CELL THERAPEUTICS INC
Form 10-Q
August 06, 2009
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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: June 30, 2009

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	**98119**
(Address of principal executive offices)	**(Zip Code)**

(206) 282-7100

(Registrant s telephone number, including area code)

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

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

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

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

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

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

Class	**Outstanding at August 3, 2009**
Common Stock, no par value	541,165,832

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	June 30, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,980	$ 10,072
Restricted cash		6,640
Securities available-for-sale		599
Accounts receivable, net		982
Note receivable from joint venture		7,500
Prepaid expenses and other current assets	2,798	2,368
Total current assets	14,778	28,161
Property and equipment, net	3,628	4,324
Goodwill	17,064	17,064
Investment in joint venture		5,830
Other assets	7,760	8,864
Total assets	$ 43,230	$ 64,243
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 11,586	$ 9,327
Accrued expenses	16,686	29,308
Warrant liability		2,830
Current portion of deferred revenue	80	80
Current portion of long-term obligations	1,560	757
Total current liabilities	29,912	42,302
Deferred revenue, less current portion	279	319
Long-term obligations, less current portion	2,174	2,907
10% convertible senior notes due 2011		19,784
9% convertible senior notes		4,104
7.5% convertible senior notes	10,045	32,601
6.75% convertible senior notes	1,500	6,926
5.75% convertible senior notes	11,483	23,808
4% convertible senior subordinated notes	43,363	55,150
Total liabilities	98,756	187,901
Commitments and contingencies		
Preferred stock, no par value:		
Authorized shares - 10,000,000		
Series A 3% convertible preferred stock, $1,000 stated value, 20,000 shares designated; 0 (unaudited) and 550 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively		417
Series B 3% convertible preferred stock, $1,000 stated value, 37,200 shares designated; 0 (unaudited) and 5,218 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively		4,031
Series C 3% convertible preferred stock, $1,000 stated value,		

20,250 shares designated; 0 (unaudited) and 4,284 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively		3,221
Series D 7% convertible preferred stock, $1,000 stated value, 6,500 shares designated; 0 (unaudited) and 1,000 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively		734
Common stock purchase warrants	2,104	
Shareholders deficit:		
Common stock, no par value:		
Authorized shares - 800,000,000		
Issued and outstanding shares - 502,342,652 (unaudited) and 186,411,922 at June 30, 2009 and December 31, 2008, respectively	1,303,612	1,188,071
Accumulated other comprehensive loss	(8,265)	(7,812)
Accumulated deficit	(1,352,870)	(1,312,320)
Total CTI shareholders deficit	(57,523)	(132,061)
Noncontrolling interest	(107)	
Total shareholders deficit	(57,630)	(132,061)
Total liabilities and shareholders deficit	$ 43,230	$ 64,243

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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Product sales	$	$ 2,870	$	$ 6,244
License and contract revenue	20	20	40	40
Total revenues	20	2,890	40	6,284
Operating expenses, net:				
Cost of product sold		767		1,657
Research and development	7,320	15,857	15,276	31,712
Selling, general and administrative	10,580	11,518	19,330	22,728
Amortization of purchased intangibles		537		934
Restructuring charges	3,820		3,944	
Gain on sale of investment in joint venture			(10,244)	
Total operating expenses, net	21,720	28,679	28,306	57,031
Loss from operations	(21,700)	(25,789)	(28,266)	(50,747)
Other income (expense):				
Investment and other income, net	37	93	71	353
Interest expense	(1,583)	(2,395)	(3,200)	(4,380)
Amortization of debt discount and issuance costs	(497)	(30,202)	(5,348)	(41,146)
Foreign exchange gain (loss)	54	76	95	(2,161)
Make-whole interest expense		(25,596)	(6,345)	(33,377)
Gain on derivative liabilities, net	1,596	31,433	7,218	43,177
Gain (loss) on exchange of convertible notes	7,201	(3,313)	7,201	(5,608)
Equity loss from investment in joint venture			(1,204)	
Settlement expense, net	(3,198)		(3,368)	
Write-off of financing arrangement costs		(2,361)		(2,361)
Other expense, net	3,610	(32,265)	(4,880)	(45,503)
Net loss before noncontrolling interest	(18,090)	(58,054)	(33,146)	(96,250)
Noncontrolling interest	63	31	152	63
Net loss attributable to CTI	(18,027)	(58,023)	(32,994)	(96,187)
Gain on restructuring of preferred stock			2,116	
Preferred stock dividends	(1)	(226)	(24)	(468)
Deemed dividends on preferred stock	(9,398)	(1,067)	(9,648)	(17,265)
Net loss attributable to CTI common shareholders	$ (27,426)	$ (59,316)	$ (40,550)	$ (113,920)
Basic and diluted net loss per common share	$ (0.06)	$ (5.18)	$ (0.11)	$ (12.28)

Shares used in calculation of basic and diluted net loss per common share	446,174	11,447	366,293	9,277

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2009	**2008**
Operating activities		
Net loss	$ (32,994)	$ (96,187)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	5,348	41,146
Non-cash gain on derivative liabilities	(7,218)	(43,177)
Gain on sale of equity investment in joint venture	(10,244)	
(Gain) loss on exchange of convertible notes	(7,201)	5,608
Depreciation and amortization	948	3,040
Equity-based compensation expense	1,909	1,907
Equity loss from investment in joint venture	1,204	
Non-cash settlement expense	70	
Noncontrolling interest	(152)	(63)
Other	(133)	(31)
Changes in operating assets and liabilities:		
Restricted cash	6,640	32,471
Interest receivable	9	(47)
Accounts receivable, net	982	(1,729)
Inventory		(302)
Prepaid expenses and other current assets	(999)	(1,588)
Other assets	(202)	2,407
Accounts payable	518	6,276
Accrued expenses	(9,412)	2,851
Other liabilities	222	(413)
Total adjustments	(17,711)	48,356
Net cash used in operating activities	(50,705)	(47,831)
Investing activities		
Proceeds received from disposition of Zevalin to joint venture, net	6,844	
Proceeds received from sale of investment in joint venture, net	15,075	
Cash paid for acquisition of Zevalin	600	(542)
Purchases of securities available-for-sale		(10,721)
Proceeds from sales of securities available-for-sale		5,312
Proceeds from maturities of securities available-for-sale		290
Purchases of property and equipment	(275)	(729)
Net cash provided by (used in) investing activities	22,244	(6,390)
Financing activities		
Proceeds from issuance of Series 1 preferred stock, net of issuance costs	18,847	
Proceeds from issuance of common stock and warrants, net of issuance costs	18,966	

Proceeds from exercise of Class A warrants	3,765	
Cash paid for the exchange of convertible notes, net of transaction costs	(7,627)	
Payment of deemed dividends on conversion of preferred stock	(3,000)	(16,198)
Proceeds from issuance of 13.5% convertible senior notes and Series E preferred stock, net of exchange of 9% convertible senior notes and issuance costs		56,290
Restricted cash from issuance of 13.5% convertible senior notes		(36,456)
Proceeds from issuance of 9% convertible senior notes, net of issuance costs		49,372
Restricted cash from issuance of 9% convertible senior notes		(13,947)
Release of restricted cash in connection with exchange of 9% convertible senior notes		1,420
Proceeds from issuance of 15% convertible senior notes, net of issuance costs		21,847
Restricted cash from issuance of 15% convertible senior notes		(10,350)
Repayment of 5.75% convertible subordinated and senior subordinated notes		(10,724)
Proceeds from sale of common stock net of offering costs		1,183
Transaction costs related to exchange of convertible subordinated and senior subordinated notes		(304)
Payment of additional offering costs related to December 2007 issuance of common stock and warrants		(473)
Payment of dividends on preferred stock	(111)	(493)
Repayment of long-term obligations	(68)	(251)
Other	(65)	(40)
Net cash provided by financing activities	30,707	40,876
Effect of exchange rate changes on cash and cash equivalents	(338)	2,251
Net decrease in cash and cash equivalents	1,908	(11,094)
Cash and cash equivalents at beginning of period	10,072	15,798
Cash and cash equivalents at end of period	$ 11,980	$ 4,704
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 11,293	$ 35,998
Cash paid for taxes	$	$
Supplemental disclosure of noncash financing and investing activities		
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	$
Conversion of Series F preferred stock to common stock	$ 3,866	$
Conversion of Series 1 preferred stock to common stock	$ 18,537	$
Issuance of common stock in exchange for convertible notes	$ 35,193	$
Conversion of Series A 3% convertible preferred stock to common stock	$	$ 4,771
Conversion of Series B 3% convertible preferred stock to common stock	$ 2,317	$ 7,850
Conversion of Series C 3% convertible preferred stock to common stock	$	$ 1,504
Conversion of Series D 7% convertible preferred stock to common stock	$	$ 2,203
Conversion of 9% convertible senior notes to common stock	$ 5,250	$ 40,820

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	$
Conversion of 10% convertible senior notes due 2011 to common stock	$ 18,000	$
Conversion of 13.5% convertible senior notes to common stock	$	$ 27,600
Conversion of Series E convertible preferred stock to 13.5% convertible senior notes	$	$ 9,118
Conversion of 5.75% convertible senior notes to common stock	$	$ 250
Extinguishment of 5.75% convertible senior subordinated notes in exchange for common stock	$	$ 8,943
Extinguishment of 5.75% convertible subordinated notes in exchange for common stock	$	$ 150
Issuance of common stock in exchange for 5.75% convertible senior subordinated and convertible subordinated notes	$	$ 11,437

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. Our operations are primarily conducted in the United States and we are currently in the process of closing down our Italian operations. 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.

Basis of Presentation

The accompanying unaudited financial information of CTI as of June 30, 2009 and for the three and six months ended June 30, 2009 and 2008 has been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to 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 six month periods ended June 30, 2009 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 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, 2008 included in our Annual Report on Form 10-K.

The consolidated balance sheet at December 31, 2008 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.

Reverse Stock-Split

On August 31, 2008, we effected a one-for-ten reverse stock split of our common stock. All impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the stock split. Impacted amounts include shares of common stock authorized and outstanding, share issuances, shares underlying preferred stock, convertible notes, warrants and stock options, shares reserved and loss per share.

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 (from the date of formation in July 2008), CTI Life Sciences Limited (from the date of formation in March 2009) and Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe), which operates as a branch of the Company.

As of June 30, 2009, we also had a 69% interest in our majority-owned subsidiary, Aequus Biopharma, Inc, or Aequus. In accordance with our fiscal 2009 adoption of Statement of Financial Accounting Standards, or SFAS, No. 160, *Noncontrolling Interests in Consolidated Statements, an amendment of ARB No. 51*, or SFAS 160, noncontrolling interest in Aequus (previously shown as minority interest) is reported below net loss in *noncontrolling interest* in the consolidated income statement and shown as a component of equity in the consolidated balance sheet.

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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.

Liquidity

The 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 financials. However, we have incurred losses since inception and, unless we execute a partnership agreement for pixantrone with terms adequate to cover our operating expenses, we expect to generate losses from operations through at least 2009 primarily due to research and development costs for pixantrone, OPAXIO and brostallicin. Our available *cash and cash equivalents* are approximately $12.0 million as of June 30, 2009. In addition, we received proceeds of approximately $41.7 million, net of underwriting discounts and commissions, in connection with the issuance of approximately 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock in July 2009. Even with this additional financing, we do not expect that we will have sufficient cash to fund our planned operations beyond January 2010, which raises substantial doubt about our ability to continue as a going concern. Accordingly, we have implemented cost saving initiatives to reduce operating expenses, including the reduction of employees related to Zevalin operations and the closure of our operations in Italy as discussed in Note 4, *Restructuring Activities*, and we continue to seek additional areas for cost reductions. However, we will also 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. 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. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

License and Contract Revenue

We may generate revenue from technology licenses, collaborative research and development arrangements, cost reimbursement contracts and research grants. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

Revenue associated with up-front license fees and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. If the time period is not defined in the agreement, we calculate the revenue recognition period based on our current estimate of the research and development period considering experience with similar projects, level of effort and the stage of development. Should there be a change in our estimate of the research and development period, we will revise the term over which the initial payment is recognized. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables.* For multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of

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the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of SEC Staff Accounting Bulletin 104, or SAB 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

Research and Development Expenses

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. In accordance with SFAS No. 2, *Accounting for Research and Development Costs*, research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for research and development activities we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed in accordance with EITF 07-3, *Accounting for Nonrefundable Advance Payment for Goods or Services to be Used in Future Research and Development Activities.* Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon completion of milestones or receipt of deliverables.

Restructuring Charges

We have recorded charges in connection with restructuring activities in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The recognition of restructuring charges requires management to make certain judgments regarding the nature, timing and amount associated with the planned restructuring activities. At the end of each reporting period, we evaluate the appropriateness of the remaining accrued balances.

Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation and amortization. Depreciation commences at the time assets are placed in service. It is calculated using the straight-line method over the estimated useful lives of the assets ranging from three to five years for assets other than leasehold improvements which are amortized over the lesser of their useful life of ten years or the term of the applicable lease using the straight-line method.

Impairment of Long-lived Assets

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values.

Value Added Tax Receivable

Our European operations are subject to Value Added Tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately $6.5 million and $6.3 million as of June 30, 2009 and December 31, 2008, respectively, of which $6.5 million and $6.2 million is included in *other assets* and $0 and $0.1 million is included in *prepaid expenses and other current assets* as of June 30, 2009 and December 31, 2008, 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. On March 26, 2009, the Italian Tax Authority, or ITA, issued a notice of assessment to CTI (Europe) based on their audit of VAT returns for the year 2003. The ITA audit concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian

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clients for services performed by CTI (Europe). In addition, the ITA has issued a pre-assessment of VAT filings for the year 2005 noting findings similar to the 2003 year. The assessment for 2003 is approximately $0.7 million including interest and penalties. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. As such, we have not booked an impairment to the carrying amount of our VAT receivable and we intend to vigorously defend ourselves against the assessment and request a dismissal on procedural grounds and merits of the case.

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 June 30, 2009 and 2008, options, warrants, unvested share awards and rights, convertible debt and convertible preferred stock aggregating 33.0 million and 13.9 million common equivalent shares, respectively, prior to the application of the treasury stock method for options and warrants, were not included in the calculation of diluted net loss per share as they are anti-dilutive.

Derivatives Embedded in Certain Debt Securities

We evaluate financial instruments for freestanding or embedded derivatives in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the statement of operations in the period of change.

Except for our 5.75% and 7.5% convertible senior notes, all of our convertible senior notes include a feature that calls for make-whole payments upon any conversion of these notes. Our 7.5% convertible senior notes include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. These make-whole features along with the conversion options on the notes represent embedded derivatives that must be accounted for separately from the related debt securities except where our convertible senior notes are recorded entirely at fair value pursuant to the guidance in EITF 96-19, *Debtor s Accounting for a Modification or Exchange of Debt Instruments,* or EITF 96-19. The fair value of the derivative for our 6.75% convertible senior notes is calculated based on a discounted cash flow model. The fair value of the derivatives related to all other convertible senior notes is calculated using a Monte Carlo simulation model that incorporates factors such as the current price of our common stock, its volatility and estimated time to expiration of the make-whole feature.

Changes in the estimated fair value of the derivative liabilities related to the convertible senior notes are included in *gain on derivative liabilities, net* and will be remeasured at the end of each reporting period until the relevant feature expires or all of the relevant notes are converted or repurchased.

Foreign Currency Translation and Transaction Gains and Losses

We record foreign currency translation adjustments and transaction gains and losses in accordance with SFAS 52, *Foreign Currency Translation.* For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders deficit. We and our subsidiaries also have transactions in foreign currencies other than the functional currency. We record transaction gains and losses in our consolidated statements of income related to the recurring measurement and settlement of such transactions.

Fair value measurements

We follow the provisions of SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price) in an orderly

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transaction between market participants at the measurement date. In measuring fair value, we consider the hierarchy for inputs provided in SFAS 157 to determine appropriate valuation approaches. Generally, our valuations are based on quoted market prices for identical assets or liabilities which we have the ability to access, or for which significant inputs are observable either directly or indirectly. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires judgment. Our assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date; however, different judgments could yield different results. Our valuation pricing models consider time value, volatility factors, current market and contractual prices for the underlying financial instruments as well as other measurements.

New Accounting Standards

On April 1, 2009, the Financial Accounting Standards Board, or FASB, issued Staff Position FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination that Arises from Contingencies*, or FSP 141(R)-1, which is effective January 1, 2009 and amends the guidance in SFAS No. 141(R), *Business Combinations*, to require that assets and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably estimated. If the acquisition date fair value of an asset acquired or a liability assumed that arises from a contingency cannot be determined, the contingency should be recognized in accordance with FASB No. 5, *Accounting for Contingencies*, and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss*, if it meets the criteria for recognition in that guidance. The adoption of this provision did not have a material impact on our financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events,* or SFAS 165 which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. In addition, SFAS 165 requires the disclosure of the date through which an entity has evaluated subsequent events and whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 is effective for annual and interim periods ending after June 15, 2009 and should be applied prospectively. We have evaluated subsequent events through the date of filing of this Quarterly Report on Form 10-Q.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162*, or SFAS 168 which identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles, or GAAP, in the United States. SFAS 168 establishes the FASB Accounting Standards Codification, or the Codification, as the source of authoritative GAAP recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative GAAP for SEC registrants. All guidance contained in the Codification carries an equal level of authority. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The implementation of the standard will not have any impact on its consolidated financial statements but will require us to reference the new codification beginning in the third quarter of 2009.

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. SFAS 130, *Reporting Comprehensive Income*, provides for unrealized gains and losses on our securities available-for-sale and net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries to be included in other comprehensive income or loss. Total comprehensive loss consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss before noncontrolling interest	$ (18,090)	$ (58,054)	$ (33,146)	$ (96,250)
Foreign currency translation gain (loss)	(246)	(161)	(454)	2,788
Net unrealized gain (loss) on securities available-for-sale		(29)	1	(29)
Comprehensive loss before noncontrolling interest	(18,336)	(58,244)	(33,599)	(93,491)
Noncontrolling interest	63	31	152	63
Comprehensive loss attributable to CTI	$ (18,273)	$ (58,213)	$ (33,447)	$ (93,428)

Information regarding the components of accumulated other comprehensive loss is as follows (in thousands):

	June 30, 2009	December 31, 2008
Foreign currency translation adjustment	$ (8,265)	$ (7,811)
Net unrealized gain (loss) on securities available-for-sale		(1)
Accumulated other comprehensive loss	$ (8,265)	$ (7,812)

3. Exchange Offers

In June 2009, we completed exchange offers whereby we issued $134.50 cash and 458 shares of common stock in exchange for each $1,000 principal amount of convertible notes exchanged. The exchange offers were open to any and all of the approximately $118.9 million balance of our convertible notes outstanding prior to exchange and the following principal amounts for each series of convertible notes were exchanged (in thousands):

	Principal Amount Exchanged
4% convertible senior subordinated notes	$ 11,787
5.75% convertible senior notes	12,087
6.75% convertible senior notes	5,500
7.5% convertible senior notes	23,208
9% convertible senior notes	335
Total principal amount exchanged	$ 52,917

In connection with the exchanges of these notes, we issued a total of approximately $7.1 million in cash and approximately 24.2 million shares of common stock. In accordance with SFAS 15, *Accounting for Debtors and Creditors for Troubled Debt Restructurings*, we recorded a $7.2 million *gain on exchange of convertible notes* for the three and six months ended June 30, 2009. This gain decreased our *net loss attributable to common shareholders* by $0.02 per share for the three and six months ended June 30, 2009. Total costs related to the transaction were

approximately $2.8 million and were allocated on a pro rata basis between *common stock* and *gain on exchange of convertible notes* based on the cash and common stock consideration issued.

4. Restructuring Activities

Italian Operations

We are in the process of closing down our Bresso, Italy operations that were used primarily for pre-clinical research and were underutilized due to our current focused business model 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 SFAS 146, *Accounting for Costs Associated with Exit and Disposal Activities,* or SFAS 146. These costs are included in *restructuring charges* for the three and six months ended June 30, 2009.

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In May 2009, we entered into a severance agreement with the unions representing the employees of our Bresso, Italy operations. This severance agreement relates to a reduction in force of 56 positions at the Bresso facility. Employee separation costs associated with the reduction in force primarily relate to severance payments that we are paying over 42 months, with the majority of these payments made through the first 15 months. For the three and six months ended June 30, 2009, we recorded approximately $2.4 million in employee termination benefits related to these Bresso employees of which $2.3 million was accrued as of June 30, 2009. Additionally, we have sent notices of termination to the six managers of the Bresso facility and are negotiating separate severance agreements with these managers, which have been accrued for as of June 30, 2009. We may incur additional employee termination benefit expense related to Bresso; however, we expect additional amounts, if any, to be immaterial.

In connection with the closure of the Bresso operations, we have certain contract termination and clean-up charges related to the facility s laboratories. For the three and six months ended June 30, 2009 we recorded $1.4 million for these charges, of which $1.0 million was accrued as of June 30, 2009. We expect the closure of the Bresso facility will be completed by October 2009.

We also have certain laboratory equipment related to the Bresso facility that we are currently preparing for sale. We continue to record this equipment as assets held for use as it has not met the criteria of assets held for sale in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets.* We estimate that the fair value of these assets, less the cost to sell, is greater than their carrying value and, as such, we have not recorded an impairment related to these assets. We expect to liquidate these assets in the third quarter of 2009.

Zevalin Operations

In connection with the sale of our 50% interest in RIT Oncology to Spectrum, we terminated certain employees directly and indirectly involved in the operations of Zevalin. During the first half of 2009, we terminated 24 Zevalin-related employees. We recorded employee separation costs of $0.1 million in accordance with SFAS 146 for the six months ended June 30, 2009 which is included in *restructuring charges.* All amounts have been paid as of June 30, 2009 and we do not expect to incur additional restructuring charges related to this transaction.

5. Convertible Notes

During the six months ended June 30, 2009 the remaining $18.0 million principal balance of our 10% convertible senior notes due 2011, or 10% notes, was converted into 131.4 million shares of our common stock. In addition $5.3 million principal balance of our 9% convertible senior notes, or 9% notes, was converted into 0.4 million shares of our common stock. In connection with these conversions we recorded *make-whole interest expense* of $5.4 million and $0.9 million for the 10% notes and the 9% notes, respectively.

In June 2009, holders of $52.9 million principal amount of convertible notes exchanged these notes for approximately $7.1 million and 24.2 million shares of our common stock as discussed further in Note 3, *Exchange Offer.*

6. Preferred Stock

Issuance of Series 1 Convertible Preferred Stock

In April 2009, we entered into a securities purchase agreement whereby we agreed to issue the following in a registered offering: (a) 15,000 shares of our Series 1 preferred stock, convertible into 50.0 million shares of our common stock at a conversion price of $0.30 per share for a purchase price of $1,000 per share of our Series 1 preferred stock and warrants described as follows, (b) Class A warrants to purchase an additional 9.2 million shares of our common stock at an exercise price of $0.41 per share and (c) Class B warrants to purchase an additional 13.3 million shares of our common stock at an exercise price of $0.41 per share. In addition, the original holder of the Series 1 preferred stock had the right to purchase up to 5,000 additional shares of our Series 1 preferred stock at $1,000 per share within 60 days of April 13, 2009. The transaction closed on April 13, 2009 and we received gross proceeds, of $15.0 million. Issuance costs related to this transaction were approximately $1.5 million which included $0.2 million related to the placement agent warrants as discussed below.

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Each share of our Series 1 preferred stock is entitled to a liquidation preference equal to the stated value of such share of our Series 1 preferred stock plus any accrued and unpaid dividends. Our Series 1 preferred stock is not entitled to dividends except to share in any dividends actually paid on our common stock. It is convertible into our common stock, at the option of the holder, at a conversion of $0.30 per share, subject to a 10% exactly blocker provision. Our Series 1 preferred stock has no voting rights except for limited protective provisions and except as is otherwise required by law.

The Class A warrants are immediately exercisable, and the Class B warrants are not exercisable until six months and one day after the date of issuance if the original holder purchases any of the 5,000 additional shares of our Series 1 preferred stock or 61 days after the date of issuance if no additional shares of our Series 1 preferred stock are purchased. The Class A warrants and Class B warrants will terminate on the fifth anniversary of the date upon which such warrants become exercisable. As the Class A and Class B warrants include a redemption feature that may be triggered upon certain liquidation events that are outside of our control, we have classified these warrants as mezzanine equity pursuant to guidance in EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. We estimated the fair value of the Class A and Class B warrants using the Black-Scholes pricing model and allocated approximately $1.5 million and $1.9 million of the $15.0 million gross proceeds to the Class A and Class B warrants, respectively pursuant to guidance in Derivative Implementation Group Statement 133 Implementation Issue No. B6, *Embedded Derivatives: Allocating the Basis of a Hybrid Instrument to the Host Contract and the Embedded Derivative* and EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments.*

In April 2009, the original holder exercised the right to purchase the additional 5,000 shares of our Series 1 preferred stock as discussed above and we received an additional $5.0 million in gross proceeds. All 20,000 shares of our Series 1 preferred stock issued were converted into 66.7 million shares of our common stock. In addition, in May 2009, all of the Class A warrants were exercised for 9.2 million shares of our common stock and we received gross proceeds of approximately $3.8 million related to this exercise.

For the three and six months ended June 30, 2009, we recognized $8.2 million in *deemed dividends on preferred stock* related to the above transactions, including approximately $3.4 million resulting from the allocation of net proceeds to the Class A and Class B warrants and approximately $4.9 million related to the beneficial conversion feature on the 20,000 shares of Series 1 preferred stock as the stock is convertible immediately.

In connection with this offering, we also issued warrants to purchase 1.0 million shares of our common stock to the placement agent which are classified as mezzanine equity due to the same redemption feature for the Class A and Class B warrants as described above. The warrants were estimated to have a fair value of $0.2 million using the Black-Scholes pricing model. These warrants have an exercise price of $0.45 per share, are exercisable in October 2009 and expire in October 2014.

Conversion and Exchange of Convertible Preferred Stock

In January 2009, 3,000 shares of our Series B convertible preferred stock, or Series B preferred stock, were converted into 44,576 shares of our common stock in connection with our litigation settlement with Tang Capital Partners LP, or Tang, as discussed in Note 10, *Legal Proceedings.* Also, in connection with this settlement, $3.0 million of our litigation payment to Tang was recorded as *deemed dividends on preferred stock* for the year ended December 31, 2008. This amount was accrued as of December 31, 2008 and paid in January 2009.

In February 2009, 250 shares of our Series A convertible preferred stock, or Series A preferred stock, were exchanged for $0.1 million and 4.0 million shares of our common stock in connection with our litigation settlement with RHP Master Fund, Ltd, or RHP, as discussed in Note 10, *Legal Proceedings*. In connection with this exchange we recorded $250,000 as *deemed dividends on preferred* stock and $170,000 as *settlement expense* for the six months ended June 30, 2009.

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Also in February 2009, 200 shares of our Series A preferred stock, 2,218 shares of our Series B preferred stock and 4,284 of our Series C convertible preferred stock, or Series C preferred stock, were exchanged for 6,702 shares of our Series F preferred stock. We recorded a gain on this exchange of $2.1 million which is recorded in *gain on restructuring of preferred stock* for the six months ended June 30, 2009. In April 2009, all 6,702 shares of our Series F preferred stock were converted into 47.9 million shares of our common stock.

In April 2009, we entered into exchange agreements for our remaining outstanding Series A and Series D preferred stock. Pursuant to the Series A preferred stock exchange agreement, we issued 0.3 million shares of our common stock in exchange for 100 shares of our Series A preferred stock and related outstanding warrants to purchase 747 shares of our common stock. Pursuant to the Series D preferred stock exchange agreement, we issued 3.5 million shares of our common stock in exchange for 1,000 shares of our Series D preferred stock and related outstanding warrants to purchase 19,138 shares of our common stock. In accordance with EITF D-42, *The Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock* and SFAS 84, *Induced Conversions of Convertible Debt*, we determined that these exchanges represented inducement offers for the Series A and Series D preferred stock and accordingly, we recorded $0.1 million and $1.1 million, respectively, as *deemed dividends on preferred stock* for the three and six months ended June 30, 2009.

As of June 30, 2009, all of our preferred stock had been converted or exchanged as discussed above.

7. Common Stock

In May 2009, we entered into a securities purchase agreement pursuant to which we issued 16.0 million shares of our common stock and warrants to purchase up to 4.8 million shares of common stock in a registered offering. Each warrant to purchase shares of common stock has an exercise price of $1.40 per share, is immediately exercisable and terminates on May 11, 2014. The purchase price for one share of common stock and a warrant exercisable for 0.30 shares of common stock was $1.25 and we received gross proceeds of $20.0 million. In connection with this offering, we also issued warrants to purchase 0.3 million shares of our common stock to the placement agent. These warrants have an exercise price of $1.56 per share, are exercisable in November 2009 and expire in November 2014. Issuance costs related to this common stock offering were approximately $1.5 million which included $0.4 million related to the fair value of the placement agent warrants which were estimated using a Black-Scholes pricing model.

8. Sale of Interest in Joint Venture

In February 2009, we exercised our option to sell all of our 50% membership interest in RIT Oncology to Spectrum and we completed the sale in March 2009 for $16.5 million. We received an initial payment of $6.5 million in gross proceeds in March 2009 and an additional $6.5 million on April 3, 2009. The remaining $3.5 million was subject to an adjustment for, among other things, payables determined to be owed between us and RIT Oncology, and was not released to us based on the outcome of an arbitration proceeding. We recorded $3.2 million in *settlement expense* related to this arbitration proceeding for the three and six months ended June 30, 2009 as discussed further in Note 10, *Legal Proceedings.* For the six months ended June 30, 2009, we recorded a one-time gain on the sale of our interest in the joint venture of $10.2 million, net of transaction costs.

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9. Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense related to employee stock options, employee stock purchases, and share awards under SFAS 123(R) for the three and six months ended June 30, 2009 and 2008, which was allocated as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research and development	$ 157	$ 271	$ 342	$ 529
Selling, general and administrative	1,192	748	1,512	1,381
Stock-based compensation expense included in operating expenses	$ 1,349	$ 1,019	$ 1,854	$ 1,910

For the three and six months ended June 30, 2009 and 2008, stock option fair value was estimated at the date of grant using the Black-Scholes pricing model, with the following weighted average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Risk-free interest rates	1.4%	2.9%	1.3%	2.9%
Expected dividend yield	None	None	None	None
Expected life (in years)	3.3	2.8	3.5	2.8
Expected volatility	88%	79%	88%	79%

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available in U.S. Treasury securities at maturity with an equivalent term. We have not declared or paid any dividends on our common stock and do not currently expect to do so in the future. The expected term of options represents the period that our stock-based awards are expected to be outstanding and was determined based on historical weighted average holding periods and projected holding periods for the remaining unexercised shares. Consideration was given to the contractual terms of our stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatility is based on the annualized daily historical volatility, including consideration of the implied volatility and market prices of traded options for comparable entities within our industry.

Our stock price volatility and option lives involve management s best estimates, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. SFAS 123(R) also requires that we recognize compensation expense for only the portion of options expected to vest. Therefore, we applied an estimated forfeiture rate that we derived from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, additional adjustments to compensation expense may be required in future periods.

10. Legal Proceedings

On January 2, 2008, Tang filed a civil action in the United States District Court for the Southern District of New York in which Tang alleged that we breached a Securities Purchase Agreement, executed on or about April 16, 2007 in connection with the issuance of our Series B preferred stock. On January 3, 2009, we entered into a settlement agreement with Tang with respect to the civil action filed by Tang on January 2, 2008. In exchange for the full release of all claims arising directly or indirectly out of or related to Tang s purchase, acquisition, ownership, interest in or rights under our Series B 3% preferred stock, we agreed to pay Tang $5.1 million which was included in *accrued expenses* as of December 31, 2008. Of the $5.1 million, $2.1 million was recorded to *settlement expense* and $3.0 million was recorded to *deemed dividends on conversion of preferred stock* for the year ended December 31, 2008. Final payment was completed on January 29, 2009. A holder of our Series C preferred stock, Enable Capital Management LLC, or Enable, filed a lawsuit on January 23, 2008 in the Supreme Court of the State of

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New York with similar claims to the Tang action. On September 29, 2008, in exchange for payment, Enable entered into a release agreement with us to fully resolve this action. On May 5, 2008, RHP Master Fund, Ltd., or RHP, a holder of our Series A preferred stock, filed suit in the United States District Court for the Southern District of New York alleging breach of contract and violation of Washington Business Corporation Act, and breach of fiduciary duty by certain officer and director defendants. On February 4, 2009, for $0.1 million and 4.0 million shares of our common stock, we settled all claims that were filed or could have been filed by RHP.

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. 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. On February 28, 2007, defendant The Lash Group, Inc. removed the case to federal 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 is scheduled for September 3, 2009. If successful on appeal, we intend to return to the United States District Court for trial. There is no guarantee that we will prevail in the appeal or at trial.

On February 20, 2009, we notified Spectrum that we had exercised our option to sell to Spectrum all of our membership interest in their 50/50 owned joint venture, RIT Oncology, and on March 2, 2009, Spectrum made the first payment totaling $6.5 million. The sale of our membership interest to Spectrum closed on March 15, 2009, and the remaining $10.0 million of the total $16.5 million purchase price was deposited into an escrow account to be paid to us in two additional installments. On April 3, 2009, $6.5 million was released to us from this escrow account and the final installment of $3.5 million, subject to an adjustment for certain operational liabilities and other obligations, was scheduled to be released to us on April 15, 2009. This final installment payment was not released to us because we and Spectrum disputed the amount of the adjustment. On April 10, 2009, we filed a demand for arbitration regarding Spectrum s payment of the final installment. On April 22, 2009, Spectrum filed a cross-claim alleging that Spectrum was entitled to the entire amount held in escrow and that Spectrum was owed additional amounts by us. The arbitration hearing was held on May 14, 2009. On May 21, 2009, the arbitrator ordered that the final installment of $3.5 million be released from the escrow account and distributed to Spectrum; additionally, we were ordered to pay $0.8 million to Spectrum. Of these amounts, $3.2 million was determined by the arbitrator to be outstanding Excluded Liabilities under the Limited Liability Company Interest Assignment Agreement entered into between Spectrum and CTI, dated March 15, 2009, of which $2.0 million was included in our *accounts payable* balance as of the settlement date. Accordingly, Spectrum is responsible for paying certain liabilities incurred or to be incurred by us totaling $3.2 million, including an obligation payable to Bayer for a clinical trial. The arbitrator s award to Spectrum also included $2.1 million related to expenses incurred by RIT Oncology. On May 26, 2009, we paid Spectrum $0.8 million. For the three and six months ended June 30, 2009, we recorded $3.2 million in settlement expense related to the arbitrators decision. This amount includes the escrow amount released to Spectrum, our payment to Spectrum and approximately $0.9 million in receivables that we recognized in prior periods and were 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.

In April 2007, we entered into a settlement agreement with the United States Attorney s Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX® (arsenic trioxide). We made the settlement payment of $10.6 million in April 2007. The settlement agreement did not address separate claims brought against us by the private party plaintiff for his attorneys fees and expenses. After further litigation concerning attorneys fees and expenses, on January 28, 2009 all remaining claims were settled for approximately $0.5 million, and in consequence, the case has been fully and finally resolved. The settlement amount was recorded to *settlement expense* for the year ended December 31, 2008 and included in *accrued expenses* as of December 31, 2008.

On May 1, 2008, i3, a contract research organization, sent a letter claiming that we owed i3 $2.2 million pursuant to clinical support work. All of these charges have been previously invoiced to us, but the invoices are being evaluated for the association of the work being billed to the contract assignments, as well as the relationship of the pass-through costs to approvable work. On November 6, 2008, i3 filed a demand for arbitration of this dispute with the American Arbitration Association, seeking damages of $2.2 million. That arbitration is pending. While it is probable that some money will be owed to i3, it is not possible at this time to estimate the amount, however we previously recorded $0.2 million in *research and development expense* related to the invoiced i3 services which is included in our *accounts payable* balance as of June 30, 2009.

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On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan court 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. 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 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. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to 5,000 to 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 to the alleged violations, which we expect to submit to CONSOB within 30 days from the notification of the relevant charges (i.e., within 30 days after July 31, 2009).

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.

11. Subsequent Events

Offering of Common Stock and Warrants

In July 2009, we issued 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock for aggregate proceeds of approximately $41.7 million, net of underwriting discounts and commissions, in a public offering of common stock and warrants. Included in the total amounts issued were 4.4 million shares of our common stock and warrants to purchase up to 1.1 million shares of our common stock that were issued upon the exercise of the underwriter s overallotment option. The shares and warrants were issued at a price to the public of $1.30 per share of our common stock and warrant to purchase 0.25 shares of our common stock. Each warrant has an exercise price of $1.70 per warrant share, is exercisable immediately upon the date of issuance and will expire nine months thereafter. We subsequently registered the shares of common stock issuable upon exercise of the warrants pursuant to our registration statement on Form S-3 which we filed with the SEC on July 31, 2009.

In connection with this offering we issued a warrant to purchase up to 0.6 million shares of our common stock at an exercise price of $1.70 per share to the underwriter of the offering. This warrant is exercisable commencing on the date six months from the issuance date and expiring five years from the closing date of the offering. We also issued a warrant to purchase up to 0.3 million shares of our common stock at an exercise price of $1.56 per share for certain financial advisory services related to the offering. This warrant is exercisable beginning in January 2010 and expires in April 2010.

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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 bisplatinates. As of June 30, 2009, we had incurred aggregate net losses of approximately $1.4 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 through at least 2009.

Pixantrone

We are developing pixantrone, a novel anthracycline derivative, for the treatment of non-Hodgkin s lymphoma, or NHL, and various other hematologic malignancies, solid tumors and immunological disorders. Pixantrone was studied in our EXTEND, or PIX 301, clinical trial, which was a phase III single-agent trial of pixantrone for patients with relapsed, 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-NDA communication we received from the Food and Drug Administration, or FDA, relating to this phase III trial, we began a rolling New Drug Application, or NDA submission to the FDA in April 2009. We completed the submission and requested priority review from the FDA in June 2009. If the NDA is granted priority review status, the FDA could provide us with a decision on the NDA before the end of 2009. In addition, in February 2009, we entered into an agreement with IDIS, Limited, or IDIS to manage pixantrone as an investigational drug on a named-patient basis in Europe. Pixantrone will be supplied by IDIS to healthcare professionals for the treatment of individual patients with relapsing aggressive non-Hodgkin s lymphoma. The program was initiated in May 2009.

The results of the EXTEND trial showed that patients randomized to treatment with pixantrone achieved a significantly higher rate of confirmed and unconfirmed complete remissions 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. The most common grade 3, 4 adverse event observed on the pixantrone arm was neutropenia in 41.2% of patients versus 19.4% on the comparator arm. However, the incidence of grade 3, 4 febrile neutropenia was only 7.4% versus 3.0% in the comparator arm. Grade 3, 4 infections had a similar incidence in both study arms (18% vs. 13%). Although the grade 3, 4 cardiac disorder was similar among the two treatment groups (1.5% vs. 1.5%), there was a slightly higher incidence of serious cardiac disorders in patients treated with pixantrone than among patients who received comparator agents (8.8% vs. 4.5%). Events considered cardiac disorders included cardiac arrest, congestive heart failure, myocardial infarction, cyanosis, pericardial effusion and tachycardia.

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We also conducted the RAPID, or PIX203, phase II study (CHOP-R vs. CPOP-R) in which pixantrone is substituted for doxorubicin in the CHOP-R regimen compared to the standard CHOP-R regimen in patients with aggressive NHL. An interim analysis of the RAPID study, reported in July 2007, showed that to date, 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 clinically significant less left ventricular ejection fraction (LVEF) drops, infections, and thrombocytopenia (a reduction in platelets in the blood), as well as significant reduction in febrile neutropenia. 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 this trial in the fourth quarter of 2009.

In July 2009, we were notified by the European Medicines Agency, or EMEA, that pixantrone is eligible to be submitted for a Marketing Authorization Application, or MAA, through the EMEA s centralized procedure. The centralized review process provides for a single coordinated review for approval of pharmaceutical products that is conducted by the EMEA on behalf of all European Union, or EU, member states. The EMEA 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. We plan to request a meeting with the EMEA to discuss the submission of the MAA for pixantrone to treat aggressive NHL in the EU member states.

OPAXIO

We are developing OPAXIO (paclitaxel poliglumex), which we have previously referred to as XYOTAX, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. While our STELLAR 2, 3 and 4 phase III clinical studies for OPAXIO, completed in the first half of 2005, did not meet their primary endpoints of superior overall survival, we believe that the reduction in toxicities coupled with superior convenience and less supportive care demonstrated in the STELLAR 4 phase III clinical trial merits consideration for approval as single-agent therapy for patients with advanced NSCLC who have poor performance status, or PS2. Currently there are no drugs approved for PS2 NSCLC patients. In March 2008, we submitted an MAA to the EMEA for first-line treatment of patients with advanced NSCLC who are PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our STELLAR clinical trials. The application is based on a positive opinion we received from the EMEA s Scientific Advice Working Party, or SAWP; the EMEA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. The discussions with the SAWP focused on using the STELLAR 4 study as primary evidence of non-inferiority and the STELLAR 3 study as supportive of the MAA. The application was accepted for review in April 2008 and the MAA has now entered the marketing approval review process, which generally takes 15 to 18 months. In July 2009, we announced that we had requested and the EMEA has agreed to an oral explanation in support of the MAA in September 2009, which extends the review for the opinion on approval until the fourth quarter of 2009.

We are also developing OPAXIO for women with pre-menopausal 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 pre-menopausal estrogen levels, represents an unmet medical need. Based on a pooled analysis of 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 was also 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 pre-menopausal estrogen levels, the subset of patients where OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. Although the FDA has established the requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting, we believe that compelling results from PGT307, along with supporting evidence from prior clinical trials, may enable us to submit an NDA in the United States. In early 2008, we limited enrollment on the PGT307 study to sites in the United States only and we will continue to evaluate opportunities to expand to international sites as resources permit.

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We are developing OPAXIO as 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 by early 2012. Based on the number of events in the database, we are requesting an interim analysis be conducted by the GOG in the second half of 2009. If the GOG agrees to this timing and the interim analysis is successful, it could lead to an NDA filing in 2010.

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 trial study, preliminary data suggests that OPAXIO may provide enhanced radiation sensitization as compared to standard therapy. Patient accrual is continuing on this study. We plan to explore with the FDA a potential U.S. phase III registration strategy for OPAXIO in this indication given the high pathologic complete response rates being reported in this study combined with the lower than expected gastrointestinal and other severe toxicities.

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, 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. SM currently uses a genomic-based platform to guide development of brostallicin. We expect to use that platform to guide 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.

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 study that is currently being 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 plans to conduct the final data analysis in 2009. Brostallicin has also demonstrated synergy with new targeted agents as well as established treatments in preclinical trials; consequently, we began a multi-arm combination study with brostallicin and other agents, including Avastin (bevacizumab) which was substantially completed in the fourth quarter of 2008.

Zevalin

In March 2009, we divested our interest in the radiopharmaceutical product Zevalin® (ibritumomab tiuxetan) by selling our 50% interest in the Zevalin joint venture, RIT Oncology, to Spectrum for $16.5 million. Previously, in December 2008, we closed our transaction with Spectrum to form RIT Oncology, to commercialize and develop Zevalin in the United States. We originally acquired the U.S. rights to develop, market and sell Zevalin from Biogen Idec Inc., or Biogen, in December 2007. We received an initial payment of $6.5 million in gross proceeds from Spectrum in March 2009, $750,000 of which was used to pay a consent fee to Biogen, and an additional $6.5 million in gross proceeds in April 2009. The remaining $3.5 million we expected to receive from Spectrum, subject to certain adjustments, was disputed and was ultimately released to Spectrum based on the outcome of an arbitration hearing held in May 2009 as discussed further in Note 10, *Legal Proceedings*. Spectrum was obligated to use a portion of the escrowed amount to pay for certain liabilities incurred by us totaling $3.2 million, including an obligation payable to Bayer for a clinical trial. In addition, as part of the divestiture transaction, we agreed to forego the right to receive up to $15 million in product sales milestone payments in connection with the original transaction establishing the joint venture.

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Research and Preclinical Development

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 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.

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 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. We believe the following accounting estimates are the most critical to us, in that they are important to the portrayal of our condensed consolidated financial statements and require our most difficult, subjective or complex judgments in the preparation of our condensed consolidated financial statements.

License and Contract Revenue

We may generate revenue from technology licenses, collaborative research and development arrangements, cost reimbursement contracts and research grants. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

Revenue associated with up-front license fees and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. If the time period is not defined in the agreement, we calculate the revenue recognition period based on our current estimate of the research and development period considering experience with similar projects, level of effort and the stage of development. Should there be a change in our estimate of the research and development period, we will revise the term over which the initial payment is recognized. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables.* For multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

Impairment of Long-lived Assets

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values.

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Valuation of Goodwill

In accordance with Statement of Financial Accounting Standards, or SFAS, No. 142*, Goodwill and Other Intangible Assets*, we review goodwill for impairment annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Goodwill is tested for impairment by comparing the fair value of our single reporting unit to its carrying value. Our estimate of fair value is based on our current market capitalization. If the implied fair value of goodwill is less than its carrying value, an impairment charge would be recorded.

Derivatives Embedded in Certain Debt Securities

We evaluate financial instruments for freestanding or embedded derivatives in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the statement of operations in the period of change.

Except for our 5.75% and 7.5% convertible senior notes, all of our convertible senior notes include a feature that calls for make-whole payments upon any conversion of these notes. Our 7.5% convertible senior notes include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. These make-whole features along with the conversion options on the notes represent embedded derivatives that must be accounted for separately from the related debt securities except where our convertible senior notes are recorded entirely at fair value pursuant to the guidance in EITF 96-19, *Debtor s Accounting for a Modification or Exchange of Debt Instruments*. The fair value of the derivative for our 6.75% convertible senior notes is calculated based on a discounted cash flow model. The fair value of the derivatives related to all other convertible senior notes is calculated using a Monte Carlo simulation model that incorporates factors such as the current price of our common stock, its volatility and estimated time to expiration of the make-whole feature.

Changes in the estimated fair value of the derivative liabilities related to the convertible senior notes are included in *gain on derivative liabilities, net* and will be remeasured at the end of each reporting period until the relevant feature expires or all of the relevant notes are converted or repurchased.

Restructuring Charges

We have recorded charges in connection with restructuring activities in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The recognition of restructuring charges requires management to make certain judgments regarding the nature, timing and amount associated with the planned restructuring activities. At the end of each reporting period, we evaluate the appropriateness of the remaining accrued balances.

Stock-Based Compensation Expense

On January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment (Revised 2004)*, or SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006.

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available in U.S. Treasury securities at maturity with an equivalent term. We have not declared or paid any dividends and do not currently expect to do so in the future. The expected term of options represents the period that our stock-based awards are expected to be outstanding and was determined based on historical weighted average holding periods and projected holding periods for the remaining unexercised shares. Consideration was given to the contractual terms of our stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatility is based on the annualized daily historical volatility, including consideration of the implied volatility and market prices of traded options for comparable entities within our industry.

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Our stock price volatility and option lives involve management s best estimates, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. SFAS 123(R) also requires that we recognize compensation expense for only the portion of options expected to vest. Therefore, we applied an estimated forfeiture rate that we derived from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, additional adjustments to compensation expense may be required in future periods.

RESULTS OF OPERATIONS

Three months ended June 30, 2009 and 2008

Product sales. Product sales for the three months ended June 30, 2008 relate to sales of Zevalin, our former commercial product acquired from Biogen in December 2007. We divested Zevalin to our 50% owned joint venture, RIT Oncology, in December 2008 and subsequently sold our 50% interest to Spectrum in March 2009.

License and contract revenue. License and contract revenue for the three months ended June 30, 2009 and 2008 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

Cost of product sold. Cost of product sold for the three months ended June 30, 2008 relates to sales of Zevalin and consists primarily of contractual royalties on product sales in addition to cost of product sold to customers. We divested Zevalin to our 50% owned joint venture, RIT Oncology, in December 2008 and subsequently sold our 50% interest to Spectrum in March 2009.

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

	Three Months Ended June 30,	
	2009	2008
Compounds under development:		
Pixantrone	$ 2,345	$ 3,765
OPAXIO	937	1,616
Brostallicin	443	1,784
Zevalin	49	1,001
Operating expenses	3,466	7,177
Discovery research	80	514
Total research and development expenses	$ 7,320	$ 15,857

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, EMEA 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 $52.0 million, $219.5 million and $8.9 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 $7.3 million for the three months ended June 30, 2009, from approximately $15.9 million for the three months ended June 30, 2008. Pixantrone costs decreased primarily due to a decrease in clinical development activity mainly related to the discontinuance of patient

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enrollment during 2008 in our RAPID and EXTEND trials. In early 2008, we closed enrollment on the RAPID trial based on adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. Additionally, we closed enrollment on the EXTEND trial during 2008 as we believed that the current accrual rate would not contribute substantially to the trial s chance of success. In addition, manufacturing activity for pixantrone also decreased. These decreases were partially offset by an increase in regulatory activities primarily related to the filing fee for the NDA submission to the FDA. Costs for our OPAXIO program decreased primarily due to a decrease in manufacturing, quality and regulatory 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 primarily 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. The decrease related to the divestiture of the Zevalin product was partially offset by a change in estimate of our costs associated with clinical studies prior to the divestiture of Zevalin. Our operating expenses decreased primarily due to a reduction in personnel and overhead costs associated with the closure of our Bresso, Italy facility as well as external consulting costs. Discovery research also decreased due to the planned closing of our Bresso, Italy operations as we shift focus to other products closer to commercialization.

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 EMEA, regulate many aspects of a product candidate s life cycle, including research and development and preclinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the availability and proximity of patients with the relevant condition. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. We have drug candidates that are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates.

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

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses decreased to approximately $10.6 million for the three months ended June 30, 2009, from approximately $11.5 million for the three months ended June 30, 2008. This is primarily due to a $1.5 million decrease in sales and marketing expenses due to the divestiture of Zevalin to RIT Oncology in December 2008 and the subsequent sale of our investment in RIT Oncology in March 2009. Our Zevalin sales force, including related selling and marketing expenses were transferred to RIT Oncology in connection with the divestiture. This reduction was offset in part by approximately $0.6 million in additional general and administrative expenses primarily due to an increase in compensation and benefits and legal fees for patents.

Amortization of purchased intangibles. Amortization of purchased intangibles for the three months ended June 30, 2008 was due to amortization of our workforce intangible related to our Italian operations, which became fully amortized during 2008, and amortization of intangible assets acquired in connection with our acquisition of Zevalin in December 2007, which were contributed to RIT Oncology in December 2008.

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Restructuring charges. Restructuring charges of $3.8 million for the three months ended June 30, 2009 relate to activities associated with the closure of our Bresso, Italy operations, including approximately $2.4 million in employee termination benefits and approximately $1.4 million in contract termination and clean-up charges related to the Bresso facilities.

Investment and other income. Investment and other income for the three months ended June 30, 2009 decreased to approximately $37,000 as compared to $93,000 for the three months ended June 30, 2008 primarily due to a lower average securities available-for-sale balance.

Interest expense. Interest expense decreased to approximately $1.6 million for the three months ended June 30, 2009 from approximately $2.4 million for the three months ended June 30, 2008. This was primarily due to a decrease of approximately $0.6 million related to our 13.5% and 15% convertible senior notes, or 13.5% and 15% notes, which were issued in April and June 2008, respectively, and were entirely converted or exchanged by the end of 2008. There was also a decrease of approximately $0.1 million in interest expense on our 5.75% convertible subordinated and senior subordinated notes due to their maturity in June 2008 as well as a decrease of approximately $0.1 million related to our 9% convertible senior notes, or 9% notes, primarily due to the conversion of $17.3 million and $5.3 million principal amount of these notes into common stock in the second quarter of 2008 and the first quarter of 2009.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs decreased to approximately $0.5 million for the three months ended June 30, 2009 from approximately $30.2 million for the three months ended June 30, 2008. This was primarily due to the accelerated amortization of issuance costs and debt discount in 2008 related to conversions of our 13.5% and 9% notes. For the three months ended June 30, 2009 as compared to the same period in 2008, the decrease in the amortization of the debt discount related to our 13.5% and 9% notes was approximately $23.5 million and $3.8 million, respectively, while the decrease in the amortization of debt issuance costs was approximately $1.7 million and $0.6 million, respectively.

Foreign exchange gain (loss). The foreign exchange gain for the three months ended June 30, 2009 and 2008 is due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

Make-whole interest expense. Make-whole interest expense of $25.6 million for the three months ended June 30, 2008 is related to $22.4 million in payments made upon the conversion of $27.6 million of our 13.5% notes and $3.2 million in payments made or accrued upon the conversion of $12.0 million of our 9% notes.

Gain on derivative liabilities, net. The gain on derivative liabilities of $1.6 million for the three months ended June 30, 2009 is primarily related 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 the issuance of our 13.5% convertible senior notes and Series E preferred stock financing in April 2008. The Series B Unit Warrant expired in the second quarter of 2009. The gain of $31.4 million for the three months ended June 30, 2008 is primarily due to a gain of $22.3 million resulting from the change in the estimated fair value of the derivative liability related to the embedded conversion option on our 13.5% notes as well as a gain of $9.2 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant.

Gain (loss) on exchange of convertible notes. The $7.2 million gain on exchange of convertible notes for the three months ended June 30, 2009 is due the exchange of $52.9 million principal amount of our convertible notes for $7.1 million in cash and approximately 24.2 million shares of common stock, net of related transaction costs. The $3.3 million loss on exchange of convertible notes for the three months ended June 30, 2008 is due to the exchange of $5.3 million of our 9% notes for our 13.5% notes, Series E preferred stock and related warrants issued in April 2008.

Settlement expense. Settlement expense of $3.2 million for the three months ended June 30, 2009 relates to the settlement of the final installment payment for the sale of our 50% interest in RIT Oncology based on the outcome

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of arbitration proceedings. This amount includes the $3.5 million escrow amount released to Spectrum, our $0.8 million payment to Spectrum 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.

Write-off of financing arrangement costs. The write-off of financing arrangement costs of $2.4 million for the three months ended June 30, 2008 is attributed to a write-off of offering costs associated with the Step-Up Equity Financing Agreement with Société Générale, including costs related to the Italian Listing Prospectus that was published in January 2008 as an Italian regulatory requirement to issue shares under this agreement. The write-off was primarily due to significant uncertainty regarding our ability to pursue further financings under the agreement which terminated in January 2009.

Six months ended June 30, 2009 and 2008

Product sales. Product sales for the six months ended June 30, 2008 relate to sales of Zevalin.

License and contract revenue. License and contract revenue for the six months ended June 30, 2009 and 2008 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

Cost of product sold. Cost of product sold for the six months ended June 30, 2008 relates to sales Zevalin and consists primarily of contractual royalties on product sales in addition to cost of product sold to customers.

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

	Six Months Ended June 30,	
	2009	**2008**
Compounds under development:		
Pixantrone	$ 3,285	$ 6,133
OPAXIO	2,244	3,258
Brostallicin	794	3,089
Zevalin	987	2,175
Operating expenses	7,655	15,781
Discovery research	311	1,276
Total research and development expenses	$ 15,276	$ 31,712

Research and development expenses decreased to approximately $15.3 million for the six months ended June 30, 2009, from approximately $31.7 million for the six months ended June 30, 2008. Pixantrone costs decreased primarily due to a decrease in clinical development activity mainly related to the discontinuance of patient enrollment during 2008 in our RAPID and EXTEND trials. In early 2008, we closed enrollment on the RAPID trial based on adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. Additionally, we closed enrollment on the EXTEND trial during 2008 as we believed that the current accrual rate would not contribute substantially to the trial s chance of success. In addition, manufacturing activity for pixantrone decreased during the period. These decreases were partially offset by an increase in regulatory activities primarily related to the filing fee for the NDA submission to the FDA. Costs for our OPAXIO program decreased primarily due to a decrease in regulatory and quality activities as well as investigator-sponsored trial costs mainly due to patient enrollment. These decreases were partially offset by an increase in clinical development activity related to our PGT307 trial, which was partially offset by a decrease in the GOG0212 study related a reduction in patient enrollment between periods. Costs for brostallicin decreased primarily due to a decrease in clinical development activities related to phase I and phase II studies. Zevalin costs decreased primarily 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. The decrease related to the divestiture of the Zevalin product was partially offset by a change in estimate of our costs associated with clinical studies prior to the divestiture of Zevalin. Our operating expenses decreased primarily due to a reduction in personnel and overhead costs associated with the closure of our Bresso, Italy facility as well as external consulting costs. Discovery research also decreased due to the planned closing of the Bresso, Italy operations as we shift focus to other products closer to commercialization.

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Selling, general and administrative expenses. Selling, general and administrative expenses decreased to approximately $19.3 million for the six months ended June 30, 2009, from approximately $22.7 million for the six months ended June 30, 2008. This is primarily due to a $2.8 million decrease in sales and marketing expenses related to the divestiture of Zevalin to RIT Oncology in December 2008 and the subsequent sale of our investment in RIT Oncology in March 2009. In addition, our compensation and benefits decreased for our general and administrative activities primarily due to a reduced headcount.

Amortization of purchased intangibles. Amortization of purchased intangibles for the six months ended June 30, 2008 was due to amortization of our workforce intangible related to our Italian operations and amortization of intangible assets acquired in connection with our acquisition of Zevalin.

Restructuring charges. Restructuring charges of $3.9 million for the six months ended June 30, 2009 primarily relate to activities associated with the closure of our Bresso, Italy operations, including approximately $2.4 million in employee termination benefits and approximately $1.4 million in contract termination and clean-up charges related to the Bresso facilities. We also incurred approximately $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 six months ended June 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.

Investment and other income. Investment and other income for the six months ended June 30, 2009 decreased to approximately $71,000 as compared to $353,000 for the six months ended June 30, 2008 primarily due to a lower average securities available-for-sale balance.

Interest expense. Interest expense decreased to approximately $3.2 million for the six months ended June 30, 2009 from approximately $4.4 million for the six months ended June 30, 2008. This was primarily due to a decrease of approximately $0.6 million related to our 13.5% and 15% notes which were issued in April and June 2008 and were entirely converted or exchanged by the end of 2008. There was also a decrease of approximately $0.3 million in interest expense on our 5.75% convertible subordinated and senior subordinated notes due to their maturity in June 2008 as well as a decrease of approximately $0.1 million related to our 9% notes primarily due to the conversion of $17.3 million and $5.3 million principal amount of these notes into common stock in the second quarter of 2008 and the first quarter of 2009. During the six months ended June 30, 2009, we also reversed approximately $0.1 million in interest expense accrued at December 31, 2008 for our 10% convertible senior notes due 2011, or 10% notes, as the remaining outstanding principal balance of these notes was converted into common stock during the first quarter of 2009.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs decreased to approximately $5.3 million for the six months ended June 30, 2009 from approximately $41.1 million for the six months ended June 30, 2008. This was primarily due to the accelerated amortization of issuance costs and debt discount in 2008 related to conversions of our 13.5% and 9% notes. For the six months ended June 30, 2009 as compared to the same period in 2008, the decrease in the amortization of the debt discount related to our 13.5% and 9% notes was approximately $23.5 million and $11.6 million, respectively, while the decrease in the amortization of debt issuance costs was approximately $1.7 million and $1.7 million, respectively. This was offset by an increase of $2.8 million in accelerated amortization of issuance costs and debt discount related to the conversion of our 10% notes during the first quarter of 2009.

Foreign exchange gain (loss). The foreign exchange gain or loss for the six months ended June 30, 2009 and 2008 is due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

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Make-whole interest expense. Make-whole interest expense of $6.3 million for the six months ended June 30, 2009 is related to $5.4 million in payments made upon the conversion of $18.0 million of our 10% notes and $0.9 million in payments made upon the conversion of $5.3 million of our 9% notes. The amount of $33.4 million for the six months ended June 30, 2008 is related to $22.4 million in payments made upon the conversion of $27.6 million of our 13.5% notes and $11.0 million in payments made or accrued upon the conversion of $40.9 million of our 9% notes.

Gain on derivative liabilities, net. The gain on derivative liabilities of $7.2 million for the six months ended June 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% 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. The gain of $43.2 million for the six months ended June 30, 2008 is primarily due to gains resulting from the change in the estimated fair value of the derivative liabilities related to the embedded conversion options on our 13.5% and 9% notes of $22.3 million and $11.8 million, respectively, as well as a gain of $9.2 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant.

Gain (loss) on exchange of convertible notes. The $7.2 million gain on exchange of convertible notes for the six months ended June 30, 2009 is due the exchange of $52.9 million principal amount of our convertible notes for $7.1 million in cash and approximately 24.2 million shares of common stock, net of related transaction costs. The loss on exchange of convertible notes of $5.6 million for the six months ended June 30, 2008 consists of a $3.3 million loss due to the exchange of $5.3 million of our 9% notes for units of our 13.5% notes, Series E preferred stock and related warrants issued in April 2008 and a loss of $2.3 million due to the extinguishment of approximately $9.1 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately 6.8 million shares of our common stock.

Equity loss from investment in joint venture. The loss of $1.2 million for the six months ended June 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.

Settlement expense. Settlement expense of $3.4 million for the six months ended June 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 $0.2 million in settlement expense related to payments made to RHP Master Fund, Ltd, or RHP, for the release of all claims against us in connection with our alleged breach of contract related to RHP s Series A preferred stock.

Write-off of financing arrangement costs. The write-off of financing arrangement costs of $2.4 million for the six months ended June 30, 2008 is attributed to a write-off of offering costs associated with the Step-Up Equity Financing Agreement with Société Générale, including costs related to the Italian Listing Prospectus that was published in January 2008 as an Italian regulatory requirement to issue shares under this agreement. The write-off was primarily due to significant uncertainty regarding our ability to pursue further financings under the agreement which terminated in January 2009.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2009, we had approximately $12.0 million in cash and cash equivalents. In addition, we received proceeds of approximately $41.7 million, net of underwriting discounts and commissions, in connection with the issuance of approximately 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock in July 2009.

Net cash used in operating activities increased to approximately $50.7 million during the six months ended June 30, 2009, compared to approximately $47.8 million for the same period during 2008 primarily due to cash paid for settlement expense in 2009 and a decrease in cash received from sales of Zevalin offset by a decrease in cash paid for interest. In addition, our selling, *general and administrative* and *research and development expenses* decreased, however this was substantially offset by an increase in cash used to decrease in our *accounts payable* and *accrued expenses* for the six months ended June 30, 2009 as compared to an increase in these liability amounts during the comparable period in 2008.

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Net cash provided by investing activities of approximately $22.2 million for the six months ended June 30, 2009 was primarily due to $6.8 million in net proceeds from Spectrum in January 2009 related to the initial formation of RIT Oncology in December 2008 and $15.1 million in net proceeds from Spectrum related to the sale of our 50% interest in RIT Oncology in 2009. Net cash used in investing activities of approximately $6.4 million for the six months ended June 30, 2008 was due to purchases of securities available-for-sale, purchases of property and equipment and cash paid for acquisition costs related to our purchase of Zevalin in December 2007 offset by proceeds from sales and maturities of securities available-for-sale.

Net cash provided by financing activities of approximately $30.7 million for the six months ended June 30, 2009 was primarily due to $19.0 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 May 2009. We also received $18.8 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. These proceeds were offset by $7.6 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. Net cash provided by financing activities of approximately $40.9 million for the six months ended June 30, 2008 was primarily due to the issuance of our 9% notes, our 13.5% notes and Series E preferred stock and our 15% notes. Proceeds from our 9% notes were approximately $35.4 million, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. We also made a deemed dividend payment of approximately $16.2 million to induce existing holders of our Series A, B, C and D convertible preferred stock to convert their shares of preferred stock into common stock in connection with this issuance. Proceeds from the issuance of our 13.5% notes and Series E preferred stock were approximately $19.8 million, net of issuance costs, restricted cash placed in escrow to fund make-whole payments and the cancellation of $5.3 million of our 9% notes and related warrants. Upon cancellation of these notes and warrants, $1.4 million was released to us from the amount placed in escrow to fund make-whole payments. We also received proceeds of approximately $11.5 million from the issuance of our 15% notes, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. Cash received from these financings were offset by the repayment of the outstanding $10.7 million principal balance on our 5.75% convertible subordinated and senior subordinated notes upon their maturity in June 2008.

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, unless we execute a partnership agreement for pixantrone with terms adequate to cover our operating expenses, we expect to generate losses from operations through at least 2009 primarily due to research and development costs for pixantrone, OPAXIO and brostallicin. We estimate our average cash burn rate for the remainder of 2009 to be between $5.5 million and $6.5 million per month and we expect that our existing cash and cash equivalents, securities available-for-sale and interest receivable including proceeds from our offerings to date is not sufficient to fund our presently anticipated operations beyond January 2010. Accordingly, we have implemented cost savings initiatives to reduce operating expenses, including the reduction of employees related to Zevalin operations and the closure of our operations in Italy and we continue to seek additional areas for cost reductions. However, we must also 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. 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 and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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

- results of our clinical trials;
- 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. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, or may adversely affect our ability to operate as a going concern. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result.

The following table includes information relating to our contractual obligations as of June 30, 2009 (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**1 Year**	**2-3 Years**	**4-5 Years**	**After 5 Years**
7.5% Convertible senior notes (1)	$ 10,250	$	$ 10,250	$	$
6.75% Convertible senior notes (2)	1,500		1,500		
5.75% Convertible senior notes (3)	10,913		10,913		
4.0% Convertible senior subordinated notes (4)	43,363		43,363		
Interest on convertible notes	4,823	3,232	1,591		
Operating leases:					
Facilities	13,306	4,705	8,256	345	
Long-term obligations (5)	2,745	1,205	1,461	79	
	$ 86,900	$ 9,142	$ 77,334	$ 424	$

(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 6.75% convertible senior notes are convertible into shares of our common stock at a conversion rate of 9.50925 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $105.16 per share.
(3) 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.
(4) The 4.0% convertible senior subordinated notes are convertible into shares of our common stock at a conversion rate of 1.85185 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $540.00 per share.
(5) Long-term obligations does not include $1.0 million related to excess facilities charges.

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Additional Milestone Activities

We have an amended agreement with PG-TXL Company L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL s polymer technology. Pursuant to this agreement we were required to pay a $0.5 million milestone payment that became due upon the acceptance of our MAA for review by the EMEA in March 2008. We may also be required to pay up to $14.4 million in additional milestone payments under this agreement including a $5.0 million payment upon approval of the MAA filing by the EMEA, which may occur in the second half of 2009. The timing of the remaining milestone payments under the amended agreement is based on trial commencements and completions and regulatory and marketing approval with the FDA and EMEA.

We have an agreement with the Gynecologic Oncology Group, or GOG, related to the GOG0212 trial which the GOG is conducting. Under this agreement we are required to pay up to $6.1 million in additional milestone payments related to the trial. Included in this amount is a $1.0 million milestone payment that became due in the fourth quarter of 2008 based on patient enrollment which remains outstanding as of August 3, 2009. We also estimate that an additional milestone payment of $1.6 million may become due in the fourth quarter of 2009 based on patient enrollment.

Under a license agreement entered into 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.

In connection with our acquisition of Systems Medicine, Inc., we may be required to pay its stockholders a maximum of $15.0 million in additional consideration (payable in cash or stock at our election, subject to certain NASDAQ limitations on the issuance of stock) upon the achievement of certain FDA regulatory milestones for brostallicin.

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.

Under our agreement with Novartis Pharmaceutical Company Ltd., or Novartis, if Novartis elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option to develop and commercialize pixantrone and we are able to negotiate a definitive agreement with Novartis, we may receive up to $374.0 million in registration and sales related milestone payments. Novartis is under no obligation to make such election or exercise such right and may never do so. Additionally, even if Novartis exercises such rights, any milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals, which we may never receive.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Market Risk

We are exposed to market risk related to changes in interest rates that could adversely affect the value of our investments. We have maintained a short-term investment portfolio consisting of interest bearing securities with an average maturity of less than one year. These securities are classified as available-for-sale . These securities are interest bearing and thus subject to interest rate risk and will fall in value if market interest rates increase. Since we generally hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected significantly by a sudden change in market interest rates related to our securities portfolio. The fair value of our securities available-for-sale at December 31, 2008 was $0.6 million and for each one percent change in interest rates, the change in the fair value of our securities available-for-sale outstanding as of this date would have been immaterial. We had no securities available-for-sale outstanding as of June 30, 2009.

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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. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Although our reporting currency is the U.S. dollar, a portion of our consolidated costs arise in euros, which we translate into U.S. dollars for purposes of financial reporting, based on exchange rates prevailing during the applicable reporting period. 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. Accordingly, changes in the value of the U.S. dollar relative to the euro might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might harm our reported results and accounts from period to period.

We have foreign exchange risk related to foreign-denominated cash and cash equivalents and interest receivable, or foreign funds. As of June 30, 2009, the balance of our foreign funds is immaterial and, consequently, any negative currency exchange movement would have an immaterial effect on the fair value of these funds.

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 Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. 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 report, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

During the second half of 2008, we began the implementation of Oracle EBS for financial reporting which was completed as of January 1, 2009. While we expect future changes and enhancements in our internal controls as a result of the new system, for the six months ended June 30, 2009, there were no significant changes in our internal controls as a result of the implementation.

Except as described above, there have been no changes to our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Other Financial Information

With respect to the unaudited condensed consolidated financial statements of Cell Therapeutics, Inc. for the six-month period ended June 30, 2008, included herein, Stonefield Josephson, Inc. (Stonefield Josephson) reported that they have applied limited procedures in accordance with professional standards for a review of such information. However, their report dated August 18, 2008 appearing below, states that they did not audit and they do not express an opinion on that unaudited financial information. Stonefield Josephson has not carried out any significant or additional audit tests beyond those which would have been necessary if their report had not been included. Accordingly, the degree of reliance on their report on such information should be restricted in light of the limited nature of the review procedures applied. Stonefield Josephson is not subject to the liability provisions of Section 11 of the Securities Act of 1933 (the Act) for their report on the unaudited condensed consolidated financial statements because that report is not a report or a part of a registration statement prepared or certified by Stonefield Josephson within the meaning of Sections 7 and 11 of the Act.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of Cell Therapeutics, Inc. as of June 30, 2009, and the related condensed consolidated statements of operations and cash flows for the six months ended June 30, 2009. These interim financial statements are the responsibility of the Company s management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with generally accepted auditing standards, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the accompanying financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the condensed consolidated financial statements, the Company has had losses since inception and expects to generate losses from operations for at least the next year, primarily due to research and development costs. Additionally, the Company will not have sufficient cash to fund planned operations for the next twelve months, which raises substantial doubt about the Company s ability to continue as a going concern. Management s plans concerning these matters are described in Note 1. These condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event the Company cannot continue in existence.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2008 and the related consolidated statements of operations, shareholders deficit, and cash flows for the year then ended (not presented herein); and in our reports dated March 16, 2009, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2008, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Stonefield Josephson, Inc.
Stonefield Josephson, Inc.
Los Angeles, California
August 6, 2009

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Recent Legal Proceedings

On January 2, 2008, Tang Capital Partners LP, or Tang, filed a civil action in the United States District Court for the Southern District of New York in which Tang alleged that we breached a Securities Purchase Agreement, executed on or about April 16, 2007 in connection with the issuance of our Series B convertible preferred stock, or Series B preferred stock. On January 3, 2009, we entered into a settlement agreement with Tang with respect to the civil action filed by Tang on January 2, 2008. In exchange for the full release of all claims arising directly or indirectly out of or related to Tang s purchase, acquisition, ownership, interest in or rights under our Series B 3% preferred stock, we agreed to pay Tang $5.1 million. Final payment was completed on January 29, 2009. A holder of our Series C convertible preferred stock, Enable Capital Management LLC, or Enable, filed a lawsuit on January 23, 2008 in the Supreme Court of the State of New York with similar claims to the Tang action. On September 29, 2008, Enable entered into a release agreement with us to fully resolve this action. On May 5, 2008, RHP Master Fund, Ltd., or RHP, a holder of our Series A convertible preferred stock filed suit in the United States District Court for the Southern District of New York alleging breach of contract and violation of Washington Business Corporation Act, and breach of fiduciary duty by certain officer and director defendants. On February 4, 2009, for $0.1 million and 4.0 million shares of our common stock, we settled all claims that were filed or could have been filed by RHP.

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. 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. On February 28, 2007, defendant The Lash Group, Inc. removed the case to federal 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 is scheduled for September 3, 2009. If successful on appeal, we intend to return to the United States District Court for trial. There is no guarantee that we will prevail in the appeal or at trial.

On February 20, 2009, we notified Spectrum that we had exercised our option to sell to Spectrum all of our membership interest in their 50/50 owned joint venture, RIT Oncology, and on March 2, 2009, Spectrum made the first payment totaling $6.5 million. The sale of our membership interest to Spectrum closed on March 15, 2009, and the remaining $10.0 million of the total $16.5 million purchase price was deposited into an escrow account to be paid to us in two additional installments. On April 3, 2009, $6.5 million was released to us from this escrow account and the final installment of $3.5 million, subject to an adjustment for certain operational liabilities and other obligations, was scheduled to be released to us on April 15, 2009. This final installment payment was not released to us because we and Spectrum disputed the amount of the adjustment. On April 10, 2009, we filed a demand for arbitration regarding Spectrum s payment of the final installment. On April 22, 2009, Spectrum filed a cross-claim alleging that Spectrum was entitled to the entire amount held in escrow and that Spectrum was owed additional amounts by us. The arbitration hearing was held on May 14, 2009. On May 21, 2009, the arbitrator ordered that the final installment of $3.5 million be released from the escrow account and distributed to Spectrum; additionally, we were ordered to pay $0.8 million to Spectrum. Of these amounts, $3.2 million was determined by the arbitrator to be outstanding Excluded Liabilities under the Limited Liability Company Interest Assignment Agreement entered into between Spectrum and CTI, dated March 15, 2009, of which $2.0 million was included in our *accounts payable* balance as of the settlement date. Accordingly, Spectrum is responsible for paying certain liabilities incurred or to be incurred by us totaling $3.2 million, including an obligation payable to Bayer for a clinical trial. The arbitrator s award to Spectrum also included $2.1 million related to expenses incurred by RIT Oncology. On May 26, 2009, we paid Spectrum $0.8 million.

In April 2007, we entered into a settlement agreement with the United States Attorney s Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX® (arsenic trioxide). We made the settlement payment of $10.6 million in April 2007. The

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settlement agreement did not address separate claims brought against us by the private party plaintiff for his attorneys fees and expenses. After further litigation concerning attorneys fees and expenses, on January 28, 2009 all remaining claims were settled for approximately $0.5 million, and in consequence, the case has been fully and finally resolved.

On May 1, 2008 i3, a contract research organization, sent a letter claiming we owed i3 $2.2 million pursuant to clinical support work. All of these charges have been previously invoiced to us, but the invoices are being evaluated for the association of the work being billed to the contract assignments, as well as the relationship of the pass-through costs to approvable work. On November 6, 2008, i3 filed a demand for arbitration of this dispute with the American Arbitration Association, seeking damages of $2.2 million. That arbitration is pending. While it is probable that some money will be owed to i3, it is not possible at this time to estimate the amount, however we previously recorded $0.2 million related to the invoiced i3 services which is included in the Company s accounts payable balance as of June 30, 2009.

On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan court 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. 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 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. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to 5,000 to 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 to the alleged violations, which we expect to submit to CONSOB within 30 days from the notification of the relevant charges (i.e., within 30 days after July 31, 2009).

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. We currently have one arbitration action, but no pending court litigation against us.

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Quarterly Report on Form 10-Q. If any of the following risks actually occur, they 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 June 30, 2009 we had cash and cash equivalents of approximately $12.0 million, which does not take into account proceeds of $41.7 million, net of underwriting discounts and commissions, received in connection with the issuance of approximately 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock in July 2009.

As of June 30, 2009, our total current liabilities were approximately $29.9 million and we also had a substantial amount of debt outstanding. The aggregate principal balance of our outstanding various series of convertible notes as of June 30, 2009 was approximately $66.0 million with interest rates ranging from 4% to 7.5%.

We expect that our existing cash and cash equivalents, securities available-for-sale, interest receivable as well as proceeds received from our offerings to date will not provide sufficient working capital to fund our presently anticipated operations beyond January 2010 and we therefore need to raise additional capital. There can be no assurance that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations, including our debt service obligations.

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Additional funds may not be available on acceptable terms, or at all; if we fail to raise significant additional funds, we may be forced to cease development of our products and operations.

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. However, additional funding may not be available on favorable terms or at all and we are subject to certain regulatory and contractual limitations on our financing activities, which may limit our ability to raise 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.

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, such as our transfer of Zevalin assets to RIT Oncology and our subsequent sale of our 50% interest in RIT Oncology.

In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the United States, which may increase our costs and adversely affect our ability to obtain financing. To the extent that we raise additional capital through the sale of equity securities, or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us.

We may 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 may 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, would 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, or otherwise modify our business strategy, which could materially harm our future business prospects.

We are currently in the process of closing down our Italian operations that were used primarily for pre-clinical research and were underutilized due to our current focused business model on the development of late-stage compounds and their commercialization. In May 2009, we entered into a severance agreement with the unions representing the employees of our Italian operations related to a reduction of 56 positions. In addition, we have sent notices of termination to the six managers of the Bresso facility and are negotiating separate severance agreements with these managers. We expect to save approximately $14 million in annual operating expenses due to the closure of our Italian operations which we expect to complete by October 2009.

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 June 30, 2009, we had an accumulated deficit of approximately $1.4 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, expenses 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.

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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 will not be able to pay all of our operating expenses or repay our debt or the interest, liquidated damages or other payments that may become due with respect to our debt.

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 common stock upon exercise of the warrants offered in this offering, 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.

Due to our 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, 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.

Our common stock is listed on The NASDAQ Capital Market and the MTA stock market in Milan, Italy 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 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 the NASDAQ Marketplace Rules. On January 23, 2009, we received an Additional Staff Determination Letter, or the Determination Letter, from The NASDAQ Stock Market, or NASDAQ, that stated the NASDAQ staff had concluded that we had violated Marketplace Rule 4350(i)(1)(C) (now 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 Stock Market.

While our stock price was $1.50 on August 3, 2009, as recently as May 2009, our stock price was below $1.00. NASDAQ reinstated the $1.00 minimum bid price requirement on August 3, 2009 and our stock price has been above $1.00 since the minimum bid price was reinstated. However, there can be no assurances that our stock price will continue to be above $1.00. At our Special Meeting of Shareholders held on March 24, 2009, the proposal to allow the Board, in its discretion, to effect a reverse stock split of our common stock was not approved by the shareholders. In the event that our stock price is below $1.00, we may not be able to effect a reverse stock split to increase our stock price if we are unable to obtain shareholder approval of a reverse stock split in the future.

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In the event our common stock is delisted from the NASDAQ markets, 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 markets 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 determines 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 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, CONSOB and NASDAQ lifted the trading halt on our stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA stock market 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 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 Stock Market, the MTA, or both for any reason or if trading in our stock is halted or suspended on The NASDAQ Stock Market, the MTA or both, such events may harm our stock price, increase the volatility of our stock price 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 Stock Market or if trading in our stock is halted or suspended on The NASDAQ Stock Market, we may become subject to certain obligations. In addition, if we are not listed on The NASDAQ Stock 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 challenges.

Our common stock is traded on the Italian MTA stock market in Milan, Italy 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 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. After working with CONSOB to meet its requirements to publish that listing prospectus for the remainder of 2007, we were finally able to publish a listing prospectus in January 2008; however, that listing prospectus was limited to shares to be issued to Société Générale under the Step-Up Equity Financing Agreement we entered into with Société Générale in 2006, which has since terminated. After meeting with CONSOB in 2008 to further discuss its requirements for a more general listing prospectus, we filed a new listing prospectus on December 31, 2008, which was rejected by CONSOB on January 16, 2009. On January 28, 2009, we filed a registration document (*i.e.,* one of the three documents that, according to European Regulation No. 809/2004 and together with our related securities note and summary, constitute a listing prospectus, which can be separately filed, examined and eventually approved by CONSOB).

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. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to 5,000 to 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 to the alleged violations, which we expect to submit to CONSOB within 30 days from the notification of the relevant charges (i.e., within 30 days after July 31, 2009).

On July 2, 2009, after several requests of supplements, clarifications and submissions of new drafts of our registration document, CONSOB informed us that the relevant administrative procedure for CONSOB s authorization to publish the registration document had expired since CONSOB alleged that we had not amended the text of the registration document to provide certain information CONSOB had requested. On July 23, 2009, we filed a new draft of the registration document, securities note and summary. Nevertheless, pending the clearance of these documents, which together constitute a complete listing prospectus that will permit us to issue common stock in an amount 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 are required to raise money using alternative forms of securities. For example, we use convertible preferred stock and convertible debt in lieu of common stock because convertible preferred stock and convertible debt, subject to the provisions of European Directive No. 71/2003 and according to the interpretations of the Committee of European Securities Regulators (CESR), are not subject to the 10% limitation imposed by European Union and Italian law.

We are subject to additional legal duties, additional operational challenges and additional political and economic risks related to our operations in Italy.

A portion of our business is currently based in Italy, although we are in the process of shutting down our operations in Italy. However, as long as we continue to have operations in Italy, we are subject to duties and risks arising from doing business in Italy. As long as we continue to have a portion of our business in Italy, we are subject to operational challenges. We may not succeed in addressing these challenges, risks and duties, any of which may be exacerbated by the geographic separation of our operations in the United States and in Italy. These risks related to doing business in Italy could harm our business, financial condition and results of operations.

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Our operations in Italy make us subject to increased risk regarding currency exchange rate fluctuations.

As long as we continue to have operations in Italy, 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 foreign currency transactions might fluctuate, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Our reporting currency will remain as the U.S. dollar; however, so long as we continue to have operations in Italy, a portion of our consolidated financial obligations will arise in euros. In addition, as long as we continue to have operations in Italy, the carrying value of some of our assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Changes in the value of the U.S. dollar as compared to the euro might have an adverse effect on our reported results of operations and financial condition.

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

Our European operations are subject to Value Added Tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately $6.5 million and $6.3 million as of June 30, 2009 and December 31, 2008, respectively. On March 26, 2009, the Italian Tax Authority, or ITA, issued a notice of assessment to CTI (Europe) based on their audit of VAT returns for the year 2003. The ITA audit concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). In addition, the ITA has issued a pre-assessment of VAT filings for the year 2005 noting findings similar to the year 2003. The assessment for the year 2003 is approximately $0.7 million including interest and penalties. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed and we intend to vigorously defend ourselves against the assessment and request a dismissal on procedural grounds and merits of the case. However, if we are unable to defend ourselves against the year 2003 assessment and if we receive an assessment for subsequent years, including the year 2005, 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.

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 International Pharmaceutical Ltd., or 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. 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.

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We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO given that our three STELLAR phase III clinical trials for the treatment of non-small cell lung cancer did not meet their primary endpoints.

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.

Our future financial success depends in part on obtaining regulatory approval of OPAXIO. In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of OPAXIO in non-small cell lung cancer. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC.

In December 2006, we closed the PIONEER clinical trial, and in 2007 we initiated a new study in the United States, PGT307, which focuses on the primary efficacy endpoint of survival in women with NSCLC and pre-menopausal estrogen levels. To conserve limited financial resources, we have decided not to initiate an additional study, the PGT306 trial, for which we have submitted a special protocol assessment, or SPA. We also feel that compelling evidence from one trial, the PGT307 trial, along with supporting evidence from earlier clinical trials, may be adequate to submit an NDA for OPAXIO even though the FDA has established a requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting. We may not receive compelling evidence or any positive results from the PGT307 trial, which would preclude our planned submission of an NDA to the FDA, and would preclude us from marketing OPAXIO for this indication in the United States.

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA for OPAXIO in Europe on March 4, 2008 based on results of the STELLAR trials. In April 2009, the MAA was accepted for review by the EMEA. In July 2009, we announced that we had requested and the EMEA has agreed to an oral explanation in support of the MAA in September 2009, which extends the review for the opinion on approval until the fourth quarter of 2009. However a successful regulatory outcome from the EMEA is not assured as the EMEA s final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the clinical data that was presented in the MAA.

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. In March 2008, we submitted an MAA to the EMEA for OPAXIO. In April 2008, the EMEA accepted the MAA for review and we expect to receive an opinion from the EMEA in the fourth quarter of 2009. In addition, on April 13, 2009, we began submission of a rolling NDA to the FDA for pixantrone to treat relapsed aggressive NHL and completed the submission and requested priority review in June 2009. If priority review status is granted, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA.

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.

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

In addition, both before and after approval, our contract manufacturers and our products are subject to numerous regulatory requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA 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, EMEA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of $10.5 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 markets paclitaxel and generic forms of paclitaxel; Sanofi-Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which

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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 payors continue to attempt to contain healthcare costs by:

challenging the prices charged for health care products and services;

limiting both coverage and the amount of reimbursement for new therapeutic products;

denying or limiting coverage for products that are approved by the FDA 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

denying coverage altogether.

The trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs 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.

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;

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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 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 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. 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

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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 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. As a result of this custody transfer, we were able to hold special meetings of the shareholders in April 2007, January 2008 and March 2009 and annual meetings of the shareholders in September 2007 and June 2008. 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.

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. In addition, brokers may only vote on

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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 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, 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 our total shares of 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 our total shares of 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. Paclitaxel is available and we have purchased it from several sources. 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 U.S. 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. One of our 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 contract and has filed a lawsuit in the Court of Milan to compel us to source pixantrone from that manufacturer.

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If we do not successfully develop our products 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. 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.

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;

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

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.

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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.

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 or results of operations, 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 probably and reasonably estimable.

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Risks Related To the Securities Markets

Our stock price 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 August 3, 2009, our stock price has ranged from a low of $0.05 to a high of $3.80. 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 2009 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, beginning in March 2005, several class action lawsuits were instituted against us and certain of our directors and officers and a derivative action lawsuit was filed against our full board of directors. While these lawsuits were dismissed with prejudice, as a result of these types of lawsuits, we could incur substantial legal fees 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 may face in the future, or that it will be adequate to cover all potential liabilities and damages.

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

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

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

In addition, as a Washington corporation, we are subject to Washington law which imposes restrictions on some transactions between a corporation and certain significant shareholders. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

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

(a) In connection with our offering of our Series 1 convertible preferred stock and warrants to purchase our common stock in April 2009, or the April offering, we issued to Rodman & Renshaw, LLC, or Rodman, a warrant to purchase up to 1,000,000 shares of our common stock at an initial exercise price of $0.45 per share for financial advisory services in connection with the April offering. In addition, in connection with our offering of our common stock and warrants to purchase our common stock in May 2009, or the May offering, we issued to Rodman an additional warrant to purchase up to 320,000 shares of our common stock at an initial exercise price of $1.5625 per share for financial advisory services in connection with the May offering. Each of the warrants issued to Rodman in the April offering and the May offering, were issued pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, or the Securities Act.

In connection with our separate concurrent fixed price exchange offers completed in June 2009 for any and all of the approximately $118.9 million principal amount of five series of our then outstanding convertible notes, holders of approximately $52.9 million principal amount of convertible notes exchanged these notes in the exchange offers for aggregate exchange consideration of approximately $7.1 million in cash and approximately 24.2 million shares of our common stock. The approximately 24.2 million shares of shares of our common stock that we issued to the tendering holders of these convertible notes in connection with the exchange offers were issued pursuant to the exemption from registration provided by Section 3(a)(9) of the Securities Act.

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 Current Report on Form 8-K, filed on June 24, 2008).

3.2 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 September 4, 2008).

3.3 Registrant s Articles of Amendment to Amended and Restated Articles of the Registrant (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on February 9, 2009).

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3.4	Registrant s Amendment to Amended and Restated Articles of Incorporation of the Registrant (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on March 27, 2009).
3.5	Registrant s Amended and Restated Bylaws (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on July 25, 2008).
4.1	Class B Common Stock Purchase Warrant, dated April 13, 2009 (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on April 13, 2009).
4.2	Common Stock Purchase Warrant, dated April 13, 2009.
4.3	Common Stock Purchase Warrant, dated May 11, 2009.
10.1	Exchange Agreement, dated April 7, 2009, between the Registrant and Milfam I L.P. (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 17, 2009).
10.2	Exchange Agreement, dated April 7, 2009, between the Registrant and CD Investment Partners Ltd. (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 17, 2009).
10.3	Securities Purchase Agreement, dated April 13, 2009 (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 13, 2009).
10.4	Securities Purchase Agreement, dated May 11, 2009 (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on May 12, 2009).
10.5	English Translation of Severance Agreement, dated May 13, 2009 (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on May 20, 2009).
15	Letter Regarding Unaudited Interim Financial Information.
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.

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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: August 6, 2009

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

Dated: August 6, 2009

By: /s/ Louis A. Bianco
Louis A. Bianco

Executive Vice President,

Finance and Administration

(Principal Financial Officer,

Chief Accounting Officer)