liabilities:		
Restricted cash		6,640
Accounts receivable, net		991
Prepaid expenses and other current assets	1,472	(1,843)
Other assets	68	(367)
Accounts payable	(2,888)	(4,436)
Accrued expenses	(4,944)	327
Long-term obligations	(532)	347
Other liabilities	(546)	(266)
Total adjustments	12,568	(2,626)
Net cash used in operating activities	(50,356)	(70,644)
Investing activities		
Purchases of property and equipment	(1,232)	(343)
Proceeds from the sales of property and equipment	82	
Proceeds received from disposition of Zevalin to joint venture, net		6,844
Proceeds received from sale of investment in joint venture, net		15,075
Proceeds from maturities of securities available-for-sale		600
Net cash provided by (used in) investing activities	(1,150)	22,176
Financing activities		
Proceeds from issuance of Series 1 preferred stock and warrants, net of issuance costs		18,745
Proceeds from issuance of Series 2 preferred stock and warrants, net of issuance costs		28,516
Proceeds from issuance of Series 3 preferred stock and warrants, net of issuance costs	27,951	

Proceeds from issuance of Series 4 preferred stock and warrants, net of issuance costs	18,621	
Proceeds from issuance of Series 5 preferred stock and warrants, net of issuance costs	19,704	
Proceeds from issuance of Series 6 preferred stock and warrants, net of issuance costs	3,603	
Proceeds from issuance of common stock and warrants, net of issuance costs		59,519
Proceeds from exercise of Class A warrants		3,765
Repayment of 4% convertible senior subordinated notes	(38,515)	
Cash paid for the exchange of convertible notes, net of transaction costs		(9,949)
Cash paid for repurchase of shares in connection with taxes on restricted stock vesting	(748)	(3,148)
Payment of deemed dividends on conversion of preferred stock		(3,000)
Payment of dividends on preferred stock		(111)
Other		(135)
Net cash provided by financing activities	30,616	94,202
Effect of exchange rate changes on cash and cash equivalents	347	(814)
Net increase (decrease) in cash and cash equivalents	(20,543)	44,920
Cash and cash equivalents at beginning of period	37,811	10,072
Cash and cash equivalents at end of period	$ 17,268	$ 54,992
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 2,401	$ 11,357
Cash paid for taxes	$	$
Supplemental disclosure of noncash financing and investing activities		
Conversion of Series 1 preferred stock to common stock	$	$ 18,537
Conversion of Series 2 preferred stock to common stock	$	$ 27,796
Conversion of Series 3 preferred stock to common stock	$ 27,761	$
Conversion of Series 4 preferred stock to common stock	$ 18,621	$
Conversion of Series 5 preferred stock to common stock	$ 19,464	$
Conversion of Series 6 preferred stock to common stock	$ 2,970	$
Conversion of Series B 3% convertible preferred stock to common stock	$	$ 2,317
Conversion of Series F preferred stock to common stock	$	$ 3,866
Conversion of 10% convertible senior notes due 2011 to common stock	$	$ 18,000
Conversion of 9% convertible senior notes to common stock	$	$ 5,250
Exchange of 4% convertible senior subordinated notes for common stock	$ 1,848	$
Exchange of Series A 3% convertible preferred stock for Series F preferred stock	$	$ 151
Exchange of Series B 3% convertible preferred stock for Series F preferred stock	$	$ 1,713
Exchange of Series C 3% convertible preferred stock for Series F preferred stock	$	$ 3,221
Issuance of Series F preferred stock for Series A, B and C convertible preferred stock	$	$ 3,931

Issuance of common stock in exchange for convertible notes	$	$ 35,193
Issuance of common stock in exchange for Series A 3% convertible preferred stock	$	$ 688
Issuance of common stock in exchange for Series D 7% convertible preferred stock	$	$ 1,793

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., or CTI or the Company, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics, an area with significant market opportunity that we believe is not adequately served by existing therapies. Subsequent to the closure of our Bresso, Italy operations in September 2009, our operations are now primarily conducted in the United States. During 2008, we had one approved drug, Zevalin® (ibritumomab tiuxetan), or Zevalin, which we acquired in 2007, generating product sales. We contributed Zevalin to a joint venture, RIT Oncology, LLC, or RIT Oncology, upon its formation in December 2008 and in March 2009 we finalized the sale of our 50% interest in RIT Oncology to the other member, Spectrum Pharmaceuticals, Inc., or Spectrum. All of our current product candidates, including pixantrone, OPAXIO 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 Europe and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, may take many years and involves expenditure of substantial resources.

Basis of Presentation

The accompanying unaudited financial information of CTI as of September 30, 2010 and for the three and nine months ended September 30, 2010 and 2009 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 month periods ended September 30, 2010 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 SEC. These unaudited financial statements and the related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2009 included in our Annual Report on Form 10-K.

The condensed consolidated balance sheet at December 31, 2009 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 condensed consolidated financial statements include the accounts of CTI and its wholly-owned subsidiaries, which include CTI Corporate Development, Inc., Systems Medicine LLC, or SM, CTI Commercial LLC, and CTI Life Sciences Limited (from the date of formation in March 2009). 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 Corporate Development, Inc. was liquidated in the fourth quarter of 2009.

As of September 30, 2010, we also had a 69% 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 (previously shown as minority interest) is reported below net loss in *noncontrolling interest* in the condensed consolidated statement of operations and shown as a component of equity in the condensed consolidated balance sheet.

Additionally, we held a 50% interest in RIT Oncology from the date of its formation in December 2008 to the sale of our interest in March 2009, which we accounted for using the equity method of accounting.

All intercompany transactions and balances are eliminated in consolidation.

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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 financial statements. However, we have incurred losses since inception and expect to generate losses for the next few years primarily due to research and development costs for pixantrone, OPAXIO and brostallicin. Our available *cash and cash equivalents* are $17.3 million as of September 30, 2010. Subsequent to period end, in October 2010, we raised $21.0 million in gross proceeds from the issuance of 21,000 shares of our Series 7 preferred stock and warrants to purchase up to 22.7 million shares of our common stock. Our Series 7 preferred stock was converted to 56.8 million shares of common stock upon closing of the transaction.

We do not expect that our existing cash and cash equivalents, including the cash received from the issuance of our Series 7 preferred stock and warrants, will be sufficient to fund our presently anticipated operations beyond the first quarter of 2011. This raises substantial doubt about our ability to continue as a going concern.

Since the second quarter of 2010, we have implemented cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned commercial pixantrone operations. However, 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.

On September 16, 2010, our shareholders approved an amendment to our amended and restated articles of incorporation to increase our authorized shares of common and preferred stock from 810,000,000 shares to 1,210,000,000 shares and to increase the total number of our authorized shares of common stock from 800,000,000 shares of common stock to 1,200,000,000 shares of common stock. As such, our board of directors has the option to issue such 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. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Value Added Tax Receivable

Our European operations were 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 $5.5 million and $6.3 million as of September 30, 2010 and December 31, 2009, respectively, of which $5.4 million and $5.9 million is included in *other assets* and $0.1 million and $0.4 million is included in *prepaid expenses and other current assets* as of September 30, 2010 and December 31, 2009, respectively. This receivable balance 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.

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On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings of the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). 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, $7.5 million, $3.4 million and $1.2 million as of September 30, 2010, respectively. On July 14, 2010, the ITA issued a notice of deposit payment to CTI (Europe) based on the 2005 assessment including interest and collection fees for an amount of 0.9 million. We successfully filed a petition with the Provincial Tax Court of Milan, or the Tax Court, for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the 2005 assessment were discussed in a public hearing before the Tax Court, which has reserved its decision in order to carefully review the arguments, relevant documents and other supporting evidence (including an appraisal from an independent expert) that our counsel filed and presented during the hearing. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have been vigorously defending against the assessments and are confident that the Tax Court will duly take into account our arguments both on procedural grounds and the merits of the case. If the Tax Court s decision is unfavorable, we will appeal to the higher courts in order to further defend our interests.

Net Loss Per Share

Basic net loss per common share is calculated based on the net 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 loss per common share assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and share awards using the treasury stock method. As of September 30, 2010 and 2009, options, warrants, unvested share awards and rights, convertible debt and convertible preferred stock aggregating 80.7 million and 45.4 million common share equivalents, respectively, prior to the application of the treasury stock method for options and warrants, are not included in the calculation of diluted net loss per share as they are anti-dilutive.

New Accounting Standards

In February 2010, the FASB issued amended guidance on subsequent events to alleviate potential conflicts between FASB guidance and SEC requirements. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements during the first quarter of 2010. The adoption of this guidance did not have a material impact on our financial statements.

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance was effective on a prospective basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. We do not anticipate the adoption of this guidance will have a material impact on our financial statements.

Reclassifications

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

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2. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Our other comprehensive income or loss includes unrealized gains and losses on our securities available-for-sale and certain net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries not recorded in the statement of operations. Total comprehensive loss consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss before noncontrolling interest	$ (12,568)	$ (35,077)	$ (63,073)	$ (68,223)
Foreign currency translation gain (loss)	(492)	(259)	252	(713)
Net unrealized gain on securities available-for-sale				1
Comprehensive loss before noncontrolling interest	(13,060)	(35,336)	(62,821)	(68,935)
Noncontrolling interest	46	53	149	205
Comprehensive loss attributable to CTI	$ (13,014)	$ (35,283)	$ (62,672)	$ (68,730)

As of September 30, 2010 and December 31, 2009, cumulative foreign currency translation adjustments accounted entirely for the ending balances of *accumulated other comprehensive loss*.

3. Convertible Notes

4% Convertible Senior Subordinated Notes

In May 2010, we entered into exchange agreements with certain holders of our 4% convertible senior subordinated notes, or 4% Notes, pursuant to which we issued approximately 4.3 million shares of common stock, upon conversion of the 4% Notes as defined in ASC 470-20, *Debt with Conversion and Other Options*, in exchange for $1.8 million aggregate outstanding principal amount of our 4% Notes. The transactions were accounted for as induced conversions since, for the purpose of ASC 470-20, the issuance of the common stock effectively resulted in the change to the conversion privileges provided in the terms of our 4% Notes at issuance. We recorded $2.0 million in *debt conversion expense* for the nine months ended September 30, 2010. In May 2010, we delivered a notice of termination of the exchange agreements to each of the holders party to the exchange agreements.

In July 2010, the remaining outstanding amount of our 4% Notes reached maturity and we made a cash payment of $39.3 million to repay the outstanding balance, including accrued interest.

4. Restructuring Activities

Italian Operations

In September 2009, we closed our Bresso, Italy operations. These operations were used primarily for pre-clinical research and were underutilized due to our current business model, which is focused on the development of late-stage compounds and their commercialization. We have recorded restructuring charges related to this closure as discussed further below in accordance with ASC 420, *Exit or Disposal Cost Obligations*.

In May 2009, we entered into a severance agreement with the unions representing the employees of our Bresso, Italy operations. Employee separation costs associated with the reduction in force primarily related to severance payments that were initially scheduled to be made over 42 months, with the majority of these payments to be made through the first 15 months. In June 2010, we made a lump sum payment to satisfy all outstanding obligations under the employee severance agreement.

In addition, we entered into separate severance or termination agreements with all of our Bresso-based scientific directors. All severance payments to our scientific directors were made as of June 30, 2010. For the three and nine months ended September 30, 2010, we did not incur any additional restructuring charges related to the closure of the Bresso operations. While we cannot predict additional amounts, if any, we do not expect to have material adjustments to this expense.

The following table summarizes the changes in the liability for restructuring activities during the nine months ended September 30, 2010 (in thousands):

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	Employee Termination Costs
Balance at December 31, 2009	$ 1,531
Foreign currency adjustments	(183)
Cash payments	(1,348)
Balance at September 30, 2010	$

5. Preferred Stock

Issuance of Series 6 Preferred Stock

In July 2010, we entered into a securities purchase agreement for the issuance of 4,060 shares of our Series 6 preferred stock, which was convertible into 11.6 million shares of our common stock, and warrants to purchase up to 5.8 million shares of our common stock for gross proceeds of $4.1 million. Issuance costs related to this transaction were $1.1 million, including $0.1 million related to the placement agent warrants as discussed below. In July 2010, at the date of closing, all 4,060 shares of our Series 6 preferred stock were converted into 11.6 million shares of our common stock.

Each share of our Series 6 preferred stock was entitled to a liquidation preference equal to the stated value of such share of our Series 6 preferred stock plus any accrued and unpaid dividends. Our Series 6 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. It was convertible into our common stock, at the option of the holder, at a conversion price of $0.35 per share, subject to a 4.99% blocker provision. A holder of Series 6 preferred stock could elect to increase the blocker provision to 9.99% by providing us with 61 days prior notice. In addition, if 1,000 or less shares of Series 6 preferred stock are outstanding, all outstanding shares of Series 6 preferred stock automatically convert into shares of common stock. The Series 6 preferred stock had voting rights to vote with the common stock on an as-converted basis.

The warrants have an exercise price of $0.42 per share of our common stock and are exercisable six months and one day after the date of issuance and expire four years, six months and one day after the date of issuance, provided that the exercisability of the warrants was subject to, and conditioned upon, (i) our receipt of shareholder approval of an amendment to our amended and restated articles of incorporation to increase the authorized shares of common stock available for issuance thereunder by 400 million shares or (ii) our notification to the holder of the warrants that shares of common stock had become available and were reserved for issuance upon exercise of the warrants. The amendment to increase our authorized shares available for issuance was approved by our shareholders at our annual meeting of shareholders held on September 16, 2010. As the warrants include a redemption feature that may be triggered upon a certain liquidation event that is outside of our control, we classified these warrants as mezzanine equity. We estimated the $1.1 million fair value of the warrants using the Black-Scholes pricing model.

Upon conversion of our Series 6 preferred stock, we recognized $3.1 million in *deemed dividends on preferred stock* related to the transaction, including $1.1 million resulting from the allocation of net proceeds to the warrants and $2.0 million related to the beneficial conversion feature on the 4,060 shares of our Series 6 preferred stock as the stock was convertible immediately.

In connection with the offering of our Series 6 preferred stock, we also issued warrants to purchase 0.3 million shares of our common stock to the placement agent which are classified in mezzanine equity due to the same redemption feature described above. The warrants were estimated to have a fair value of $0.1 million using the Black-Scholes pricing model. These warrants have an exercise price of $0.42 per share and are exercisable after six months and one day after the date of issuance and expire four years, six months and one day after the date of issuance. The exercisability of the warrants was also subject to, and conditioned upon, our receipt of the shareholder approval described above.

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6. Warrants

In July 2010, we entered into a privately negotiated exchange agreement with a certain investor to exchange existing warrants to purchase 4.32 million shares of common stock at an exercise price of $1.18 per share for new warrants to purchase the same number of shares of common stock at an exercise price of $0.42 per share. The terms of the new warrants issued upon exchange are substantially similar to the warrants issued in the Series 6 preferred stock transaction (see Note 5, *Preferred Stock*) with the exception that the new warrants do not contain any redemption feature that may be triggered upon a certain liquidation event that is outside our control. We estimated the $0.8 million fair value of the new warrants using the Black-Scholes pricing model, which are recorded in permanent equity.

7. Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2010 and 2009, which was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$ 340	$ 1,466	$ 2,494	$ 1,808
Selling, general and administrative	574	9,907	13,766	11,475
Stock-based compensation expense included in operating expenses	$ 914	$ 11,373	$ 16,260	$ 13,283

For the three and nine months ended September 30, 2010, we incurred stock-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
December 2009 performance awards	$	$	$ 13,954	$
Restricted stock	843	11,274	2,165	12,998
Options	71	99	141	285
Total stock-based compensation expense	$ 914	$ 11,373	$ 16,260	$ 13,283

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8. Legal Proceedings

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. (Lash) and Documedics Acquisition Co., Inc., our former third-party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by us in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX and other claims. On February 28, 2007, Lash removed the case to U.S. District Court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims and we filed a timely notice of appeal in the Ninth Circuit Court of Appeals. An appeal hearing was held on August 31, 2009, and on November 18, 2009, the Ninth Circuit reversed the trial court and held that the False Claims Act (FCA) did not preclude us from seeking recovery and bringing claims against Lash for indemnification under our Service Agreement based upon its acts that gave rise to the Government s FCA and other claims. On December 1, 2009, Lash filed a petition for rehearing with the Ninth Circuit Court of Appeals, which was formally denied on January 6, 2010. The case has been remanded for trial in the District Court. On April 30, 2010, the District Court denied a motion by Lash to strike our supplemental damages disclosure, and granted our motion for leave to amend our complaint to more fully address our claims for supplemental and independent damages. On May 21, 2010, the Court issued a minute order setting trial and related dates. On May 24, 2010, Lash filed its answer to the amended complaint and asserted counterclaims for contractual indemnification, common law indemnification and contribution, and declaratory relief. On June 3, 2010, Lash filed a motion to bifurcate the trial to address in the first phase only its assertion that our claims are barred due to FCA liability. We opposed the motion, and on June 10, 2010, we filed our own motion to strike Lash s affirmative defense based on its FCA liability claim. On August 3, 2010 the court entered an order denying Lash s motion to bifurcate and granting our motion to strike Lash s FCA liability affirmative defense. The case is currently scheduled for trial on September 6, 2011. There is no guarantee that we will prevail at trial.

On December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, namely: (a) the non-disclosure without delay of the press release mentioned under previous point (i) and the subsequent incomplete disclosure of the relevant information through the press releases dated January 9 and 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the three 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 August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (x) notified us that it has begun the preliminary investigation for its decision on these administrative proceedings and (y) provided us with a preliminary investigation report in reply to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. Based on our assessment, the likelihood that these pecuniary administrative sanctions will be imposed on the Company is probable.

Separately, 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 the press release disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM of 9.66% notes into shares of common stock that occurred between October 24 and November 19, 2008; and (ii) the contents of the opinion expressed, with respect to our 2008 financial statements, by the auditor Stonefield Josephson, Inc. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58.1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one 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

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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 has begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in reply 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 will have to evaluate before imposing any possible administrative sanctions. Based on our assessment, the likelihood that these pecuniary administrative sanctions will be imposed on the Company is probable.

On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings of the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). 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, $7.5 million, $3.4 million and $1.2 million as of September 30, 2010, respectively. On July 14, 2010, the ITA issued a notice of deposit payment to CTI (Europe) based on the 2005 assessment including interest and collection fees for an amount of 0.9 million. We successfully filed a petition with the Provincial Tax Court of Milan, or the Tax Court, for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the 2005 assessment were discussed in a public hearing before the Tax Court, which has reserved its decision in order to carefully review the arguments, relevant documents and other supporting evidence (including an appraisal from an independent expert) that our counsel filed and presented during the hearing. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have been vigorously defending against the assessments and are confident that the Tax Court will duly take into account our arguments both on procedural grounds and the merits of the case. If the Tax Court s decision is unfavorable, we will appeal to the higher courts in order to further defend our interests.

On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan to compel us to source pixantrone from Sicor according to the terms of a supply agreement executed between Sicor and NovusPharma on October 4, 2002. 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. The next hearing date regarding admission of evidence and testimony is scheduled for November 11, 2010. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On March 12, 2010, a purported securities class action complaint was filed in the United States District Court for the Western District of Washington against us and certain of our officers and directors, styled *Cyril Sabbagh, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-sv-00414), or the *Sabbagh* action. On March 19, 2010, a substantially similar class action complaint was filed in the same court, styled *Michael Laquidari, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-cv-00480), or the *Laquidari* action. On March 31, 2010, a third substantially similar class action complaint was filed in the same court, styled *William Snyder, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., James A. Bianco, Phillip M. Nudelman, Louis A. Bianco, John H. Bauer, Richard L. Love, Mary O. Mundinger, Jack W. Singer, Frederick W. Telling and Rodman & Renshaw, LLC* (Case No. 2:10-cv-00559), or the *Snyder* action. The securities actions are pending before Judge Marsha Pechman in the Western District of Washington. The securities complaints allege that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiffs in the *Sabbagh* and *Laquidari* actions seek unspecified damages on behalf of a putative class of purchasers of our securities from May 5, 2009 through February 8, 2010. The plaintiffs in the *Snyder* action seek unspecified damages on behalf of a putative class of purchasers of our securities from May 5, 2009 through March 19, 2010, including purchasers of securities issued pursuant to or traceable to our July 22, 2009 public offering. On May 11, 2010, motions were filed to consolidate the securities actions and to appoint lead plaintiff and lead plaintiffs counsel. On August 2, 2010, the court consolidated the three securities actions, appointed lead plaintiffs, and approved lead plaintiffs counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint. On October 27, 2010, the defendants filed a motion to dismiss. The lawsuits are at a preliminary stage in the proceedings. We believe that the securities actions are without merit and intend to defend them vigorously.

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On April 1, 2010, a shareholder derivative action was filed in the United States District Court for the Western District of Washington, styled *Joseph Shackleton, derivatively on behalf of nominal defendant Cell Therapeutics. Inc., v. John H Bauer, et al. and Cell Therapeutics, Inc.,* (Case No: 2:10-cv-00564 (USDC, W.D. Wash)). Subsequent lawsuits were filed. On April 5, 2010, a shareholder derivative action was filed in the United States District Court for the Western District of Washington, styled *Terry Marbury, derivatively on behalf of Cell Therapeutics, Inc., v. James A Bianco, et al.,* (Case No: 2:10-cv-00578 (USDC, W.D. Wash.)). On April 13, 2010, a shareholder derivative action was filed in the United States District Court for the Western District of Washington, styled *Paul Cyrek, derivatively on behalf of Cell Therapeutics, Inc., v. John H. Bauer, et al.,* (Case No: 2:10-cv-00625 (USDC, W.D. Wash)). On June 1, 2010, a shareholder derivative action was filed in the United States District Court for the Western District of Washington, styled *Carey Souda v. John H Bauer, et al.,* (Case No: 2:10-cv-00905). These four shareholder derivative actions filed against our board of directors have been consolidated and are pending before Judge Marsha Pechman. On July 27, 2010, a shareholder derivative action was filed in the United States District Court for the Western District of Washington, styled, *Brandon Bohland v. John H. Bauer et al.* (Case No. 2:10-cv-1213), or the *Bohland* action, and was subsequently transferred to Judge Pechman. On October 4, 2010, a sixth shareholder derivative action was filed in the Superior Court of Washington, County of King, styled *Lawrence J. Alexander, derivatively on behalf of Cell Therapeutics, Inc. v. James A. Bianco, et al.* (Case No. 10-2-34849-2-SEA), or the *Alexander* action. On October 5, 2010, the *Alexander* action was removed to the United States District Court for the Western District of Washington and assigned to Judge Pechman. The *Bohland* and *Alexander* actions are pending consolidation with the other four derivative actions. Also pending are motions concerning lead plaintiff appointment.

For the shareholder derivative complaints, no estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On July 28, 2010, the former General Manager of our Italian Branch office, CTI (Europe), initiated a Court proceeding against us to challenge the former General Manager s dismissal which occurred in 2009. The former General Manager s claims are based on the alleged unlawfulness and lack of justifications of his dismissal. The former General Manager alleges that he has suffered and requests compensation for damages ranging up to approximately 0.7 million, or $1.0 million as of September 30, 2010, plus the costs of the proceedings. The first hearing is scheduled for December 9, 2010. We are entitled to file a brief regarding our defenses any time prior to ten days before the hearing. Management believes that the allegations in the claim are without merit and intend to defend the claim vigorously.

In addition to the litigation 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.

9. Subsequent Events

In October 2010, we entered into a securities purchase agreement, pursuant to which we agreed to issue in a registered offering an aggregate of 21,000 shares of our Series 7 preferred stock, initially convertible into approximately 56.8 million shares of our common stock and warrants to purchase up to approximately 22.7 million shares of our common stock for gross proceeds of $21.0 million. All 21,000 shares of the Series 7 preferred stock were converted into 56.8 million shares of our common stock upon closing of the transaction in October 2010.

The warrants have an exercise price of $0.45 per share of our common stock. The warrants are exercisable at any time on or after the six month and one day anniversary of the date of initial issuance and on or before the five year and one day anniversary of the date of the initial issuance.

Each share of Series 7 preferred stock is entitled to a liquidation preference equal to the stated value 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 7 preferred stock is 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 7 preferred stock is convertible into common stock, at the option of the holder, at an initial conversion price of $0.37 per share, subject to a 4.99% blocker provision. A holder of Series 7 preferred stock may elect to increase the blocker provision to 9.99% by providing 61 days prior notice, and the maximum percentage will automatically increase to 19.99% in the event of an automatic conversion. The Series 7 preferred stock has no voting rights.

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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 research, 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 pixantrone, OPAXIO , brostallicin and novel bisplatinum analogues. As of September 30, 2010, we had incurred aggregate net losses of approximately $1.5 billion since inception. Unless we execute a partnership agreement for pixantrone with terms adequate to cover our operating expenses, we expect to generate losses from operations for the next few years.

Pixantrone

We are developing pixantrone, a novel aza-anthracenedione, for the treatment of non-Hodgkin s lymphoma, or NHL, and various other hematologic malignancies, and solid tumors. Pixantrone was studied in our EXTEND, or PIX301, clinical trial, which was a phase III single-agent trial of pixantrone 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. Based on the outcome of the EXTEND trial and on the basis of pre-New Drug Application, or NDA, communication we received from the Food and Drug Administration, or FDA, relating to this phase III trial, we began a rolling NDA submission to the FDA in April 2009. We completed the submission in June 2009.

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, pixantrone, which will be used for clinical supplies.

On March 22, 2010, the FDA s Oncologic Drugs Advisory Committee, or ODAC, panel voted unanimously that the clinical trial data was not adequate to support approval of pixantrone for this patient population. In early April 2010, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone recommending that we design and conduct an additional trial to demonstrate the safety and effectiveness of pixantrone. The Company met with FDA in August 2010 at an end of review meeting at which time the FDA informed us that the pixantrone IND and NDA applications were being transferred to the newly formed Division of Hematology Drug Products. The Company is preparing for the initiation of an additional pixantrone clinical study, PIX306, that would serve as either a post-approval confirmatory study, if pixantrone were to be approved on the basis of the current NDA, or as a registration study for approval in the U.S. On August 3, 2010, we filed for a Special Protocol Assessment, or SPA, with the FDA for the design of our additional clinical study of pixantrone. On September 24, 2010 the SPA package with expanded information was submitted to the newly formed Division of Hematology Drug Products.

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The results of the EXTEND trial showed that patients randomized to treatment with pixantrone 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. Pixantrone was safely 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 pixantrone-treated subjects across studies were neutropenia and leukopenia. Use of growth factor support was minimal. Other common adverse events (any grade) included infection, anemia, leukopenia, thrombocytopenia, asthenia, pyrexia and cough. Overall, the incidence of grade 3 or greater cardiac adverse events was 7% (5 patients) on the pixantrone arm and 2% (1 patient) on the comparator arm. There were an equal number of deaths due to an adverse event in both the pixantrone and comparator arm.

We also conducted the RAPID, or PIX203, phase II clinical trial study (CHOP-R vs. CPOP-R) in which pixantrone is substituted for doxorubicin in the CPOP-R regimen compared to the standard CHOP-R regimen in patients with aggressive NHL. An interim analysis of the RAPID trial, reported in July 2007, showed that at that time, a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). Patients on the pixantrone arm of the study had less left ventricular ejection fraction (LVEF) drops, infections, and thrombocytopenia (a reduction in platelets in the blood). A further preliminary analysis of cardiac safety data showed that the patients in the pixantrone regimen (CPOP-R) experienced a lower incidence of >20% LVEF decline (2% vs. 13%) than patients in the doxorubicin control arm (CHOP-R) and that their incidence of symptomatic Congestive Heart Failure, or CHF, were lower in the pixantrone arm with no patients developing CHF in the pixantrone arm compared to 5% of the patients in the control arm. In early 2008, we closed enrollment on the RAPID trial because we had adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. We expect to report results from the RAPID trial in the fourth quarter of 2010.

In July 2009, we were notified by the European Medicines Agency, or the EMA, that pixantrone is eligible to be submitted for a Marketing Authorization Application, or 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 European Union, or EU, member states. The EMA also designated pixantrone as a New Active Substance, or NAS; if approved, compounds designated as an NAS receive a 10-year market exclusivity period in EU member states. In September 2009, we applied to the EMA for orphan drug designation for pixantrone, 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 pixantrone for treating relapsed, refractory aggressive NHL in Europe. In April 2010, the EMA recommended that we submit an updated PIP for pixantrone following discussions with us about the preclinical and clinical pixantrone data, including EXTEND, and the desire to explore the potential benefits pixantrone 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. On October 19, 2010, we announced that the PDCO had adopted an opinion agreeing to our PIP. The PDCO also recommended deferral of the initiation of the clinical studies until after the drug receives EMA approval. We expect the EMA s decision on adoption of the PDCO s recommendations in the fourth quarter of 2010. We anticipate the formal MAA filing for pixantrone for the treatment of relapsed or refractory aggressive NHL in the fourth quarter of 2010.

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. facility for the production of pixantrone drug substance. In July 2010, we signed a supply agreement with NerPharMa, S.r.l. for pixantrone drug product manufacturing. The five-year contract provides for both the commercial and clinical supply of pixantrone drug product.

In the second quarter of 2010, the North Central Cancer Treatment Group, or NCCTG, opened for enrollment a phase II study of pixantrone in patients with HER2-negative metastatic breast cancer who have tumor progression after at least two, but not more than three, prior chemotherapy regimens.

OPAXIO

We are currently focusing our development of OPAXIO (paclitaxel poliglumex), which we have previously referred to as XYOTAX, as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study, the GOG0212 trial, is under the control of the Gynecologic Oncology Group, or GOG, and is expected to enroll 1,100 patients with more than 740 patients enrolled as of September 2010. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival and based on current enrollment and study duration, the interim analysis could be conducted as early as 2011. If successful, we could utilize those results to form the basis of a New Drug Application for OPAXIO.

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In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced non-small cell lung cancer, or 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, or SAWP; 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.

In June 2009, we announced that, in a study released from Brown University at the 2009 American Society for Clinical Oncology Annual Meeting, patients with cancer of the lower esophagus had evidence of a high pathological complete response rate when given OPAXIO in addition to cisplatin and full-course radiotherapy. In this phase II clinical trial study, data suggests that OPAXIO may provide enhanced radiation sensitization as compared to standard therapy. We plan to meet with the FDA following completion of the clinical study report to explore a potential phase III registration study utilizing OPAXIO as a radiation sensitizer in the treatment of esophageal cancer.

We continue to monitor the use of OPAXIO in women with premenopausal levels of estrogen, regardless of age, who have advanced NSCLC with normal or poor performance status. We believe the lack of safe and effective treatment for women with advanced first-line NSCLC, who have premenopausal estrogen levels, represents an unmet medical need. Based on a pooled analysis of the STELLAR 3 and 4 phase III trials for treatment of first-line NSCLC PS2 patients, we believe that there is a demonstrated statistically significant survival advantage among women receiving OPAXIO when compared to women or men receiving standard chemotherapy. A survival advantage for women over men also was demonstrated in a first-line phase II clinical trial of OPAXIO and carboplatin, known as the PGT202 trial, supporting the potential benefit observed in the STELLAR 3 and 4 trials. In September 2007, we initiated our PGT307 trial which focuses exclusively on NSCLC in women with premenopausal estrogen levels, the subset of patients where OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. Due to limited resources, during the second quarter of 2010 we ceased enrollment in the PGT307 trial and a clinical study report will be prepared.

Brostallicin

We are developing brostallicin through our wholly-owned subsidiary, Systems Medicine LLC, or SM, which holds 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. We expect to use that platform to guide the development of our licensed oncology products in the future. We also have a strategic affiliation with the Translational Genomics Research Institute, or TGen, and have the ability to use TGen s extensive genomic platform and high throughput capabilities to target a cancer drug s context-of-vulnerability, which is intended to guide clinical trials toward patient populations where the highest likelihood of success should be observed, thereby potentially lowering risk and shortening time to market.

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.

A phase II study of brostallicin in relapsed, refractory soft tissue sarcoma met its predefined activity and safety hurdles and resulted in a first-line phase II clinical trial study that was conducted by the European Organization for Research and Treatment of Cancer, or EORTC. Planned enrollment for this study was completed in August 2008 and the EORTC conducted final data analysis in 2009. The data was reported at the American Society of Clinical Oncology Annual Meeting in June 2010. The EORTC trial demonstrated, in this hard to treat patient group, a modest level of clinical activity with an acceptable level of toxicity. No further development is planned in this indication. A multi-arm phase I combination study with brostallicin and other agents, including Avastin (bevacizumab), was completed in the first quarter of 2009. Brostallicin also has demonstrated synergy with new targeted agents as well as established treatments in preclinical trials.

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Research and Preclinical Development

Platinates constitute an important class of cornerstone chemotherapy agents used to treat a wide variety of cancers. There are three currently commercially available platinates (cisplatin, carboplatin, and oxaliplatin) which are first-line agents in ovarian cancer, lung cancer, testicular cancer, and colorectal cancer and are also used in a broad variety of other diseases. We are developing new analogues of the dinuclear-platinum complex CT-3610 that is more potent than any of the commercially available platinates. These bisplatinates have a different mechanism of action than the commercially available platinum compounds and are substantially more active on many preclinical models including those with resistance to monoplatinates. We have initiated active pharmaceutical ingredient and formulation development as prerequisites to Investigational New Drug application enabling activities for bisplatinates.

Critical Accounting 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 Consolidated Financial Condition and Results of Operations,* of our Annual Report on Form 10-K for the year ended December 31, 2009, we consider our policies for license and contract revenue, impairment of long-lived assets, valuation of goodwill, derivatives embedded in certain debt or equity securities, restructuring charges and stock-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, 2009.

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RESULTS OF OPERATIONS

Three months ended September 30, 2010 and 2009

License and contract revenue. License and contract revenue for the three months ended September 30, 2009 represents recognition of deferred revenue from the sale of Lisofylline material to DiaKine.

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

	Three Months Ended September 30,	
	2010	2009
Compounds under development:		
Pixantrone	$ 1,287	$ 1,612
OPAXIO	436	858
Brostallicin	59	50
Operating expenses	3,300	5,009
Discovery research	19	73
Total research and development expenses	$ 5,101	$ 7,602

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. Operating costs include our personnel and occupancy expenses associated with developing these compounds. Discovery research costs include primarily personnel, occupancy and laboratory expenses associated with the discovery and identification of new drug targets and lead 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 pixantrone, OPAXIO and brostallicin are approximately $60.3 million, $222.4 million and $9.4 million, respectively. Costs for pixantrone 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 brostallicin prior to our acquisition of SM in July 2007 are also excluded from this amount.

Research and development expenses decreased to approximately $5.1 million for the three months ended September 30, 2010 from approximately $7.6 million for the three months ended September 30, 2009. Pixantrone costs decreased primarily due to a decrease in clinical and manufacturing activity. Clinical activity decreased due to a decrease in the EXTEND trial related to its wind-down. This decrease is partially offset by an increase in the RAPID trial as it continues to incur costs during its wind-down. In addition, costs related to the additional clinical study of pixantrone, PIX306, were incurred related to its intended startup. Manufacturing expenses decreased due to a reduction of pre-commercialization activities related to pixantrone. Costs for our OPAXIO program decreased primarily due to decreases in clinical and quality activities. Costs for brostallicin relate primarily to clinical development activities associated with phase I and phase II studies. Our operating expenses decreased primarily due to decreases in non-cash stock-based compensation expense and discretionary bonuses. Discovery research expense relates to the costs incurred in preclinical activities.

Our lead drug candidates pixantrone, OPAXIO and brostallicin are currently in clinical trials. 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

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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.

Pixantrone. Pixantrone 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 pixantrone 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 pixantrone because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials and our clinical trial for pixantrone has not commenced. 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 pixantrone will be completed or when we will be able to begin commercializing pixantrone to generate material net cash inflows.

OPAXIO. OPAXIO (paclitaxel poliglumex, CT-2103) 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 and esophageal cancer. We are 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.

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 metastatic triple-negative breast cancer, or 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 for which enrollment is subject to their control 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-3610). 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-3610, that is more potent than cisplatin. CT-3610 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-3610 because, among other reasons, a third party is conducting the preclinical trial for CT-3610, no clinical trial design for CT-3610 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

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estimate the date on which clinical development of CT-3610 will be completed or when we will be able to begin commercializing CT-3610 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 completed timely are discussed in more detail in the following risk factors, which begin on page 30 of this Form 10-Q: *Our financial condition may be adversely affected 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.* ; *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 decreased to approximately $7.9 million for the three months ended September 30, 2010 from approximately $19.7 million for the three months ended September 30, 2009. This decrease was primarily related to a $9.3 million decrease in non-cash stock-based compensation expense. Additionally, there were decreases in discretionary bonus expense and professional services.

Restructuring charges and related gain on sale of assets, net. We recorded restructuring charges of $0.2 million for the three months ended September 30, 2009 related to adjustments to employee termination benefits associated with the closure of our Bresso, Italy operations. This amount was offset by a gain of approximately $0.3 million on the sale of assets related to the Bresso operations.

Interest expense. Interest expense decreased to approximately $0.4 million for the three months ended September 30, 2010 from approximately $0.8 million for the three months ended September 30, 2009. This decrease is primarily due to the exchanges of $42.3 million principal balance of our 5.75%, 6.75% and 7.5% convertible senior notes and $14.8 million of our 4% convertible senior subordinated notes, or 4% Notes, in 2009. In addition, we fully repaid the $38.5 million outstanding principal balance of our 4% Notes in July 2010.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs for the three months ended September 30, 2010 and 2009 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 gain for the three months ended September 30, 2010 and 2009 is due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

Gain on exchange of convertible notes. The $0.2 million gain on exchange of convertible notes for the three months ended September 30, 2009 is due to the exchange of $3.0 million of our 4% Notes and $1.5 million of our 6.75% convertible senior notes as well as accrued and unpaid interest on these notes for 3.3 million shares of our common stock.

Milestone modification expense. Milestone modification expense for the three months ended September 30, 2009 was due to the amendment of our acquisition agreement of Systems Medicine, Inc., or SMI, pursuant to which we acquired SMI in a stock-for-stock merger in July 2007. Under the amended agreement, we agreed to distribute a $6.0 million payment in shares of our common stock to the former SMI stockholders as consideration for the replacement of $15.0 million in potential milestone payments to the former SMI stockholders. The payment in shares of our common stock was subject to CTI shareholder approval, which was obtained at our annual shareholders meeting in October 2009. We issued the former SMI stockholders approximately 5.6 million shares of our common stock in connection with the substitute payment.

Settlement expense. Settlement expense of $1.3 million for the three months ended September 30, 2009 relates to a payment of approximately $1.6 million made in accordance with our settlement agreement with Ingenix Pharmaceuticals Services, Inc., or Ingenix, whereby each party agreed to a full release of the other party from any and all claims related to our dispute with Ingenix. The settlement expense recorded is net of $0.3 million in payables to Ingenix that were relieved from our books.

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Nine months ended September 30, 2010 and 2009

License and contract revenue. License and contract revenue for the nine months ended September 30, 2010 and 2009 represents recognition of deferred revenue from the sale of Lisofylline material to DiaKine.

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

	Nine months Ended September 30,	
	2010	**2009**
Compounds under development:		
Pixantrone	$ 5,195	$ 4,897
OPAXIO	1,818	3,102
Brostallicin	223	844
Zevalin		987
Operating expenses	11,589	12,677
Discovery research	550	371
Total research and development expenses	$ 19,375	$ 22,878

Research and development expenses decreased to approximately $19.4 million for the nine months ended September 30, 2010 from approximately $22.9 million for the nine months ended September 30, 2009. Pixantrone costs increased primarily due to an increase in clinical development activity mainly related to costs associated with our RAPID trial as we continued to incur costs during the study wind-down. In addition, there was an increase in activities associated with investigator-sponsored trials, advisory board meetings and consulting services associated with the startup of the additional clinical study of pixantrone, PIX306. These increases were partially offset by decreases in regulatory costs and manufacturing activity. Regulatory costs decreased due to the non-recurring expense associated with the filing fee for the NDA submission to the FDA, which was incurred in the second quarter of 2009. Manufacturing expenses decreased due to the reduction of pre-commercialization activities related to pixantrone. Costs for our OPAXIO program decreased primarily due to a decrease in regulatory, clinical development and quality activities. Costs for brostallicin decreased primarily due to a decrease in clinical development activities related to phase I and phase II studies. Zevalin costs decreased due to the contribution of the product to RIT Oncology, the joint venture we formed with Spectrum on December 15, 2008 which assumed all related Zevalin expenses subsequent to that date. Our operating expenses decreased primarily due to a reduction in headcount between periods, partially offset by an increase in non-cash stock-based compensation expense. Discovery research expense relates to costs incurred in preclinical activities.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $39.4 million for the nine months ended September 30, 2010 from approximately $39.0 million for the nine months ended September 30, 2009. This is primarily due to a $2.3 million increase in non-cash stock-based compensation expense and an increase in expenses related to sales personnel for the expected pixantrone launch in the first quarter of 2010. These increases were primarily offset by a decrease in overhead costs associated with our Bresso, Italy operations due to office closure, as well as decreases in discretionary bonus expense and professional services.

Restructuring charges and related gain on sale of assets, net. Restructuring charges of $3.8 million for the nine months ended September 30, 2009 primarily relate to activities associated with the closure of our Bresso, Italy operations, including approximately $2.6 million in employee termination benefits and approximately $1.4 million in contract termination and clean-up charges related to the Bresso facilities. These amounts were offset by a gain of $0.3 million on the sale of assets related to the Bresso operations. In addition, we incurred $0.1 million in restructuring charges related to employee separation costs associated with the termination of Zevalin-related employees in connection with the sale of our 50% interest in RIT Oncology to Spectrum.

Gain on sale of investment in joint venture. During the nine months ended September 30, 2009, we recorded a $10.2 million one-time gain on the sale of our 50% interest in RIT Oncology in March 2009. This amount was based on the difference between $16.5 million in gross proceeds and the approximately $4.6 million book value of our investment in RIT Oncology at the time of sale, net of approximately $1.6 million in transaction costs.

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Interest expense. Interest expense decreased to approximately $1.9 million for the nine months ended September 30, 2010 from approximately $4.0 million for the nine months ended September 30, 2009. This decrease is primarily due to the exchanges of $42.3 million principal balance of our 5.75%, 6.75% and 7.5% convertible senior notes and $14.8 million of our 4% Notes in 2009. In addition, we fully repaid the $38.5 million outstanding principal balance of our 4% Notes in July 2010.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs decreased to approximately $0.6 million for the nine months ended September 30, 2010 from approximately $5.6 million for the nine months ended September 30, 2009. During the nine months ended September 30, 2009, conversions of our 9% and 10% convertible senior notes resulted in accelerated amortization of debt discount and issuance costs of $4.4 million. In addition, amortization of debt discount and issuance costs decreased by $0.5 million due to accelerated amortization of debt discount and amortization costs on our 5.75% and 7.5% convertible senior notes and 4% Notes as a result of exchanges and conversions in 2009 reducing the remaining cost basis and discount amount to be amortized over the remaining term of the respective convertible notes.

Foreign exchange gain (loss). The foreign exchange loss for the nine months ended September 30, 2010 and foreign exchange gain for the nine months ended September 30, 2009 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

Debt conversion expense. Debt conversion expense of $2.0 million for the nine months ended September 30, 2010 is related to the exchange of $1.8 million principal balance of our 4% Notes in May 2010 for approximately 4.3 million shares of our common stock.

Make-whole interest expense. Make-whole interest expense of $6.3 million for the nine months ended September 30, 2009 is related to $5.4 million in payments made upon the conversion of $18.0 million of our 10% convertible senior notes and $0.9 million in payments made upon the conversion of $5.3 million of our 9% convertible senior notes.

Gain on derivative liabilities, net. The gain on derivative liabilities of $7.2 million for the nine months ended September 30, 2009 is primarily due to a gain of $4.4 million resulting from the change in the estimated fair value of the derivative liability related to the embedded conversion option on our 10% convertible senior notes as well as a gain of $2.8 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant that was issued in connection with our 13.5% convertible senior notes and Series E preferred stock financing in April 2008 and modified in July 2008 in connection with the issuance of our 18.33% convertible senior notes. The Series B Unit Warrant expired in the second quarter of 2009.

Gain on exchange of convertible notes. The $7.4 million gain on exchange of convertible notes for the nine months ended September 30, 2009 is primarily related to the exchange of $52.9 million principal amount of portions of our 9%, 7.5%, 6.75%, 5.75% convertible senior and 4% Notes for $7.1 million in cash and approximately 24.2 million shares of common stock, net of related transaction costs.

***Equity loss from investment in joint venture*.** The loss of $1.2 million for the nine months ended September 30, 2009 relates to our 50% interest in RIT Oncology, prior to the sale of this interest in March 2009, which we accounted for using the equity method of accounting.

Milestone modification expense. Milestone modification expense for the nine months ended September 30, 2009 was due to the amendment of our acquisition agreement of Systems Medicine, Inc., or SMI, pursuant to which we acquired SMI in a stock-for-stock merger in July 2007. Under the amended agreement, we agreed to distribute a $6.0 million payment in shares of our common stock to the former SMI stockholders as consideration for the replacement of $15.0 million in potential milestone payments to the former SMI stockholders. The payment in shares of our common stock was subject to CTI shareholder approval, which was obtained at our annual shareholders meeting in October 2009. We issued the former SMI stockholders approximately 5.6 million shares of our common stock in connection with the substitute payment.

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Settlement expense. Settlement expense of $4.7 million for the nine months ended September 30, 2009 is primarily due to $3.2 million related to amounts paid to Spectrum for the settlement of the final installment payment related to our sale of our 50% interest in RIT Oncology based on the outcome of arbitration proceedings. This amount includes the $3.5 million escrow amount released to Spectrum, our $0.8 million payment to Spectrum based on arbitration proceedings and approximately $0.9 million in receivables recognized in prior periods and owed to us by RIT Oncology. The settlement amount is also net of approximately $2.0 million in payables assumed by Spectrum on our behalf. We also incurred $1.3 million in settlement expense related to the payment made in accordance with our settlement agreement with Ingenix whereby each party agreed to a full release of the other party from any and all claims related to our dispute with Ingenix.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2010, we had approximately $17.3 million in cash and cash equivalents.

Net cash used in operating activities decreased to approximately $50.4 million during the nine months ended September 30, 2010 compared to approximately $70.6 million for the same period during 2009 primarily due to a reduction in interest payments on convertible notes and a decrease in operating expenses, including *research and development* expense and *selling, general and administrative* expense, excluding the allocation of non-cash stock-based compensation. The decrease is also attributable to non-recurring cash payments made in connection with settlement of legal matters during the nine months ended September 30, 2009.

Net cash used in investing activities of approximately $1.2 million for the nine months ended September 30, 2010 was primarily due to purchases of property and equipment. Net cash provided by investing activities of approximately $22.2 million for the nine months ended September 30, 2009 was primarily due to $6.8 million in net proceeds received from Spectrum in January 2009 related to the initial formation of RIT Oncology in December 2008 and $15.1 million in net proceeds received from Spectrum related to the subsequent sale of our 50% interest in RIT Oncology in 2009.

Net cash provided by financing activities of approximately $30.6 million for the nine months ended September 30, 2010 was primarily due to the issuances of our Series 3, 4, 5 and 6 preferred stock. We received $28.0 million in net proceeds from the issuance of 30,000 shares of our Series 3 preferred stock and warrants to purchase approximately 8.6 million shares of our common stock in January 2010. We also received $18.6 million in net proceeds from the issuance of 20,000 shares of our Series 4 preferred stock and warrants to purchase 20.0 million shares of our common stock in April 2010. In addition, we received $19.7 million in net proceeds from the issuance of 21,000 shares of Series 5 preferred stock and warrants to purchase approximately 26.3 million contingently issuable shares of our common stock in May 2010. In July 2010, we received $3.6 million in net proceeds from the issuance of 4,060 shares of our Series 6 preferred stock and warrants to purchase 5.8 million shares of our common stock. These proceeds were offset by a $38.5 million payment to retire down the outstanding principal balance on our 4% Notes in July 2010 in addition to $0.7 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 $94.2 million for the nine months ended September 30, 2009 was primarily due to $40.6 million in net proceeds from the issuance of 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock in a public offering in July 2009 as well as $18.9 million in net proceeds from the issuance of 16.0 million shares of our common stock and warrants to purchase 4.8 million shares of our common stock in May 2009. In addition, we received $18.7 million in net proceeds from the issuance of 20,000 shares of our Series 1 preferred stock and related Class A and Class B warrants in April 2009, as well as $3.8 million upon the exercise of the Class A warrants in May 2009. We also received $28.5 million in net proceeds from the issuance of 30,000 shares of our Series 2 preferred stock and warrants to purchase up to 4.7 million shares of our common stock in August 2009. These proceeds were offset by $9.9 million in cash paid, net of transaction costs and in addition to 24.2 million shares of our common stock, for the exchange of $52.9 million principal amount of our convertible notes. We also made a $3.0 million deemed dividend payment in connection with our settlement with Tang Capital Partners LP for full release of all claims against us in connection with our alleged breach of contract related to Tang s Series B preferred stock. This amount was accrued as of December 31, 2008 and paid in January 2009.

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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. We have incurred net losses since inception and expect to generate losses from operations for the next few years primarily due to research and development costs for pixantrone, OPAXIO and brostallicin. Subsequent to period end, in October 2010, we raised $21.0 million in gross proceeds from the issuance of 21,000 shares of our Series 7 preferred stock and warrants to purchase up to 22.7 million shares of our common stock. Our Series 7 preferred stock was converted to 56.8 million shares of common stock upon closing of the transaction.

We do not expect that our existing cash and cash equivalents, including the cash received from the issuance of our Series 7 preferred stock and warrants, will be sufficient to fund our presently anticipated operations beyond the first quarter of 2011. This raises substantial doubt about our ability to continue as a going concern.

Since the second quarter of 2010, we have implemented cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned commercial pixantrone operations. We project our net cash operating expenses for 2010 to be approximately $60 million. We will need to raise additional funds and are currently exploring alternative sources of financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources.

On September 16, 2010, our shareholders approved an amendment to our amended and restated articles of incorporation to increase our authorized shares of common and preferred stock from 810,000,000 shares to 1,210,000,000 shares and to increase the total number of our authorized shares of common stock from 800,000,000 shares of common stock to 1,200,000,000 shares of common stock. As such, our board of directors has the option to issue such shares depending on our financial needs and market opportunities, if deemed to be in the best interest of the shareholders. 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; and
- competitive market developments.

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.

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The following table includes information relating to our contractual obligations as of September 30, 2010 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
7.5% convertible senior notes (1)	$ 10,250	$ 10,250	$	$	$
5.75% convertible senior notes (2)	10,913		10,913		
Interest on convertible notes	1,205	1,074	131		
Operating leases:					
Facilities	8,331	4,357	3,846	128	
Long-term obligations (3)	1,196	457	726	13	
	$ 31,895	$ 16,138	$ 15,616	$ 141	$

(1) The 7.5% convertible senior notes are convertible into shares of our common stock at a conversion rate of 11.96298 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $83.59 per share.
(2) The 5.75% convertible senior notes are convertible into shares of our common stock at a conversion rate of 33.33333 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $30.00 per share.
(3) Long-term obligations do not include $0.6 million related to excess facilities charges.

Manufacturing Supply Agreement

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 pixantrone. The NerPharMa Agreement is a five year non-exclusive agreement and provides for both the commercial and clinical supply of pixantrone. 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 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.

License Agreements and Additional Milestone Activities

PG-TXL

We have an agreement with PG-TXL, or the PG-TXL Agreement, 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 Gynecologic Oncology Group, or GOG, related to the GOG0212 trial which the GOG is conducting. We recorded a $1.6 million payment due to the GOG based on the 650 patient enrollment milestone achieved in the first quarter of 2010. As of September 30, 2010, this amount is included in *accounts payable*. Under this agreement we are required to pay up to $3.5 million in additional milestone payments related to the trial of which $1.7 million may become due in the next 4 to 6 months based on current planned patient enrollment and $0.5 million may become due in 2011 upon receipt of the interim analysis and data transfer.

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 with Novartis, or the Novartis Agreement, 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 its 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 pixantrone based on agreed terms. If Novartis exercises its option on pixantrone 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 pixantrone worldwide net sales. Royalty payments to us for pixantrone are based on worldwide pixantrone 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 pixantrone are based on sales volumes in the U.S. and sales volumes in other countries.

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Royalties for OPAXIO and pixantrone are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its Development Rights until the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement or (ii) Novartis determination, in its sole discretion, to terminate 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, 2010, 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 pixantrone 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, 2010, our foreign currency transactions are 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, 2010, we had a net asset balance excluding intercompany payables and receivables in our European branches denominated in euros. As of September 30, 2010, if the euro were to weaken 20% against the dollar, our net asset balance would decrease by approximately $1.1 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 Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and EVP of Finance have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the 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

Information pertaining to legal proceedings can be found in Part I under the caption Item 1. Financial Statements Note 8. Legal Proceedings and is incorporated by reference herein.

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Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The occurrence of any of the following risks described below and elsewhere in this document, including the risk that our actual results may differ materially from those anticipated in these forward-looking statements, could materially adversely affect our business, financial condition, operating results or prospects and the trading price of our 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 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, 2010, we had cash and cash equivalents of $17.3 million. As of September 30, 2010, our total current liabilities were $25.9 million. The aggregate principal balance of our outstanding 7.5% and 5.75% convertible senior notes as of September 30, 2010 was $21.2 million. We repaid the outstanding principal amount and accrued but unpaid interest on our 4% notes in July 2010. We do not expect that our existing cash and cash equivalents, as well as proceeds received from our offerings to date, will provide sufficient working capital to fund our presently anticipated operations beyond the first quarter of 2011.

Raising additional capital will likely require that we issue additional shares of our common stock. 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 have held preliminary discussions with several investment funds regarding a potential investment in our company, but we have no current agreements or commitments with respect to any investment by these investment funds or any other investors. There can be no assurance that our discussions with these investment funds or any other investors will result in an investment in our company or that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations, including our debt service obligations.

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 Italy and the United States and we may be subject to certain contractual limitations, which may increase our costs and adversely affect 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 pixantrone, OPAXIO and brostallicin, and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. A bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to pixantrone, OPAXIO and brostallicin.

We need to implement a reduction in expenses across our operations.

We need substantial additional capital to fund our current operations. 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.

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During 2009, we finalized the closure our Italian operations that we used primarily for pre-clinical research. These operations were underutilized due to our current business model that is focused on the development of late-stage compounds and their commercialization. In connection with this closure, we entered into a severance agreement with the unions representing the employees of our Italian operations related to a reduction in force of our Italian employees. On April 12, 2010, we conducted an immediate reduction in force of 36 employees due to an implementation of a cost reduction plan.

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, 2010, we had an accumulated deficit of $1.5 billion. We are pursuing regulatory approval for pixantrone, OPAXIO 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 products currently in development or otherwise.

Our debt and operating expenses exceed our net revenues.

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. Unless we raise substantial additional capital and reduce our operating expenses, we may not be able to pay all of our operating expenses or repay our debt or the interest on our debt, liquidated damages or other payments that may become due with respect to our debt. In the event we are unable to reduce our expenses and/or repay our debt or the interest on our debt, 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. A bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to pixantrone, OPAXIO and brostallicin.

We may be unable to use our net operating losses.

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 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 the 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, 2009, 2008 and 2007 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.

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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.

Effective with the opening of trading on January 8, 2009, the U.S. listing of our common stock was transferred to The NASDAQ Capital Market, subject to meeting a minimum market value of listed securities of $35 million. The NASDAQ Stock Market LLC s, or NASDAQ, Listing Qualifications Panel, or the Panel, approved this transfer after our market capitalization did not comply with the minimum market capitalization required for companies listed on The NASDAQ Global Market, and we presented a plan to the Panel for regaining compliance with NASDAQ Marketplace Rules. On January 23, 2009, we received an Additional Staff Determination Letter from NASDAQ that stated that NASDAQ staff had concluded that we had violated NASDAQ Marketplace Rule 4350(i)(1)(C) (now NASDAQ Marketplace Rule 5635), which requires shareholder approval in connection with an acquisition if the issuance or potential issuance is greater than 20% of the pre-acquisition shares outstanding, and that we had at times not complied with Marketplace Rule 4310(c)(17) regarding submission of a Listing of Additional Shares form. On February 18, 2009, we updated the Panel on our plan for regaining compliance and requested an extension of the deadline to regain compliance with the minimum market capitalization requirement for The NASDAQ Capital Market. On March 6, 2009, we were notified by NASDAQ that the Panel had determined to continue the listing of our common stock on The NASDAQ Capital Market, subject to the condition that, on or before April 6, 2009, we demonstrate compliance with all applicable standards for continued listing on The NASDAQ Capital Market, including the $35 million minimum market capitalization requirement. In addition, the Panel issued a public reprimand for our prior failures to comply with the shareholder approval requirements and late filing of Listing of Additional Shares forms. On April 2, 2009, we were notified by NASDAQ that we had complied with the Panel s decision dated March 6, 2009, and, accordingly, the Panel had determined to continue the listing of our common stock on The NASDAQ Capital Market.

NASDAQ reinstated the $1.00 minimum bid price requirement on August 3, 2009 and there can be no assurance that our common stock price will be $1.00 or above. On May 3, 2010, we received notice from NASDAQ indicating that for the last 30 consecutive business days the closing bid price of our common stock was below the minimum $1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2). This notification has no immediate effect on the listing of or the ability to trade our common stock on The NASDAQ Capital Market. In accordance with NASDAQ Marketplace Rule 5810(c)(3)(A), we have been provided a grace period of 180 calendar days, or until November 1, 2010, to regain compliance. We will achieve compliance if the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive trading days before November 1, 2010. Alternatively, we may be eligible for an additional 180-day grace period if we meet all of the initial listing standards of NASDAQ, with the exception of the closing bid price. We believe that we are currently in compliance with all of the initial listing standards other than the minimum shareholders equity standard and the closing bid price described above. We believe that the net proceeds from our offering of Series 7 preferred stock, which closed on October 22, 2010, enabled us to achieve the minimum shareholders equity requirement and, therefore, comply with all of the initial listing standards prior to November 1, 2010. However, NASDAQ is responsible for determining whether the net proceeds from that offering enabled us to achieve the minimum shareholders equity requirement. If NASDAQ agrees with our determination, then we believe that we will be eligible for the additional 180-day grace period. There can be no assurance that our closing bid price will achieve $1.00 per share or more for the applicable period or achieve the minimum shareholders equity. If we are unable to attain compliance with the minimum bid price, whether by effecting a reverse stock split of our common stock or otherwise, or if we fail to meet all of the initial listing standards, with the exception of the closing bid price, we may be delisted. In addition, if we fail to maintain the minimum value of listed securities, we may be delisted. In the event that we receive a delisting determination from NASDAQ, we may request a hearing before the Panel. Following the hearing request, our common stock would continue to be listed on The NASDAQ Capital Market pending the conclusion of the hearing process and during any extension period which may be granted by the Panel. There can be no assurance that the Panel would delay an unfavorable delisting decision or grant any extension period.

The level of trading activity of our common stock may decline if it is no longer listed on The NASDAQ Capital Market. Furthermore, our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, 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 and make it more difficult for investors to sell shares of our common stock.

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In the event our common stock is delisted from The NASDAQ Capital Market, we currently expect that our common stock would be eligible to be listed on the OTC Bulletin Board or Pink Sheets. We do not know what impact delisting from The NASDAQ Capital Market may have on our listing with the Borsa Italiana.

Although we continue to be listed on The NASDAQ Capital Market, trading in our common stock may be halted or suspended due to market conditions or if NASDAQ, CONSOB or the Borsa Italiana determine that trading in our common stock is inadvisable. Trading in our common stock was halted by the Borsa Italiana on February 10, 2009, and, as a consequence, trading in our common stock was also halted by NASDAQ. After we provided CONSOB with additional information and clarification on our business operations and financial condition, as requested, and published a press release containing such information in Italy, the Borsa Italiana, and NASDAQ lifted the trading halts on our common stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA and resumed trading prior to opening of the MTA the next day after we filed a press release regarding the explanatory paragraph in our auditor s reports on our December 31, 2008 and 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. As a consequence, NASDAQ also halted trading in our common stock on March 23, 2009, but re-initiated trading later that day. Although we file press releases with CONSOB at the end of each month regarding our business and financial condition, CONSOB may make additional inquiries about our business and financial conditions at any time, and there can be no guarantee that the Borsa Italiana, CONSOB or NASDAQ will not halt trading in our shares again in the future.

If our common stock ceases to be listed for trading on The NASDAQ Capital Market or the MTA, or both, for any reason, or if trading in our stock is halted or suspended on The NASDAQ Capital Market or the MTA or both, such events may harm the trading price of our securities, increase the volatility of the trading price of our securities and make it more difficult for investors to buy or sell shares of our common stock. Moreover, if our common stock ceases to be listed for trading on The NASDAQ Capital Market or if trading in our stock is halted or suspended on The NASDAQ Capital Market, we may become subject to certain obligations. In addition, if we are not listed on The NASDAQ Capital Market and/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 have a material adverse effect on our ability to raise the capital we need.

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, which is the public authority responsible for regulating the Italian securities market, and the Borsa Italiana, which ensures the development of the managed market 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.

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In addition, under Italian law, we must publish a listing prospectus that has been 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. We have attempted to publish a listing prospectus in Italy to cover our general offerings for the past two years, beginning in April 2007. If we are unable to maintain a listing prospectus to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities that are not subject to the listing prospectus requirements, including convertible preferred stock and convertible debt not issued on an E.U. regulated market, in lieu of common stock. Such convertible preferred stock and convertible debt might also be converted into common stock without the prior publication of a listing prospectus according to Section 57 of the CONSOB s Rules no. 11971/99, as subsequently amended.

Moreover, on December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, as follows: (a) the non-disclosure without delay of the press release described above and the subsequent incomplete disclosure of the relevant information through press releases dated January 9, 2009 and January 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the three 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 August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (i) notified us that it has begun the preliminary investigation for its decision on these administrative proceedings and (ii) provided us with a preliminary investigation report in reply to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions.

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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 the press release 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, applicable to each one 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 (i) notified us that it has begun the preliminary investigation for its decision on these administrative proceedings and (ii) provided us with a preliminary investigation report in reply 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 will have to evaluate before imposing any possible administrative sanctions.

Our assets and liabilities that remain in our Italian branches 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 Italian branches 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 a value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is $5.5 million and $6.3 million as of September 30, 2010 and December 31, 2009, respectively. On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings of the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). 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 0.8million, or approximately $0.7 million, $7.5 million, $3.4 million and $1.2 million as of September 30, 2010, respectively. On July 14, 2010, the ITA issued a notice of deposit payment to CTI (Europe) based on the 2005 assessment including interest and collection fees for an amount of 0.9 million. We successfully filed a petition with the Provincial Tax Court of Milan, or the Tax Court, for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the 2005 assessment were discussed in a public hearing before the Tax Court, which has reserved its decision in order to carefully review the arguments, relevant documents and other supporting evidence (including an appraisal from an independent expert) that our counsel filed and presented during the hearing. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have been vigorously defending against the assessments and expect that the Tax Court will take into account our arguments both on the procedural grounds and on the merits of the case. If the Tax Court s decision is unfavorable, we will appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments, and if we receive an assessment for subsequent years, it may harm our results of operations and financial condition.

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

Because we do not currently have any marketed products producing revenue, 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.

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

We have entered into a License and Co-Development agreement related to OPAXIO and pixantrone 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 pixantrone. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to pixantrone 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 pixantrone, 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 pixantrone or OPAXIO with a third party. As announced on April 9, 2010, we received a Complete Response Letter from the Food and Drug Administration, or FDA, regarding our New Drug Application, or NDA, for pixantrone. The FDA cited as its primary reason for the action its concerns previously raised at the Oncologic Drugs Advisory Committee, or ODAC, meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of pixantrone. 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 pixantrone 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.

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.

At the ODAC meeting on March 22, 2010, the ODAC panel did not recommend approval of our NDA for pixantrone. Subsequently, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010 and recommended that we conduct an additional clinical trial to demonstrate the safety and effectiveness of pixantrone. Moreover, we expect that we will need at least an additional clinical trial to obtain FDA approval of our NDA for pixantrone and we do not know what this trial will cost or whether the FDA will accept our SPA for this trial. We may also need more than one additional clinical trial or we may need to take additional steps to obtain regulatory approval of pixantrone. 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 our NDA for pixantrone 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.

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. This study, the GOG0212 trial, is under the control of the GOG and is expected to enroll 1,100 patients with more than 740 patients enrolled as of September 30, 2010. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival and based on current enrollment and study duration, the interim analysis could be conducted as early as 2011. If successful, we could utilize those results to form the basis of a New Drug Application, 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 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 our planned submission

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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 non-small cell lung cancer, or 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, or SAWP; 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. 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. None of our current product candidates have received approval for marketing in any country. On April 13, 2009, we began submission of a rolling NDA to the FDA for pixantrone to treat relapsed aggressive NHL. We completed the submission in June 2009 and as announced on April 9, 2010, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone. The FDA cited as its primary reason for the action its concerns previously raised at the Oncologic Drugs Advisory Committee, or ODAC, meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of pixantrone. Based on the FDA s ODAC presentation, which provided ODAC and us with alternative options to consider to make investigational drugs available to patients if drugs need to be studied further prior to approval, we will evaluate the establishment of an expanded access program for pixantrone while we conduct an additional study in aggressive NHL.

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 debt and operating expenses, our business, financial condition and results of operations will be adversely affected.

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, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA 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.

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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:

- Because pixantrone is intended to provide less toxic treatments to patients who have failed standard chemotherapy treatment, if we are successful in bringing pixantrone to market, it is not expected to compete directly with many existing chemotherapies. However, pixantrone will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®), and new anti-cancer drugs with reduced toxicity that may be developed and marketed.

- If we are successful in bringing OPAXIO to market, we will face direct competition from oncology-focused multinational corporations. OPAXIO will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products. Such corporations include, among others, Bristol-Myers Squibb Co. 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 Abraxis, which markets Abraxane . In addition, other companies such as NeoPharm Inc. and Telik, Inc. are also developing products, which could compete with OPAXIO.

- 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 payers 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 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 marketing approval; and

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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 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 reimbursement might not be available or sufficient. If adequate third-party 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 (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. 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 operate profitably.

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

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

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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 have a material adverse effect on 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 pixantrone, OPAXIO, brostallicin, 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 pixantrone and brostallicin. 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.

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.

We and certain of our officers and directors are named as defendants in purported securities class action and shareholder derivative lawsuits filed in the U.S. District Court for the Western District of Washington. These securities class action lawsuits are brought on behalf of a putative class of purchasers of our securities from May 5, 2009 through March 19, 2010, and seek unspecified damages. As is typical in this type of litigation, additional purported securities class action and shareholder derivative lawsuits containing substantially similar allegations could be filed in the near future. All of the purported securities class actions have been consolidated into one securities class action, a lead plaintiff has been appointed, and a consolidated amended complaint has been filed. The defendants filed a motion to dismiss on October 27, 2010. We expect that all of the shareholder derivative lawsuits will also be consolidated into one derivative action. Motions are currently pending concerning lead plaintiff appointment in the derivative actions. 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.

When polymers are linked, or conjugated, to drugs, the results are referred to as polymer-drug conjugates. We are developing drug delivery technology that links chemotherapy to biodegradable polymers. For example, OPAXIO is paclitaxel, the active ingredient in Taxol®, one of the world s best selling cancer drugs, linked to polyglutamate. We may not receive a patent for all of our polymer-drug conjugates and we may be challenged by the holder of a patent covering the underlying drug and/or methods for its use or manufacture.

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.

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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 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.

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.

We attempt to monitor patent filings for patents that may be relevant to 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 these 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 a third-party s 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 may be unable to obtain a quorum for meetings of our shareholders or obtain necessary shareholder approvals and therefore be unable to take certain corporate actions.

Our amended and restated articles of incorporation require that a quorum, consisting of one-third of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our amended and restated articles of incorporation, such as an amendment to increase our authorized capital stock, require the approval of a majority of our outstanding shares. 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 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 informed before such record date and taking no action to direct the voting of such shares. Under Rule 452 of the New York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as the uncontested election of directors, an amendment to our amended and restated articles of incorporation to increase authorized shares that are to be used for general corporate purposes, and the ratification of our auditors. We were able to obtain a quorum to hold special meetings of the shareholders in April 2007, January 2008 and March 2009 and annual meetings of the shareholders in September 2007, June 2008, October 2009 and September 2010. At the meeting in June 2008, our shareholders approved a proposal to reduce our quorum requirement from a majority of outstanding voting shares to one-third of outstanding voting shares. However, obtaining a quorum at future meetings even at the lower threshold 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 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.

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If we are unable to obtain a quorum at our shareholder meetings and thus fail to get shareholder approval of corporate actions, such failure could have a materially adverse effect on us. Even if we obtain quorum, we may not obtain enough votes to approve matters to be resolved upon at the shareholders meeting. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452 of the New York Stock Exchange, and we may not be able to obtain the required number of votes to approve certain proposals (i.e., such as a proposal to increase the number of authorized shares) that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. 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 have a material adverse effect on 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 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 NASDAQ. 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, but we might not be successful in obtaining the required shareholder approval for such an issuance, 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 obtain financing due to shareholder approval difficulties, such failure may have a material adverse effect on 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.

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 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 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.

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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 pixantrone and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both pixantrone 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 pixantrone. 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 pixantrone from that manufacturer. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. The next hearing date is scheduled for November 11, 2010.

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. All of our compounds currently are in research or development, and have not received marketing approval.

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 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;
- 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, we do not have a marketed product, and unless we are able to develop one of our product candidates, such as pixantrone, into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixantrone, OPAXIO and brostallicin are currently in clinical trials; these clinical trials 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. All of our product candidates in clinical development are in-licensed from a third-party, including pixantrone, OPAXIO and brostallicin.

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

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We 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. 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;
- 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
- 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 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 have limited experience in conducting clinical trials. 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 adversely affected. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be adversely affected.

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 Gynecologic Oncology Group 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 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.

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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 adversely affect 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.

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.

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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 have a material adverse impact on 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 materially adversely affected 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 adversely affected 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 Iraq, 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. In June 2009, the World Health Organization declared an H1N1 influenza, or swine flu, pandemic, and such 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 the severity of the H1N1 influenza pandemic increase or other 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 of the H1N1 pandemic, 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.

Higher health care costs could adversely affect our business.

We will be impacted by the recent passage of 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 have a material adverse effect on our business, financial condition and results of operations.

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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 22, 2010, our stock price has ranged from a low of $0.12 to a high of $1.40. Fluctuations in the trading price or liquidity of our common stock may adversely affect 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 of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

our issuance of additional debt, equity or other securities, which we need to pursue in 2010 to generate additional funds to cover our current debt and 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;

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 are 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 May 5, 2009 through March 19, 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.

The market price of our common stock may be adversely affected 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 adversely affected 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

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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 adversely affect the market price of shares of our common stock.

We are not restricted from issuing additional shares of common stock or preferred stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of common stock or preferred stock or any substantially similar securities. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, or the perception that such sales could occur in the future.

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

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

Item 5. Other

Not applicable.

Item 6. Exhibits

(a) Exhibits

3.1	Registrant s Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008).
3.2	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on February 9, 2009).
3.3	Registrant s Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on March 27, 2009).
3.4	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 13, 2009).
3.5	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on August 21, 2009).
3.6	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on December 28, 2009).
3.7	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on January 19, 2010).
3.8	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on April 5, 2010).
3.9	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on May 27, 2010).
3.10	Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on July 27, 2010).
3.11	Registrant s Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on September 17, 2010).

3.12 Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on October 22, 2010).

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

4.1 Form of Series 6 Preferred Stock Certificate (incorporated by reference to the exhibits to the Registrant s Quarterly Report on Form 10-Q, filed on August 6, 2010).

4.2 Form of Common Stock Purchase Warrant, dated July 27, 2010 (incorporated by reference to the exhibits to the Registrant s Quarterly Report on Form 10-Q, filed on August 6, 2010).

4.3 Form of Series 7 Preferred Stock Certificate, dated October 22, 2010 (incorporated by reference to the exhibits to the Registrants Current Report on Form 8-K, filed on October 22, 2010).

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4.4	Form of Common Stock Purchase Warrant, dated October 22, 2010 (incorporated by reference to the exhibits to the Registrants Current Report on Form 8-K, filed on October 22, 2010).
10.1	Form of Securities Purchase Agreement, dated July 25, 2010 (incorporated by reference to the exhibits to the Registrant s Quarterly Report on Form 10-Q, filed on August 6, 2010).
10.2	Form of Warrant Exchange Agreement, dated July 25, 2010 (incorporated by reference to the exhibits to the Registrant s Quarterly Report on Form 10-Q, filed on August 6, 2010).
10.3	Letter Agreement, dated July 25, 2010, by and between the Registrant and Rodman & Renshaw, LLC (incorporated by reference to the exhibits to the Registrant s Quarterly Report on Form 10-Q, filed on August 6, 2010).
10.4	Drug Product Manufacturing Supply Agreement, dated July 13, 2010, by and between NerPharMa, S.r.l. and the Registrant (incorporated by reference to the exhibits to the Registrant s Quarterly Report on Form 10-Q, filed on August 6, 2010).
10.5	2007 Equity Incentive Plan, as amended and restated (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on September 17, 2010).
10.6	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Directors, dated July 12, 2010.*
10.7	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Employees, dated July 12, 2010.*
10.8	Form of Securities Purchase Agreement, dated October 19, 2010 (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on October 22, 2010).
10.9	Letter Agreement, dated October 19, 2010, by and between the Registrant and Rodman & Renshaw, LLC (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on October 22, 2010).
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

* Filed herewith.
Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

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SIGNATURES

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

CELL THERAPEUTICS, INC.
(Registrant)

Dated: October 28, 2010

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

Dated: October 28, 2010

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