CELL THERAPEUTICS INC
Form 10-Q
November 07, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended: September 30, 2008

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 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 November 6, 2008**
Common Stock, no par value	58,464,608

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CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,530	$ 15,798
Restricted cash	29,441	
Securities available-for-sale	1,196	2,548
Interest receivable	13	46
Accounts receivable, net	1,590	51
Inventory, net	414	290
Prepaid expenses and other current assets	4,159	3,904
Total current assets	47,343	22,637
Property and equipment, net	4,426	6,025
Goodwill	17,064	17,064
Other intangibles, net	14,638	15,957
Other assets	10,275	11,830
Total assets	$ 93,746	$ 73,513
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 11,144	$ 6,595
Accrued expenses	24,944	26,034
Warrant liability	2,820	
Current portion of deferred revenue	80	80
Current portion of long-term obligations	730	1,020
Current portion of convertible senior subordinated notes		16,907
Current portion of convertible subordinated notes		2,910
Total current liabilities	39,718	53,546
Deferred revenue, less current portion	339	398
Long-term obligations, less current portion	9,203	9,879
18.33% convertible senior notes	15,485	
15.5% convertible senior notes	14,214	
15% convertible senior notes	17,540	
9% convertible senior notes	4,027	
7.5% convertible senior notes	32,505	32,220
6.75% convertible senior notes	6,923	6,922
5.75% convertible senior notes	23,619	23,287
4% convertible senior subordinated notes	55,150	55,150
Total liabilities	218,723	181,402
Commitments and contingencies		
Minority interest in subsidiary		
Preferred stock, no par value:		
Authorized shares - 10,000,000		

Series A 3% Convertible Preferred Stock, $1,000 stated value, 20,000 shares designated; 550 and 6,850 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	417	5,188
Series B 3% Convertible Preferred Stock, $1,000 stated value, 37,200 shares designated; 5,218 and 15,380 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	4,031	11,881
Series C 3% Convertible Preferred Stock, $1,000 stated value, 20,250 shares designated; 4,284 and 8,284 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	3,221	6,229
Series D 7% Convertible Preferred Stock, $1,000 stated value, 6,500 shares designated; 1,000 and 4,000 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	734	2,938
Shareholders deficit:		
Common stock, no par value:		
Authorized shares - 400,000,000		
Issued and outstanding shares - 26,256,426 and 6,244,423 at September 30, 2008 and December 31, 2007, respectively	1,142,573	979,295
Accumulated other comprehensive loss	(4,974)	(4,007)
Accumulated deficit	(1,270,979)	(1,109,413)
Total shareholders deficit	(133,380)	(134,125)
Total liabilities and shareholders deficit	$ 93,746	$ 73,513

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Product sales	$ 2,580	$	$ 8,824	$
License and contract revenue	20	20	60	60
Total revenues	2,600	20	8,884	60
Operating expenses:				
Cost of product sold	692		2,349	
Research and development	11,326	18,566	43,038	50,368
Selling, general and administrative	7,834	8,874	30,526	24,594
Amortization of purchased intangibles	606	219	1,540	638
Acquired in-process research and development		21,343	36	21,343
Total operating expenses	20,458	49,002	77,489	96,943
Loss from operations	(17,858)	(48,982)	(68,605)	(96,883)
Other income (expense):				
Investment and other income, net	146	626	499	2,067
Interest expense	(2,575)	(2,127)	(6,955)	(6,146)
Amortization of debt discount and issuance costs	(11,113)	(336)	(52,259)	(3,911)
Foreign exchange gain	3,070	2,308	909	3,142
Make-whole interest expense	(19,135)		(52,512)	(2,310)
Gain on derivative liabilities, net	12,915	4	56,092	3,618
Loss on exchange of convertible notes	(10,272)		(15,880)	
Write-off of financing arrangement costs			(2,361)	
Settlement expense	(799)		(799)	(160)
Other income (expense), net	(27,763)	475	(73,266)	(3,700)
Loss before minority interest	(45,621)	(48,507)	(141,871)	(100,583)
Minority interest in net loss of subsidiary	32	36	95	36
Net loss	(45,589)	(48,471)	(141,776)	(100,547)
Preferred stock beneficial conversion feature		(3,918)	(1,067)	(8,301)
Preferred stock dividends	(106)	(214)	(574)	(395)
Deemed dividends on conversion of preferred stock	(1,951)		(18,149)	
Net loss attributable to common shareholders	$ (47,646)	$ (52,603)	$ (161,566)	$ (109,243)
Basic and diluted net loss per common share	$ (2.83)	$ (10.91)	$ (13.68)	$ (25.48)
Shares used in calculation of basic and diluted net loss per common share	16,812	4,820	11,807	4,287

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2008	**2007**
Operating activities		
Net loss	$ (141,776)	$ (100,547)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	52,259	3,910
Non-cash gain on derivative liabilities	(56,092)	(3,618)
Acquired in-process research and development	36	21,343
Non-cash loss on exchange of convertible notes	15,880	
Depreciation and amortization	4,417	3,806
Equity-based compensation expense	2,984	954
Minority interest in net loss of subsidiary	(95)	(36)
Other	(72)	(358)
Changes in operating assets and liabilities:		
Restricted cash	52,673	
Interest receivable	33	209
Accounts receivable, net	(1,540)	
Inventory	(123)	
Prepaid expenses and other current assets	(374)	711
Other assets	3,135	(2,183)
Accounts payable	4,585	(974)
Accrued expenses	(471)	(6,358)
Deferred revenue	(60)	(60)
Excess facilities obligations	(357)	(1,843)
Other long-term obligations	(124)	76
Total adjustments	76,694	15,579
Net cash used in operating activities	(65,082)	(84,968)
Investing activities		
Cash paid for acquisition of Zevalin	(542)	
Cash acquired in acquisition of Systems Medicine, Inc., net		675
Purchases of securities available-for-sale	(10,721)	(34,682)
Proceeds from sales of securities available-for-sale	11,047	7,484
Proceeds from maturities of securities available-for-sale	974	37,872
Purchases of property and equipment	(1,252)	(1,066)
Net cash provided by (used in) investing activities	(494)	10,283
Financing activities		
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	56,087	
Restricted cash from issuance of 13.5% convertible senior notes	(36,456)	
Proceeds from issuance of 9% convertible senior notes, net of issuance costs	49,317	

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	21,804	
Restricted cash from issuance of 15% convertible senior notes	(10,350)	
Proceeds from issuance of 18.33% convertible senior notes, net of repurchase of 13.5% convertible senior notes and issuance costs	26,278	
Restricted cash from issuance of 18.33% convertible senior notes	(24,471)	
Release of restricted cash in connection with repurchase of 13.5% convertible senior notes	6,525	
Proceeds from issuance of 10% convertible senior notes, net of issuance costs	8,689	
Restricted cash from issuance of 10% convertible senior notes	(3,600)	
Proceeds from issuance of 15.5% convertible senior notes, net of issuance costs	14,211	
Restricted cash from issuance of 15.5% convertible senior notes	(8,811)	
Deemed dividends on conversion of preferred stock	(18,149)	
Repayment of 5.75% convertible subordinated and senior subordinated notes	(10,724)	
Proceeds from sale of common stock, net of offering costs	5,080	
Transaction costs related to exchange of convertible subordinated and senior subordinated notes	(304)	
Proceeds from issuance of Series A 3% convertible preferred stock and warrants, net		18,608
Proceeds from issuance of Series B 3% convertible preferred stock and warrants, net		34,844
Proceeds from issuance of Series C 3% convertible preferred stock and warrants, net		18,955
Payment of additional offering costs related to December 2007 issuance of common stock and warrants	(473)	
Payment of dividends on preferred stock	(601)	(183)
Repayment of long-term obligations	(341)	(79)
Other	(39)	
Net cash provided by financing activities	61,145	72,145
Effect of exchange rate changes on cash and cash equivalents	(837)	(2,889)
Net decrease in cash and cash equivalents	(5,268)	(5,429)
Cash and cash equivalents at beginning of period	15,798	17,129
Cash and cash equivalents at end of period	$ 10,530	$ 11,700
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 56,510	$ 6,556
Cash paid for taxes	$	$
Supplemental disclosure of noncash financing and investing activities		
Conversion of Series A 3% convertible preferred stock to common stock	$ 4,771	$ 9,959
Conversion of Series B 3% convertible preferred stock to common stock	$ 7,850	$ 16,859
Conversion of Series C 3% convertible preferred stock to common stock	$ 3,008	$ 8,998
Conversion of Series D 7% convertible preferred stock to common stock	$ 2,203	$
Conversion of Series E 13.5% convertible preferred stock to 13.5% convertible senior notes	$ 9,118	$
Conversion of 9% convertible senior notes to common stock	$ 40,820	$
Conversion of 13.5% convertible senior notes to common stock	$ 27,600	$
Conversion of 18.33% convertible senior notes to common stock	$ 28,250	$
Conversion of 10% convertible senior notes to common stock	$ 9,000	$
Conversion of 7.5% convertible senior notes to common stock	$	$ 15,294

Conversion of 5.75% convertible senior notes to common stock	$	250	$	
Issuance of common stock for acquisition of Systems Medicine, Inc.	$		$	19,872
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 Italy. We currently have one approved drug, Zevalin, which we acquired in 2007, generating product sales. All our other product candidates, including OPAXIO, pixantrone and brostallicin, are under development.

Basis of Presentation

The accompanying unaudited financial information of CTI as of September 30, 2008 and for the three and nine months ended September 30, 2008 and 2007 has been prepared in accordance with accounting principles generally accepted in the United States of America 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 the Company s financial position at such date and the operating results and cash flows for such periods. Operating results for the three and nine month periods ended September 30, 2008 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 Securities and Exchange Commission. 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, 2007 included in our Form 10-K.

The consolidated balance sheet at December 31, 2007 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 (see Note 3, *Reverse Stock Split)*. 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 Cell Therapeutics, Inc. and its wholly owned subsidiaries which include CTI Corporate Development, Inc., Systems Medicine LLC, or SM, (from the date of acquisition in July 2007), CTI Commercial LLC (from the date of formation in July 2008) and Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe), which was merged into Cell Therapeutics, Inc. on November 30, 2007 and now operates as a branch of the Company. In addition, CTI Technologies, Inc. was liquidated in the fourth quarter of 2007.

As of September 30, 2008, the Company also has a 69% interest in its majority owned subsidiary, Aequus Biopharma, Inc. Stock ownership by outside and related parties in Aequus Biopharma, Inc. is recorded as *minority interest in subsidiary* and stated net after allocation of losses in the subsidiary.

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All intercompany transactions and balances are eliminated in consolidation.

Liquidity

Our accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve month period following the date of these financials. However, we have incurred losses since inception and we expect to generate losses from operations for at least the next year primarily due to research and development costs for Zevalin, OPAXIO (paclitaxel poliglumex), pixantrone and brostallicin. Our available *cash and cash equivalents, securities available-for-sale* and *interest receivable* are approximately $11.7 million as of September 30, 2008. In addition, in October 2008 we issued $24.7 million of 9.66% convertible senior notes, or 9.66% notes, for net proceeds, before fees and expenses, of $7.5 million after taking into account $7.2 million placed in escrow to fund make-whole payments and interest payments on the notes, our repurchase of $18.2 million of our 15% notes as well as $8.2 million in cash released from escrow related to the repurchased notes. Even with this additional financing, we will not have sufficient cash to fund our planned operations through the end of the fourth quarter, which raises substantial doubt about our ability to continue as a going concern. Accordingly, we have implemented cost saving initiatives to reduce operating expenses 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. There is an additional $44.5 million in aggregate exercise price under the B unit warrant as discussed in Note 5*, Series B Unit Purchase Warrant*. However, no exercise of that additional aggregate exercise amount may be made unless and until both the purchaser of the B unit warrant and the Company agree to the exercise. Therefore, neither party can compel the exercise of the remainder of the B unit warrant. Additionally, as discussed in Note 6, *Equity Line of Credit*, the remaining amount under our line of credit is the lesser of approximately $8.0 million in gross proceeds or approximately 1.2 million shares of our common stock which, based on our stock price of $0.33 as of November 3, 2008, would be approximately $0.4 million in gross proceeds. 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.

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. All product sales are currently derived from Zevalin. Product sales are generally recorded upon shipment, net of an allowance for estimated product returns and rebates. We analyze historical return patterns for our products in determining an appropriate estimate for our returns allowance. We may need to adjust our estimates if actual results vary, which could have an impact on our earnings in the period of adjustment. If customers have product acceptance rights or product return rights and we are unable to reasonably estimate returns related to that customer or market, we defer revenue recognition until such rights have expired.

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

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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 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.

Cost of Product Sold

Cost of product sold consists of the cost of the product sold to our customers, including any necessary allowances for excess inventory that may expire and become unsaleable. We currently purchase Zevalin from Biogen Idec pursuant to a supply agreement entered into in connection with the acquisition of this product. Contractual royalties based on product sales are also included in cost of product sold.

Inventory

Inventory is stated at the lower of cost or market. We determine cost based on the specific identification method. If the cost of the inventory exceeds the expected market value, provisions are recorded for the difference between the cost and the net realizable value. When required, an allowance for excess inventory that may expire and become unsaleable is recorded. All inventory as of September 30, 2008 consists of finished goods inventory for Zevalin.

Accounts Receivable

Our accounts receivable balance includes trade receivables related to Zevalin as of September 30, 2008 and is net of an allowance for product returns totaling approximately $117,000 for the period. We analyze historical returns patterns for our products in determining an appropriate estimate for our returns allowance. This estimate is evaluated periodically and adjusted, if necessary. Actual returns are written off against the existing allowance. An allowance for doubtful accounts is based on estimates of losses related to customer receivable balances. We estimate the allowance based upon the age of the outstanding receivables and our historical experience of collections, adjusting for risk of loss for specific customer accounts. We periodically review the estimation process and make changes to the estimates as necessary. When it is deemed probable that a customer account is uncollectible, that balance is written off against the existing allowance. As of September 30, 2008, customer payments had generally been made in a timely manner and no estimate for doubtful accounts was deemed necessary.

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 Statement of Financial Accounting Standards, or 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.

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Acquired in-process research and development

Costs to acquire in-process research and development, or IPRD, projects and technologies which have no alternative future use and which have not reached technological feasibility as of acquisition date are expensed as incurred.

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 10 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 $7.0 million and $7.2 million as of September 30, 2008 and December 31, 2007, respectively, of which $5.4 million and $6.5 million is included in *other assets* and $1.6 million and $0.7 million is included in *prepaid expenses and other current assets* as of September 30, 2008 and December 31, 2007, 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.

Net Loss Per Share

Basic net loss per common share is calculated based on the net loss attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted net loss per common share assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and share awards using the treasury stock method. As of September 30, 2008 and 2007, options, warrants, unvested share awards and rights, convertible debt and convertible preferred stock aggregating 26,576,119 and 2,171,248, 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 Statement of Financial Accounting Standards, or 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.

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Our 18.33%, 15.5%, 15%, 13.5%, 10%, 9% and 6.75% 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. 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. The Company and its 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 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.

Recently Adopted Accounting Pronouncements

On January 1, 2008, we adopted certain provisions of SFAS 157 which provides guidance on how to measure assets and liabilities that use fair value. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. 157-2 which delays the effective date of SFAS 157 one year for all nonfinancial assets and nonfinancial liabilities, except those recognized or disclosed at fair value in the financial statements on a recurring basis. The partial adoption of SFAS 157 did not have a material impact on our financial statements. We will adopt the provisions of SFAS 157 as it relates to nonfinancial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis on January 1, 2009 and we are evaluating the impact, if any, the full adoption will have on our financial statements.

On January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115,* or SFAS 159. This Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. As we did not elect fair value treatment for qualifying instruments that existed as of January 1, 2008, the adoption of the Statement did not have an impact on our financial statements. We may elect to measure qualifying instruments at fair value in the future.

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On January 1, 2008, we adopted EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,* or EITF 07-3, which provides guidance on whether non-refundable advance payments for goods or services that will be performed in future research and development activities should be accounted for as research and development costs or deferred and capitalized until the goods have been delivered or the related services have been rendered. Adoption of this standard did not have a material impact on our financial statements.

Recently Issued Accounting Pronouncements

On December 4, 2007, Statement of Financial Accounting Standards No. 141(R), *Business Combinations,* or SFAS 141(R), was issued. This standard will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize IPRD as an indefinite lived intangible asset and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. The acquiring company will be required to expense the acquisition costs rather than add them to the cost of the acquisition. The standard is effective for transactions occurring on or after January 1, 2009. We are evaluating the impact this standard will have on our financial statements.

On December 4, 2007, Statement of Financial Accounting Standards No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*, or SFAS 160, was issued. This standard changes the accounting for and reporting of noncontrolling or minority interests in consolidated financial statements. The standard is effective January 1, 2009 however the presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests shall be applied retrospectively. We are evaluating the impact, if any, this standard will have on our financial statements.

In November 2007, the EITF reached a consensus on Issue 07-1. EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property,* is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaborative agreement should be presented in the income statement and certain related disclosure questions. EITF 07-1 is effective for periods beginning after December 15, 2008.We are evaluating the requirements of these issues and have not yet determined the impact on the financial statements.

In March 2008, Statement of Financial Accounting Standards No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133,* or SFAS 161, was issued. This standard enhances disclosures about an entity s derivative and hedging activities and thereby improves the transparency of financial reporting. The standard is effective for fiscal years beginning after November 15, 2008. This standard encourages but does not require comparative disclosures for earlier period at initial adoption. We are currently evaluating the impact this standard will have on our financial statements.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. This standard identifies the source of accounting principles and the framework for selecting principles to be used in the preparation and presentation of financial statements in accordance with generally accepted accounting principles. SFAS 162 directs the hierarchy to the entity, rather than the independent auditors. This standard is effective 60 days after the Securities and Exchange Commission approves the Public Company Accounting Oversight Board amendments to remove the hierarchy of generally accepted accounting principles from the auditing standards. We do not anticipate that the adoption of this standard will have an effect on our consolidated financial statements.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity s Own Stock*, or EITF 07-5. EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument s contingent exercise and settlement provisions. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

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In June 2008, the FASB issued EITF Issue No. 08-4, *Transition Guidance for Conforming Changes to Issue No. 98-5*, or EITF 08-4. The objective of EITF 08-4 is to provide transition guidance for conforming changes made to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* that result from EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments,* and SFAS Issue No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity.* EITF 08-4 is effective for financial statements issued for fiscal years ending after December 15, 2008 and early application is permitted. We are currently evaluating the impact of EITF 08-4 on the accounting for our convertible notes and related warrant transactions.

Reclassifications

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

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 was $49.3 million and $49.8 million for the three month periods ended September 30, 2008 and 2007, respectively. Total comprehensive loss was $142.7 million and $102.4 million for the nine month periods ended September 30, 2008 and 2007.

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

	September 30, 2008	December 31, 2007
Foreign currency translation adjustment	$ (4,968)	$ (4,010)
Net unrealized gain (loss) on securities available-for-sale	(6)	3
Accumulated other comprehensive loss	$ (4,974)	$ (4,007)

3. Reverse Stock Split

At our Special Meeting in Lieu of Annual Meeting of Shareholders held on June 19, 2008, our shareholders approved a proposal to authorize our Board of Directors, in its discretion, to effect a reverse split of our outstanding common stock without further action by shareholders. In August 2008, our Board of Directors approved a one-for-ten reverse stock split of our common stock and on August 31, 2008 the reverse stock split became effective. As a result of the reverse stock split, every ten shares of our issued and outstanding common stock were automatically combined into one issued and outstanding share. Fractional shares calculated in the split were rounded down to the nearest share and no fractional shares were issued. In lieu of fractional shares, shareholders received cash at a rate of $0.23 per whole pre-split share. The reverse stock split affected all of the holders of our common stock uniformly and did not affect any shareholder s percentage of ownership interest. Any shares of our common stock or shares of common stock underlying options, warrants, convertible preferred stock and convertible notes were proportionately reduced and the exercise price of any warrants or options and the conversion prices of any convertible preferred stock or convertible notes were proportionately increased in accordance with the terms of the related agreements. All impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the reverse stock split.

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4. Convertible Notes

10% Convertible Senior Notes

In September 2008, we issued $9.0 million aggregate principal amount of our 10% notes under a securities purchase agreement. Additionally in connection with the issuance, the holder of the 10% notes converted 1,000 shares of our Series C preferred stock into 25,640 shares of our common stock, induced by an aggregate cash payment of $150,000. We also paid to the holder of the notes and its affiliates approximately $1.2 million in exchange for the prospective satisfaction of 50% of any final judgment which may ever be rendered on any and all claims for any relief whatsoever that have been alleged, or that could have been alleged, in our litigation with Enable Capital Management LLC (the holder of the notes) as described further in Note 11, *Litigation Proceedings*.

We recorded issuance costs of approximately $0.4 million related to the issuance of our 10% notes which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the four-year life of the notes. Net proceeds from the issuance were approximately $7.3 million after deducting the $1.2 million litigation related payment, the $150,000 conversion inducement and related expenses and commissions. In addition, $3.6 million of this amount was restricted and held in escrow to fund potential make-whole payments as described below.

Since the holders of the Series C preferred stock have an option to redeem the stated value of their preferred stock for cash at any time after the two- year anniversary of the original issue date in July 2007, we concluded that the inducement of $150,000 was not representative of a sufficient inducement to Enable to convert their Series C preferred stock given the value underlying the common stock issued upon conversion. Accordingly, we allocated our total payment of $1.4 million and determined that $1.0 million and $0.4 million pertained to the inducement and to the settlement expense, respectively. The inducement payment of $1.0 million is recorded as a deemed dividend in the current period pursuant to the provisions of EITF Topic D-42, *The Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock.*

The 10% notes are due on September 15, 2012 and interest is payable semi-annually in May and November. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity or repurchase at an initial conversion price of $1.27 per share, which is subject to adjustments in certain circumstances. This conversion price is equivalent to approximately 787.40 shares of common stock per $1,000 principal amount of the notes. Subject to certain conditions, the notes will automatically convert if, at any time after September 15, 2009 and on or prior to the maturity date, the closing price of our common stock has exceeded 200% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. Upon a change of control, the holder can require us to repurchase the notes at 100% of their principal amount for cash, plus accrued and unpaid interest due up to, but not including the repurchase date. In addition, upon any conversion, we are required to pay the holder of the notes a make-whole payment equal to $400.00 per $1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date. An amount adequate to pay the make-whole interest on all outstanding notes will be held in escrow for a period of one year.

This agreement also gave us the right, subject to certain stock price, trading volume and milestone preconditions, to require the holder of the 10% notes to purchase an additional $9.0 million aggregate principal amount of our 10% notes pursuant to an all-or-none issuer put option which would expire no later than October 15, 2008. If we exercised our put option for the second $9.0 million of 10% notes, additional similar payments of $150,000 and $1.2 million would be made and an additional 1,000 shares of our Series C preferred stock would be converted into 25,640 shares of our common stock by the holder of the 10% notes. Pursuant to guidance in SFAS 133, we determined that the put option was an embedded derivative which requires bifurcation from the 10% notes. The put option was valued using a Black-Scholes option pricing model and the inputs relating to the preconditions were derived based on 1,000 Monte Carlo simulation runs. As of the issue date, the put option was estimated to have a fair value of approximately $0.1 million and recorded in accordance with guidance in Derivative Implementation Group Statement 133 Implementation Issue No. B15, *Embedded Derivatives: Separate Accounting for Multiple Derivative Features Embedded in a Single Hybrid Instrument*.

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In September 2008, the agreement was amended to provide for an increase in the principal amount of the notes pursuant to the put option to approximately $14.2 million and an increase in the interest rate to 15.5% as described below. In addition, we were able to exercise our put option immediately without being subject to the preconditions included in the original agreement. This amendment constituted a modification of terms related to the put option and the increase in its fair value of approximately $2.5 million was taken into earnings and is included in *gain on derivative liabilities, net* for the three and nine months ended September 30, 2008.

The conversion option of the 10% notes represents an embedded derivative liability which requires bifurcation from the underlying notes in accordance with SFAS 133 since the 10% notes are deemed non-conventional debt which does not qualify for the paragraph 11(a) scope exception due to the make-whole interest provision. At the issuance of the 10% notes, the embedded conversion option was estimated to have a fair value of approximately $3.5 million, which was then bundled with the value of the put option derivative asset of $0.1 million as described above. The resulting debt discount of approximately $3.4 million was being accreted over the four year life of the notes as additional interest expense using the effective interest method. We recorded interest expense of approximately $3.4 million for the three and nine months ended September 30, 2008 which is included in *amortization of debt discount and issuance costs* and relates to accelerated accretion due to note conversions. At September 30, 2008, there was no derivative liability outstanding due to note conversions and the change in derivative liability of $3.4 million is included in *gain on derivative liabilities, net* for the three and nine months ended September 30, 2008.

As of September 30, 2008, all $9.0 million of our 10% notes had been converted into 7,086,614 shares of our common stock. In connection with the conversion of the notes, we made make-whole interest payments of approximately $3.6 million.

15.5% Convertible Senior Notes

Also in September 2008, we issued approximately $14.2 million of our 15.5% notes under an amendment to the securities purchase agreement for our 10% notes as described above. Similar to the 10% notes and also as described above, we made payments of $150,000 and $1.2 million and an additional 1,000 shares of our Series C preferred stock were converted into 25,640 shares of our common stock.

We recorded issuance costs of approximately $0.3 million related to the issuance of our 15.5% notes which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the four-year life of the notes. Net proceeds from the issuance were approximately $12.5 million after deducting the $1.2 million litigation related payment, the $150,000 conversion inducement, related expenses and commissions. In addition, $8.8 million of this amount was restricted and held in escrow to fund potential make-whole payments as described below.

Similar to the allocation described for the 10% notes above, we determined that $1.0 million and $0.4 million of our payment to Enable pertained to the inducement and to the settlement expense, respectively. The inducement payment of $1.0 million is recorded as a deemed dividend in the current period pursuant to the provisions of EITF Topic D-42, *The Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock.*

The notes are due on September 29, 2012 and interest is payable semi-annually in May and November. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity or repurchase at an initial conversion price of $1.27 per share, which is subject to adjustments in certain circumstances. This conversion price is equivalent to approximately 787.4 shares of common stock per $1,000 principal amount of the notes. Subject to certain conditions, the notes will automatically convert if, at any time after September 29, 2009 and on or prior to the maturity date, the closing price of our common stock has exceeded 200% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. Upon a change of control, the holder can require us to repurchase the notes at 100% of their principal amount for cash, plus accrued and unpaid interest due up to, but not including the repurchase date. In addition, upon any conversion, we are required to pay the holder of the notes a make-whole payment equal to $620 per $1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date. An amount adequate to pay the make-whole interest on all outstanding notes will be held in escrow for a period of one year.

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The conversion option of the 15.5% notes represents an embedded derivative which requires bifurcation from the underlying notes in accordance with SFAS 133 since the 15.5% notes are deemed non-conventional debt which does not qualify for the paragraph 11(a) scope exception due to the make-whole interest provision. At the issuance of the 15.5% notes, the embedded conversion option was estimated to have a fair value of approximately $8.6 million. The resulting debt discount of approximately $8.6 million is being accreted over the four year life of the notes as additional interest expense using the effective interest method. We recorded interest expense of approximately $4,000 for the three and nine months ended September 30, 2008. The estimated fair value of the derivative liability will be adjusted quarterly for changes in the estimated market value. At September 30, 2008, the fair value of the derivative liability remained unchanged at $8.6 million and was recorded in *15.5% convertible senior notes.*

As of September 30, 2008, there had been no conversions of our 15.5% notes and we still had approximately $8.8 million in *restricted cash* held in an escrow account to fund any potential remaining make-whole payments related to the 15.5% notes. As of November 3, 2008, all $14.2 million of 15.5% notes had been converted into approximately 11.2 million shares of our common stock.

13.5% Convertible Senior Notes

In April 2008, we issued $36.0 million aggregate principal amount of our 13.5% notes and $9.0 million aggregate principal amount of our Series E 13.5% convertible exchangeable preferred stock, or Series E preferred stock, which was subsequently exchanged for our 13.5% notes as described below. We also issued warrants to purchase 2,848,101 shares of our common stock, or A Warrants, at an exercise price of $9.50 per share and a Series B Unit Warrant, or B Unit Warrant, to purchase up to $67.5 million aggregate principal of 12.5% convertible senior notes, or 12.5% notes, and additional A Warrants. As discussed in Note 5, *Series B Unit Purchase Warrant,* the B Unit Warrant was amended in June and July 2008 and included a reduction to $7.90 in the exercise price of the warrants issued in connection with the 13.5% notes as well certain A Warrants issued on exercise of the B Unit Warrant. The amendments also provided an increase in the interest rate on the notes to be issued upon exercise of the B Unit Warrant.

All of the securities were issued to a single institutional investor for the total purchase price of approximately $64.6 million in gross proceeds, of which approximately $5.3 million aggregate principal amount of our 9% notes and the related warrants issued with the 9% notes, or 9% warrants, were credited towards the purchase price. Additionally, approximately $36.5 million of cash was restricted and held in escrow to fund potential make-whole payments. After taking these credits into account, as well as issuance costs of approximately $3.3 million, net proceeds from the 13.5% notes issuance were approximately $19.6 million.

The 13.5% notes are due on April 30, 2014 with interest payable semi-annually in May and November. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity at an initial conversion price of $7.90, which is subject to adjustments in certain circumstances. This conversion rate is equivalent to approximately 126.582 shares of common stock per $1,000 principal amount of the notes. In addition, upon any conversion or upon exercise by the holder of a one-time right to require early redemption of the 13.5% notes which may be exercised in May 2011, we are required to pay the holder of the notes a make-whole interest payment equal to $810 per $1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date. An amount adequate to pay the make-whole interest on all outstanding notes will be held in escrow for a period of one year.

In June 2008, all of our Series E preferred stock and its accrued and unpaid dividend was exchanged by the holder for an additional $9.1 million aggregate principal of our 13.5% notes. There were no conversions of Series E preferred stock into common stock prior to this exchange. Upon issuance of the Series E preferred stock, we recorded beneficial conversion feature charges of approximately $1.1 million related to the conversion price for our Series E preferred stock and the resulting discount of $1.1 million was fully recognized as a dividend through the date of the Series E preferred stock exchange and is included in *preferred stock beneficial conversion feature* for the nine months ended September 30, 2008. Upon exchange, the additional embedded derivative related to the conversion option of approximately $7.0 million, inclusive of the $1.1 million which was originally recorded in equity as a beneficial conversion feature, and the resulting debt discount of $5.9 million were recorded.

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In July 2008, as described in Note 5*, Series B Unit Purchase Warrant,* we entered into a Second Amendment of the Securities Purchase Agreement and Series B Unit Purchase Warrant with the holder, pursuant to which the remaining original exercise amount of $44.5 million of the B Unit Warrant was exercised in July and August 2008 and a portion of the proceeds from the issuance of $44.5 million principal of our 18.33% notes thereunder were used to repurchase the remaining outstanding amount of $17.5 million of our 13.5% notes as well as 1,101,265 of warrants related to these notes. In addition, the remaining amount held in escrow related to the 13.5% notes was distributed whereby we received approximately $6.5 million and the holder of the 13.5% notes received approximately $7.6 million.

The repurchase of our 13.5% notes using the proceeds from the issuance of our 18.33% notes was accounted for as a debt exchange pursuant to the provisions of EITF 96-16, *Debtor s Accounting for a Modification or Exchange of Debt Instruments*. The 13.5% notes were deemed extinguished since the exchange resulted in substantially different cash flows. We recognized a loss of approximately $10.3 million on the exchange which is included in *loss on exchange of convertible notes* for the three and nine months ended September 30, 2008.

The conversion option of the 13.5% notes represented an embedded derivative which required bifurcation from the underlying notes in accordance with SFAS 133 since our 13.5% notes were deemed non-conventional debt and did not qualify for the paragraph 11(a) scope exception of SFAS 133 due to the make-whole interest provision in the 13.5% notes.

The total estimated fair value of the conversion option derivative liability of $34.1 million was adjusted quarterly for changes in the estimated market value. The change in the estimated fair value for the three and nine months ended September 30, 2008 was $14.2 million and $34.1 million, respectively. Of these amounts $46,000 and $20.0 million is included in *gain on derivative liabilities, net* for the three and nine months ended September 30, 2008 respectively and $14.1 million is included in the *loss on exchange of convertible notes* for both periods. In addition, we recorded $2.3 million related to the change in the fair value component of the 13.5% notes which is also included in *gain on derivative liabilities, net* for the nine months ended September 30, 2008. At September 30, 2008, as all 13.5% notes had been converted or repurchased, as discussed above, no value was assigned to the fair value of the derivative.

The total debt discount of $38.4 million, which includes an additional $0.4 million that was recorded in connection with the modification to the exercise price of the A Warrants in July 2008 as discussed above, was being accreted over the six-year life of the notes as additional interest expense using the effective interest rate method. We recorded a change in the debt discount of $14.9 million and $38.4 million for the three and nine months ended September 30, 2008, of which $14.9 million is included in the *loss on exchange of convertible notes* for both periods and $23.5 million was included in *amortization of debt discount and issuance costs* for the nine months ended September 30, 2008.

A total of $27.6 million of our 13.5% notes were converted into approximately 3.5 million shares of common stock during the nine months ended September 30, 2008. In connection with the conversion of the notes, we made make-whole interest payments of approximately $22.4 million which is included in *make-whole interest expense* for the nine months ended September 30, 2008.

15% Convertible Senior Notes

In June 2008, following the first amendment of the B Unit Warrant to increase the interest rate on the notes to be issued thereunder and in connection with the exercise of the B Unit Warrant, as described further in Note 5, *Series B Unit Purchase Warrant,* we issued $23.0 million aggregate principal amount of our 15% notes. We recorded issuance costs related to the 15% notes of approximately $1.2 million which are recorded in other assets and are being amortized to interest expense using the effective interest method over the three-year life of the notes. Upon exercise of the B Unit Warrant, we also issued additional A Warrants to purchase 1,455,696 shares of common stock at an exercise price of $9.50 per share. The A Warrants became exercisable and the 15% notes became convertible upon shareholders approval to increase the authorized shares of common stock in June 2008. The warrants will expire on June 19, 2013. Net proceeds from the 15% notes issuance were approximately $11.4 million after taking into account $10.4 million of restricted cash held in escrow to fund potential make-whole payments as described below.

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The notes are due June 12, 2011 with interest payable semi-annually in May and November. The notes are convertible, at the option of the holder, into shares of our common stock at any time after the authorized share approval and on or prior to maturity or repurchase at an initial conversion price of $7.90 per share, which is subject to adjustments in certain circumstances. This conversion price is equivalent to 126.582 shares of common stock per $1,000 principal amount of the notes. Upon any conversion, we are required to pay the holder of the notes a make-whole interest payment equal to $450 per $1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date. An amount adequate to pay the make-whole interest on all outstanding notes will be held in escrow for a period of one year.

The conversion option of the 15% notes represents an embedded derivative which requires bifurcation from the underlying notes in accordance with SFAS 133 since the 15% notes are deemed non-conventional debt which does not qualify for the paragraph 11(a) scope exception due to the make-whole interest provision.

At the issuance of the 15% notes, the embedded conversion option was estimated to have a fair value of approximately $4.6 million. The resulting debt discount of approximately $4.6 million along with the discount resulting from allocation of proceeds to the A Warrants of approximately $1.4 million is being accreted over the three year life of the notes as additional interest expense using the effective interest method. We recorded interest expense of approximately $0.4 million and $0.5 million for the three and nine months ended September 30, 2008, respectively. The estimated fair value of the derivative liability will be adjusted quarterly for changes in the estimated market value. The change in the estimated fair value of the derivative liability for the three and nine months ended September 30, 2008 was a gain of approximately $4.6 million and $4.5 million, respectively, and is included in *gain on derivative liabilities, net*. At September 30, 2008, the fair value of the derivative was approximately $0.1 million, which was recorded in *15% convertible senior notes*.

As of September 30, 2008, there had been no conversions of our 15% notes into common stock, and accordingly no make-whole payments had been made. Approximately $10.4 million is included in restricted cash and is being held in an escrow account to fund any potential make-whole payments related to the 15% notes. In October 2008, in connection with the issuance of our 9.66% notes, we repurchased approximately $18.2 million of these notes and $8.2 million of related cash was released from escrow as discussed in Note 12, *Subsequent Events.*

18.33% Convertible Senior Notes

In connection with the exercise of $44.5 million of the B Unit Warrant in July and August 2008 as described above, we issued $44.5 million aggregate principal amount of our 18.33% notes. We recorded issuance costs related to the 18.33% notes of approximately $0.8 million which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the three-year life of the notes. In connection with the exercise of the B Unit Warrant, we also issued additional A Warrants to purchase 2,816,455 shares of common stock at an exercise price of $7.90 per share which are exercisable immediately and expire on June 19, 2013. Net proceeds from the 18.33% notes issuance were approximately $1.8 million after taking into account issuance costs, approximately $24.5 million of restricted cash held in escrow to fund potential make-whole payments as described below and approximately $17.5 million used to repurchase the remaining outstanding principal amount of our 13.5% notes and 1,101,265 of related warrants as discussed above. In addition to the $1.8 million in net proceeds, approximately $6.5 million of the remaining amount held in escrow related to our 13.5% notes was released to us upon our repurchase of these notes.

We issued $22.25 million aggregate principal amount of the 18.33% notes in July 2008 which are due on July 24, 2011 and $22.25 million aggregate principal amount of the 18.33% notes in August 2008 which are due on August 19, 2011. Interest is payable semi-annually in May and November for all notes. The notes are convertible, at the option of the holder, into shares of our common stock at any time on or prior to maturity or repurchase at an initial conversion price of $7.90 per share, which is subject to adjustments in certain circumstances. This conversion price is equivalent to approximately 126.582 shares of common stock per $1,000 principal amount of the notes. Subject to certain conditions, the notes will automatically convert if, at any time after July 24, 2009 (for the first $22.25 million issued) or August 19, 2009 (for the remaining $22.25 million issued) and on or prior to the maturity date, the closing price of the common stock has exceeded 200% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. Upon a change of control, the holder can require us to repurchase the notes at 100% of their principal amount for cash, plus accrued and unpaid interest due up to, but not

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including the repurchase date. In addition, upon any conversion, we are required to pay the holder of the notes a make-whole interest payment equal to $549.9 per $1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

The total proceeds of $44.5 million and the $0.7 million fair value of the 1,101,265 repurchased A Warrants discussed above were allocated between the 18.33% notes and the 18.33% A Warrants using a relative market value approach based on Accounting Principles Board, or APB, Opinion 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants.* The allocations made to the 18.33% notes and 18.33% A Warrants were approximately $43.4 million and $1.8 million, respectively. The resulting debt discount was approximately $6.9 million, which arose from approximately $9.4 million and $1.8 million of allocations made to the embedded conversion option and the 18.33% A warrant, respectively, offset by a $4.3 million discount attributed to the exchanges with the 13.5% notes. The debt discount is being accreted over the three year life of the notes as additional interest expense using the effective interest method. We recorded interest expense of approximately $5.5 million for the period ended September 30, 2008 primarily related to accelerated accretion due to note conversions.

The conversion option of the 18.33% notes represents an embedded derivative which requires bifurcation from the underlying notes in accordance with SFAS 133 since the 18.33% notes are deemed non-conventional debt which does not qualify for the paragraph 11(a) scope exception due to the make-whole interest provision.

At the issuance of the 18.33% notes, the embedded conversion option was estimated to have a fair value of approximately $9.4 million, of which $3.6 million was included in approximately $18.9 million fair value of the 18.33% notes initially recorded in connection with the debt exchange transactions as described in *13.5% Convertible Senior Notes*. The estimated fair value of the derivative liability will be adjusted quarterly for changes in the estimated market value. The estimated fair value of the derivative liability for the nine months ended September 30, 2008 decreased approximately $5.7 million, and is included in *gain on derivative liabilities, net*. At September 30, 2008, the fair value of the derivative was approximately $0.1 million, which was recorded in *18.33% convertible senior notes.*

During the three months ended September 30, 2008, $28.3 million of 18.33% notes were converted into 3.6 million shares of common stock. In connection with the conversion of the notes, we had make-whole interest payments of approximately $15.5 million which are included in *make-whole interest expense* for the three months ended September 30, 2008. As of September 30, 2008, we had approximately $8.9 million of restricted cash held in escrow to fund any potential make-whole payments related to these notes.

9% Convertible Senior Notes

In March 2008, we issued approximately $51.7 million aggregate principal amount of our 9% notes. The notes are due March 4, 2012 with interest payable semi-annually in March and September. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity or repurchase at an initial conversion rate of 70.922 shares of common stock per $1,000 principal amount of the notes, which is subject to adjustments in certain circumstances. This conversion rate is equivalent to a conversion price of approximately $14.10 per share. We recorded issuance costs related to the 9% notes of approximately $2.3 million which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the four-year life of the notes. We also issued warrants to purchase an additional 732,695 shares of common stock at an exercise price of $14.10 per share. Additionally, in connection with the issuance, certain existing holders of our Series A, B, C and D convertible preferred stock converted their shares of preferred stock into approximately 0.4 million shares of common stock, induced by an aggregate cash payment of approximately $16.2 million, which is recorded as *deemed dividends on conversion of preferred stock* for the nine months ended September 30, 2008 pursuant to the provisions of EITF Topic D-42*,The Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock.* Net proceeds from the 9% notes issuance were approximately $33.1 million after deducting the cash inducement and related issuance costs. In addition, $13.9 million of this amount was restricted and held in escrow to fund potential make-whole payments as described below. An amount adequate to pay the make-whole interest on all outstanding notes will be held in escrow for a period of one year.

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As of September 30, 2008, a total of $40.8 million of our 9% notes had been converted into approximately 2.9 million shares of common stock. In connection with the conversion of the notes, we had make-whole interest payments of approximately $11.0 million which is included in *make-whole interest expense* for the nine months ended September 30, 2008. There were no conversions during the three months ended September 30, 2008. In addition, in connection with the issuance of our 13.5% notes in April 2008, $5.3 million of the 9% notes and 74,468 of related warrants were cancelled. In connection with this cancellation, approximately $1.4 million of restricted cash was released to us from escrow. As of September 30, 2008, approximately $1.2 million is included in *restricted cash* and is being held in an escrow account to fund any potential remaining make-whole payments related to the 9% notes.

The interest make-whole provision along with the conversion option of the 9% notes represents an embedded derivative which is required to be accounted for separate from the underlying notes. At the issuance of the 9% notes, the embedded derivative was estimated to have a fair value of approximately $13.0 million. The resulting discount, along with the discount resulting from allocation of proceeds to stock warrants of $3.4 million, is being accreted over the life of the notes as additional interest expense using the effective interest method. We recorded interest expense of $0.1 million and $13.1 million for the three and nine month periods ended September 30, 2008, respectively. The amount for the nine months ended September 30, 2008 primarily relates to accelerated accretion due to note conversions. The estimated fair value of the derivative liability will be adjusted quarterly for changes in the estimated market value. The change in the estimated fair value for the three and nine month periods ended September 30, 2008 was a gain of $12.0 million and $0.2 million, respectively, and is included in *gain on derivative liabilities, net*. At September 30, 2008, the fair value of the derivative was $14,000, which was recorded in *9% convertible senior notes*. In connection with the exchange of $5.3 million of our 9% notes which were exchanged for units of our 13.5% notes and other securities in April 2008, we recognized a loss of approximately $3.3 million, which includes unamortized debt discount and fair value of the embedded derivative related to the exchanged notes of $1.7 million and $1.0 million, respectively. This loss was included in *loss on exchange of convertible notes* for the nine months ended September 30, 2008.

7.5% Convertible Senior Notes

The interest make-whole provision along with the automatic conversion provision of the 7.5% notes represents an embedded derivative which is required to be accounted for separate from the underlying notes and was recorded as a derivative liability and a discount to the carrying value of the notes. The resulting discount to the notes is being accreted over the life of the notes as additional interest expense using the effective interest method and is included in *amortization of debt discount and issuance costs*. Accordingly, we recorded interest expense of $0.1 million for each of the three months ended September 30, 2008 and 2007 and $0.3 million and $2.8 million for the nine months ended September 30, 2008 and 2007, respectively. The expense recorded for the nine months ended September 30, 2007 was primarily related to accelerated accretion due to note conversions. The change in the estimated fair value of the derivative liability was a loss of $20,000 and a gain of $3.5 million for the three and nine months ended September 30, 2007, respectively and was included in *gain on derivative liabilities, net*. As of September 30, 2008 and December 31, 2007, there was no value assigned to the derivative liability and accordingly, there was no gain or loss related to the change in fair value recorded for the three or nine months ended September 30, 2008.

There were no conversions of our 7.5% notes during the three or nine months ended September 30, 2008. During the nine months ended September 30, 2007, $15.3 million of our 7.5% notes were converted into 0.2 million shares of common stock, respectively. There were no conversions during the three months ended September 30, 2007. In connection with the conversion of $13.6 million of these notes, we made discretionary interest make-whole payments of approximately $2.3 million which is included in *make-whole interest expense* for the nine months ended September 30, 2007. There was no make-whole interest expense for the three months ended September 30, 2007.

6.75% Convertible Senior Notes

The interest make-whole provision along with the conversion option of the 6.75% notes represents an embedded derivative which is required to be accounted for separate from the underlying notes and was recorded as a derivative liability and a discount to the carrying value of the notes. The resulting discount to the notes is being accreted over the life of the notes as additional interest expense using the effective interest method and is included in *amortization*

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of debt discount and issuance costs. Accordingly, we recorded interest expense of approximately $20,000 for the three months ended September 30, 2008 and 2007 and interest expense of approximately $60,000 for the nine months ended September 30, 2008 and 2007. The estimated fair value of the derivative liability was approximately $0.1 million at September 30, 2008 and December 31, 2007 and was recorded in 6.75% convertible senior notes. The change in the estimated fair value for the three months ended September 30, 2008 and 2007 was approximately $19,000 and $25,000, respectively, and was approximately $60,000 and $80,000 for the nine months ended September 30, 2008 and 2007. These amounts were included in gain on derivative liabilities, net.

5.75% Convertible Senior Notes

In accordance with the provisions in EITF 96-19, our 5.75% convertible senior notes were initially recorded at fair value. The resulting discount relating to the difference between the face value and the fair value is being accreted over the life of the notes as additional interest expense using the effective interest method. Accordingly, we recorded interest expense of approximately $0.2 million and $0.6 million for the three and nine months ended September 30, 2008, respectively.

During the nine months ended September 30, 2008, approximately $0.3 million of our 5.75% convertible senior notes were converted into approximately 8,000 shares of our common stock. There were no conversions during the three months ended September 30, 2008.

5.75% Convertible Subordinated and Senior Subordinated Notes

In February 2008, $150,000 of our 5.75% convertible subordinated notes and approximately $8.9 million of our 5.75% convertible senior subordinated notes were cancelled in exchange for approximately 11,000 and 0.7 million shares of our common stock, respectively. The exchange was accounted for in accordance with provisions in APB No. 26, *Early Extinguishment of Debt* and FTB 80-1. We recorded a loss on the exchange of approximately $2.3 million attributed to the difference between the reacquisition price and the net carrying amount of the extinguished notes which is included in *loss on exchange of convertible notes* for the nine months ended September 30, 2008.

In June 2008, the remaining outstanding amount of these notes reached maturity and we made a cash payment of approximately $11.0 million to repay the outstanding balance, including accrued interest.

5. Series B Unit Purchase Warrant

As described in Note 4, *Convertible Notes,* a B Unit Warrant was issued with our 13.5% notes and other financial instruments in April 2008. At issuance, the B Unit Warrant consisted of a warrant to purchase 67,500 units consisting of 12.5% Convertible Senior Notes with an exercise price equal to $1,000 per unit and additional A Warrants at an exercise price of $9.50 per share.

We considered guidance in SFAS 133, SFAS 150 Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, and EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock,* and determined that the B Unit Warrant is a liability instrument that is marked to fair value with changes in value recognized through earnings at each reporting period. At the issuance, we estimated the fair value of the B Unit Warrant to be approximately $21.3 million.

In June 2008, we entered into an Amendment to the Securities Purchase Agreement and Series B Unit Purchase Warrant with the holder, which provided for an increase in interest rate of the convertible notes issuable upon exercise of the B Unit Warrant from 12.5% to 15% and also required $23.0 million of partial exercise of the B Unit Warrant. The amendment constituted a modification of terms and accordingly, the increase of approximately $2.3 million in the fair value of the B Unit Warrant was expensed in the current period and is included in *gain on derivative liabilities, net* for the nine months ended September 30, 2008. Subsequent to the modification, $23.0 million of the B Unit Warrant was exercised by the holder, resulting in the issuance of $23.0 million aggregate principal amount our 15% notes and additional A Warrants to purchase 1,455,696 shares of common stock at an exercise price of $9.50 per share. The exercise of the B Unit Warrant resulted in a premium to our 15% notes of approximately $3.8 million, which was recorded in equity pursuant to paragraph 18 of APB Opinion 14. Additionally, beneficial conversion charges related to the conversion price of the underlying securities were calculated in accordance with Issue 14 of EITF 00-27. Since the amount of deemed proceeds exceeded the fair value of common stock into which the underlying instruments can be converted, no beneficial conversion charges were recognized.

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In July 2008, we entered into a Second Amendment of Securities Purchase Agreement and Series B Unit Purchase Warrant, or Second Amendment, with the holder, which provided for an increase in the interest rate of the convertible notes issuable upon exercise of the B Unit Warrant from 15% to 18.33%. In addition, the July 2008 amendment also amended the exercise price of the A Warrants issued in connection with the 13.5% notes and certain of the A Warrants to be issued under the B Unit Warrant from $9.50 per share to $7.90 per share. The B Unit Warrant was also amended to increase its aggregate exercise price from $67.5 million to $112 million and to require the partial exercise in two closings of equal amounts of $22.5 million in July and August 2008. The remaining $44.5 million in aggregate exercise price can only be exercised by mutual agreement of the holder and us and is contingent on the satisfaction of certain regulatory requirements.

The modifications resulting from the Second Amendment as described also constituted a modification of terms and resulted in an increase to the fair value of the B Unit Warrant of $6.1 million which was expensed during the current period and is included in *gain on derivative liabilities, net* for the three and nine months ended September 30, 2008. These modifications were valued using Black-Scholes and Monte Carlo simulation models. The modification to the exercise price of the A Warrants was valued using the Black-Scholes option pricing model, which resulted in an increase to equity and additional discount to the notes of $0.4 million.

The partial exercises of the B Unit Warrant in July and August resulted in a premium to our 18.33% notes of approximately $7.4 million, which is recorded in equity pursuant to paragraph 18 of APB Opinion 14. Beneficial conversion charges related to the conversion price of the underlying securities were calculated in accordance with Issue 14 of EITF 00-27. Since the amount of deemed proceeds exceeded the fair value of common stock into which the underlying instruments can be converted, no beneficial conversion charges were recognized.

The estimated fair value of the derivative liability is adjusted quarterly for changes in the estimated market value. As of September 30, 2008, the remaining B Unit Warrant was estimated to have a fair value of approximately $2.8 million. The change in the estimated fair value of the B Unit Warrant for the three and nine months ended September 30, 2008 was a loss of approximately $1.9 million and a gain of approximately $7.3 million, respectively, and is included in *gain on derivative liabilities*, *net*.

6. Equity Line of Credit

In July 2008, we entered into a Securities Purchase Agreement with Midsummer Investment, Ltd., or Midsummer. Pursuant to the purchase agreement, we issued to Midsummer a warrant to purchase up to the lesser of $12.0 million in shares of our common stock or the number of shares of common stock equal to 19.9% of our outstanding common stock on July 29, 2008 (2,781,260 shares), in order to effectuate an equity line of credit relationship. The warrant is a freestanding financial instrument, which is transferable upon the assignment of the corresponding rights of the holder under the Securities Purchase Agreement. Under the agreement, as amended on August 6, 2008, following a commencement notice by us, Midsummer is obliged to (subject to customary conditions applicable to each respective closing) exercise the warrant every three trading days for an amount of stock measured by a formula based on the trading volume of our common stock on the Milan stock exchange, or MTA, during the three trading days prior to the closing date, or the pricing period, with the issuance amount for each pricing period equal to the sum for the three prior trading days of 15% of our trading volume on the MTA for each respective trading day. We are able to suspend exercises of the warrant at our discretion and we can choose to reactivate the equity line of credit following any such suspension until the warrant has been exercised in full. The price per share for each such issuance is 85% of the volume weighted average price of our shares on the MTA for the pricing period.

We considered guidance in SFAS 133, SFAS 150 and EITF 00-19 and determined that the warrant met the scope exception provided in paragraph 11(a) of SFAS 133. Further, pursuant to the provisions of EITF 00-19, the warrant is classified in permanent equity and is initially recorded at fair value since it requires physical settlement and also meets the conditions in paragraph 12-32 of EITF 00-19. At issuance, the warrant was estimated to have a fair value of approximately $0.9 million which was recorded in equity with the corresponding amount capitalized as

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offering costs and amortized over the use of the equity line of credit as a reduction of equity related to the issuances of common stock under the agreement. The fair value of the warrant was determined using a Monte Carlo simulation model and other simulations to predict behavior of our stock prices and volatility on the MTA.

Pursuant to the purchase agreement, we were deemed to have issued a commencement notice upon the signing of the purchase agreement such that the first closing date under the agreement was August 4, 2008. Under the terms of the deemed commencement notice, additional closings occurred every three trading days until August 26, 2008 at which point we suspended exercises of the warrant and, as of November 3, 2008, we have not reactivated the equity line.

During the three and nine months ended September 30, 2008, we issued 1,544,946 shares and received approximately $4.0 million in gross proceeds under this agreement. These proceeds were offset by an allocation of $0.6 million of offering costs, including $0.5 million related to the amortization of the fair value of the warrant as discussed above. The remaining amount to be issued under the warrant is the lesser of approximately $8.0 million in gross proceeds or approximately 1.2 million shares of our common stock which, based on our stock price of $0.33 as of November 3, 2008, would be approximately $0.4 million in gross proceeds.

7. Convertible Preferred Stock

The following amount of shares of our convertible preferred stock were converted into the following number of shares of our common stock in connection with the issuance of our 9% convertible senior notes in March 2008:

	Shares of Preferred Stock Converted	Shares of Common Stock Issued
Series A 3% convertible preferred stock	6,300	94,170
Series B 3% convertible preferred stock	10,162	150,994
Series C 3% convertible preferred stock	2,000	51,282
Series D 7% convertible preferred stock	3,000	114,832

In addition, in September 2008, 2,000 shares of our Series C preferred stock were converted into 51,281 shares of our common stock in connection with the issuance of our 10% and 15.5% convertible notes as discussed further in Note 4, *Convertible Notes.* As of September 30, 2008 and December 31, 2007, we had $107,000 and $252,000, respectively, in dividends accrued for our Series A, B, C and D convertible preferred stock which is included in *accrued expenses*.

For the three months ended September 30, 2007, we recorded a beneficial conversion feature charge related to the effective conversion price for our Series C preferred stock of approximately $3.9 million. For the nine months ended September 30, 2007, we recorded charges for beneficial conversion features related to the effective conversion price of our Series A, Series B and Series C preferred stock of approximately $2.6 million, $1.8 million and $3.9 million, respectively. These were recorded as dividends and are included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

Certain triggering events will cause our Series A, B, C and D convertible preferred stock to become redeemable. In addition, at any time after the two-year anniversary of the original issue date of our Series A, B, C and D preferred stock, and subject to the prior rights of any preferred stock previously issued, holders of our preferred stock have the right to require us to redeem any of their outstanding preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. Our Series A, B, C and D preferred stock were issued in February, April, July and December 2007, respectively. For more information regarding the triggering events and redemption rights, see Note 7, *Convertible Preferred Stock*, to our consolidated financial statements for the year ended December 31, 2007, included in our Form 10-K that was filed with the Securities and Exchange Commission on March 26, 2008.

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8. 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 nine months ended September 30, 2008 and 2007, which was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development	$ 683	$ 183	$ 2,064	$ 495
Selling, general and administrative	406	217	935	459
Stock-based compensation expense included in operating expenses	$ 1,089	$ 400	$ 2,999	$ 954

Fair value was estimated at the date of grant using the Black-Scholes pricing model, with the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Risk-free interest rates	2.7%	4.1%	2.8%	4.4%
Expected dividend yield	None	None	None	None
Expected life (in years)	2.1	2.7	2.7	3.1
Expected volatility	79%	76%	79%	76%

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.

9. Financing Agreement

In January 2008, we sold 80,000 shares to Société Générale under our Step-Up Equity Financing Agreement. These shares were sold in a registered offering at an issue price of 10.70, or approximately $15.90, per share and we received gross proceeds of approximately $1.3 million. Per the agreement, we were required to pay an amount equal to 3.5% of the selling price, or approximately $44,000. In addition, we incurred other issuance costs of approximately $31,000. Net proceeds from the issuance were approximately $1.2 million.

In June 2008, we received notice from counsel for Société Générale asserting that the agreement was terminated by Société Générale effective June 6, 2008 on the basis that the going concern statement included in our Annual Report on Form 10-K, as well as the notice we received from Nasdaq on April 16, 2008 regarding our failure to comply with the minimum price requirements under the listing requirements of the Nasdaq Global Market, constitute a

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material adverse change under the agreement, permitting Société Générale to terminate the agreement. Upon receipt of this notice, we wrote-off capitalized offering costs of $2.4 million, including costs associated with this agreement as well as costs related to the Italian Listing Prospectus that was published in January 2008 as an Italian regulatory requirement to issue shares under this agreement. These amounts were expensed due to significant uncertainty regarding our ability to pursue further financings under the agreement and are included in *write-off of financing arrangement costs* for the nine months ended September 30, 2008. However, notwithstanding the write-off, we disagree with Société Générale s allegations that such events permit Société Générale to terminate the agreement and we are reviewing our options to cause Société Générale to continue to provide financing under the agreement. However, there can be no assurance that Société Générale will do so.

10. Restructuring Activities

During 2005, we reduced our workforce in the U.S. and Europe and, in conjunction with this, we vacated a portion of our laboratory and office facilities and recorded excess facilities charges.

The following table summarizes the changes in the liability for restructuring activities during the nine months ended September 30, 2008 (in thousands):

	Excess Facilities Charges	Employee Separation Costs
Balance at December 31, 2007	$ 1,547	$ 9
Adjustments	133	1
Payments	(489)	(10)
Balance at September 30, 2008	$ 1,191	$

Charges for excess facilities relate to our lease obligation for excess laboratory and office space in the U.S. that we have vacated as a result of the restructuring plan. Pursuant to SFAS 146, we recorded restructuring charges in 2005 when we ceased using this space. The liability is calculated as the present value of total lease commitments, net of any estimated sublease income. We recorded additional restructuring expense of approximately $31,000 and $0.1 million for the three months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007 we recorded additional restructuring expense of approximately $0.1 million for both periods. These amounts are included in *selling, general and administrative* expense. These additional charges were due to changes in our estimate of the timing and amount of cash flows related to these excess facilities as well as adjustments due to the passage of time. We will periodically evaluate our existing needs and other future commitments to determine whether we should record additional excess facilities charges or adjustments to such charges. As of September 30, 2008 and December 31, 2007 respectively, approximately $0.4 million and $0.5 million of the liability for restructuring activities is included in *current portion of long-term obligations* and approximately $0.8 million and $1.0 million is included in *long-term obligations, less current portion.*

11. Legal Proceedings

Based on language (the Disputed Language) contained in the Articles of Amendment to our Articles of Incorporation (the Amendments) filed in connection with the issuance of the Company s Series A, Series B and Series C Convertible Preferred Stock (the Preferred Stock), certain holders thereof (the Shareholders) asserted a right to consent (or not) to the transactions contemplated by the Exchange Agreements entered into by us and certain holders of our then existing convertible debt on December 12, 2007 (the Exchange). We are of the view that inclusion of the Disputed Language in the Amendments constitutes a scrivener s error without legal force or effect, and filed Articles of Correction with the Secretary of State of Washington in accordance with Section 23B.01.240 of the Revised Code of Washington. On January 2, 2008, Tang Capital Partners LP (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 Series B Preferred Stock. Tang alleges that our filing of Articles of Correction to the Articles of Amendment to the Amended and Restated Articles of Incorporation on or around December 11, 2007, materially and adversely altered the powers, preferences or rights conferred through its Securities Purchase Agreement, thereby constituting a Triggering Event. On September 23, 2008, Tang filed a motion with the court for issuance of

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a judgment in their favor, and there is not yet a court schedule on proceedings related to this motion. Tang seeks a judgment ordering CTI to redeem its Preferred Stock for 130% of the Stated Value of such stock of $3 million, plus interest at 18% per annum on this amount from approximately December 17, 2007 to the date of judgment, plus attorneys fees. As of this date, CTI estimates that the amount of such a judgment to which it is exposed if CTI does not prevail will be approximately $2.1 million comprised of alleged contractual penalties, interest and attorneys fees and an additional $3 million to redeem the principal value of the Preferred Stock. The interest and attorneys fees components may increase with time if the litigation continues.

Another holder of our Series C Preferred Stock, Enable Capital Management LLC (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 March 21, 2008, Enable filed an amended complaint, asserting an additional claim against us for breach of contract and breach of the covenant of good faith and fair dealing. Enable alleges that on or about March 4, 2008, we committed a further breach of our obligations by offering and/or paying consideration to certain holders of our preferred stock to induce those holders to convert their preferred stock into common stock without making the same offer to Enable. On September 29, 2008, in exchange for payment as discussed further in Note 4, *Convertible Notes*, Enable entered into a release agreement with us to fully resolve this action.

On May 5, 2008, RHP Master Fund, Ltd. (RHP), a holder of our Series A Preferred Stock filed suit in the United States District Court for the Southern District of New York against us and certain officers and directors alleging breach of contract and violation of Washington Business Corporation Act by us and breach of fiduciary duty by the officer and director defendants. RHP alleges claims similar to those raised in Enable s amended complaint, namely that we breached our obligations to RHP by offering and paying consideration to certain holders of our Series A Preferred Stock to induce those holders to convert their preferred stock into common stock as part of the March 4, 2008 financing transaction without making the same offer to RHP. Following the filing of a motion to dismiss the complaint by the officer and director defendants, RHP filed an amended complaint on July 31, 2008. The amended complaint asserts the same causes of action as the original complaint. We dispute each of the claims asserted against us, and litigation is ongoing. At this time, we are not able to make a determination whether the likelihood of an unfavorable outcome is probable or remote.

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® (arsenic trioxide), seeking recovery of damages, including losses incurred by the Company in connection with our above referenced USAO investigation, defense and settlement of claims by the government 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 against The Lash Group. The parties have completed production of documents and fact witness depositions, and served expert reports. On June 19, 2008, the trial court entered judgment dismissing our claims for indemnification against The Lash Group on the legal ground that all False Claims Act (FCA) defendants are legally barred from filing such claims, notwithstanding that there has been no finding that the defendant engaged in any wrongdoing, and notwithstanding that the party sued may have been directly responsible for the conduct at issue in the FCA as a result of its erroneous advice, negligent services, and its own false and misleading statements about reimbursement to the government and physicians. We disagree with the Court s legal conclusion that negligent consultants may not be sued for indemnification pursuant to the express language of their contracts, and on July 19, 2008, we filed a Notice of Appeal with the Ninth Circuit Court of Appeals. We will seek a ruling that no law prohibits a defendant who settles FCA claims with the government from pursuing meritorious claims for contractual indemnification from responsible consultants. If successful, we intend to return to the United States District Court for trial, and seek more than $20 million in damages for liabilities and business losses that we contend were caused by Lash s negligent or reckless advice and its misleading communications concerning Medicare s obligation to reimburse doctors for TRISENOX. There is no guarantee that we will prevail on appeal or at trial.

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. We made the settlement payment of $10.6 million in April 2007, which included a settlement amount of $10.5 million and interest accrued on that amount since the date of reaching an agreement in principle. The settlement agreement did not address separate claims brought against us by the private party plaintiff. The private party plaintiff filed a petition for attorney s fees and costs in the approximate amount of $1.4 million on July 31, 2008. We have filed materials in opposition to this petition. There is no guarantee that we will partially or wholly prevail in opposing the petition for fees. At this time, no estimate of loss can be made.

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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.

12. Subsequent Events

In October 2008, we entered into a securities purchase agreement with a single institutional investor pursuant to which we issued $24.7 million aggregate principal amount of our 9.66% notes and repurchased $18.2 million of our 15% notes and related warrants to purchase approximately 1.2 million shares of common stock. In connection with the repurchase of the 15% notes and warrants, $8.2 million was released from the escrow account established to pay the make-whole and interest payments on the 15% notes.

The 9.66% notes are due October 22, 2011 and bear an annual interest rate of 9.66%. They are convertible into common stock at the option of the holder at a conversion price of $0.38 per share. The notes will automatically convert if, at any time after October 22, 2009 and prior to maturity, the closing price of the common stock has exceeded $0.76 for at least 20 trading days within any 30 consecutive trading day period, subject to certain conditions (a triggering event). The amount of notes that shall automatically convert on a triggering event may be limited, depending upon the volume weighted average price of the common stock at that time. Once a triggering event has occurred, a new 30 trading day period for which an automatic conversion may be triggered shall commence.

Upon optional or automatic conversion of the 9.66% notes, we shall be required to pay a make-whole amount to the holders of the converted notes equal to $289.80 per $1,000 principal amount of the converted notes less any interest paid on such notes before conversion. An amount adequate to pay the make-whole payments on the notes will be held in escrow for a period of one year. Net proceeds from the issuance of the 9.66% notes, before fees and expenses, were $7.5 million after taking into account $7.2 million placed in escrow to fund make-whole payments and interest payments on the notes, our repurchase of $18.2 million of our 15% notes as well as $8.2 million in cash released from escrow related to the repurchased notes.

As of November 6, 2008, $7.7 million of 9.66% notes had been converted into 20,263,152 shares of our common stock.

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

The following discussion should be read in conjunction with the Condensed Consolidated Financial Statements and the related notes included in Item 1 of this Form 10-Q. The following discussion contains forward-looking statements which involve risks and uncertainties. When used in this 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 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 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 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 developing paclitaxel poliglumex, or OPAXIO, which we had previously referred to as XYOTAX, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. Based on feedback related to our European marketing application submission, we rebranded XYOTAX and therefore now refer to it by the brand name OPAXIO. As announced in March and May 2005, our STELLAR 2, 3, and 4 phase III clinical studies for OPAXIO did not meet their primary endpoints of superior overall survival. However, we believe that the reduction in toxicities coupled with superior convenience and less medical resource utilization 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 patients with PS2 NSCLC. On March 4, 2008, we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or 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 noninferiority 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. In April 2008, we announced that the MAA was accepted for review by the EMEA, resulting in initiation of the marketing approval review process. This review process generally takes 15 to 18 months.

We are also developing OPAXIO for women with pre-menopausal levels of estrogen who have advanced NSCLC with normal or poor performance status. The basis for this clinical study was in part related to a pooled analysis of STELLAR 3 and 4 phase III trials for treatment of first-line NSCLC patients who have PS2, which we believe demonstrates a 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 December 2005, we initiated a phase III clinical trial, known as the PIONEER, or PGT305, study, for OPAXIO as first-line monotherapy in PS2 women with NSCLC. In December 2006, we agreed with the recommendation of the Data Safety Monitoring Board to close the PIONEER lung cancer clinical trial due, in part, to the diminishing utility of the PIONEER trial given our plans to submit a new protocol to the U.S. Food and Drug Administration, or FDA. In early 2007, we submitted two new protocols under a Special Protocol Assessment, or SPA, to the FDA. The new trials, known as PGT306 and

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PGT307, focus 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. 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. We initiated the PGT307 trial in September 2007. 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 a single trial, PGT307, along with supporting evidence from prior clinical trials, may enable us to submit a new drug application, or NDA, in the United States. In early 2008, we limited enrollment on the PGT307 study to U.S. sites only, until either approval of the MAA by the EMEA or until positive results from the GOG0212 trial of OPAXIO for first-line maintenance therapy in ovarian cancer, as discussed below, are reported.

We are also 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, known as GOG0212, is under the control of the Gynecologic Oncology Group and is expected to enroll 1,100 patients by early 2012. A potential interim analysis, based on the number of events in the database, is planned for late 2009 and, if successful, could lead to an NDA filing in 2010.

We are developing pixantrone, a novel anthracycline derivative, for the treatment of non-Hodgkin s lymphoma, or NHL. An interim analysis of our ongoing phase III study of pixantrone, known as the EXTEND or PIX301 study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study continued. In September 2007, we announced that we had reduced the enrollment target and decided to conduct a full analysis of the EXTEND trial, instead of an interim analysis as previously planned. In March 2008, we completed enrollment of approximately 140 patients in the EXTEND trial, 104 of whom are currently evaluable according to Histological Intent to Treat, or HITT, criteria. In November 2008, we announced that we closed the data set for preliminary analysis of the primary endpoint in the EXTEND trial and we plan to report top-line results in November 2008 as well. If final study results are adequate, we could begin a rolling submission of an NDA with the FDA in early 2009. The FDA agreed that randomized safety data from the RAPID study (CHOP-R vs. CPOP-R) could be used to support the EXTEND results in an NDA submission for pixantrone. The RAPID, or PIX203, study is a phase II study in which pixantrone is substituted for doxorubicin in the CHOP-R regimen compared to the standard CHOP-R regimen in patients with previously untreated diffuse large B-cell lymphoma. An interim analysis of the RAPID study was reported in July 2007. The interim analysis of the study 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 reductions in the incidence of severe heart damage, 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 also launched a phase III trial of pixantrone in indolent NHL, the PIX303 trial, in September 2007, which was designed to evaluate the combination of fludarabine, pixantrone and rituximab versus fludarabine and rituximab in patients who have received at least one prior treatment for relapsed or refractory indolent NHL. We closed the PIX303 trial in early 2008 based on, among other considerations, our plans to refocus the Company s resources on obtaining pixantrone approval based on the EXTEND phase III trial before making additional substantive investments in alternative indications for pixantrone as well as the changing competitive landscape in second line follicular NHL. In May 2007, we received fast track designation from the FDA for pixantrone for the treatment of relapsed or refractory indolent NHL.

We are developing brostallicin, which is a small molecule, anti-cancer drug with a novel, unique mechanism of action and composition of matter patent coverage, through our wholly owned subsidiary, Systems Medicine, LLC, or SM. Data in more than 200 patients treated with brostallicin in phase I/II clinical trials reveal evidence of activity in patients with refractory cancer and patient/physician-friendly dosage and administration. A phase II study of brostallicin in relapsed/refractory soft tissue sarcoma met its pre-defined 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 data from that trial is expected to be available for analysis in early 2009. Additionally, we initiated a phase II myxoid liposarcoma trial in

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2007 which was closed to enrollment in October 2008 due to changing business objectives. 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 is a form of cancer therapy called radioimmunotherapy. Zevalin is a CD20-directed, radiotherapeutic antibody indicated as part of the therapeutic regimen for treatment of relapsed or refractory, low-grade or follicular B-cell NHL, including patients with rituximab refractory follicular NHL. It was approved by the FDA in February 2002 as the first radioimmunotherapeutic agent for the treatment of NHL. At the American Society of Hematology meeting in December 2007, Bayer Schering, which holds the rights to Zevalin outside of the United States, published the results of their Phase III first-line indolent NHL trial of Zevalin, known as the FIT trial. In April 2008, based on these results, Bayer Schering received approval from the European Medicines Commission for use of Zevalin as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. We were able to obtain access to the data from the FIT trial under the Access Agreement that we entered into with Bayer Schering in June 2008. Under the terms of the agreement, we made an initial payment of $2.0 million and beginning January 1, 2009, we will also pay royalties on net product sales until an aggregate of $11.5 million in royalties has been paid. In September 2008, following a meeting with the FDA, we announced that data from the FIT trial would be sufficient to support a submission for a supplemental biologics license application, or sBLA. We submitted the sBLA on September 30, 2008 and it was received by the FDA on October 1, 2008. The sBLA proposed a label expansion to include use of Zevalin as consolidation therapy after remission induction in previously untreated patients with follicular NHL. We also requested priority review for the submission, which if granted, would result in a six month review period. If this sBLA is approved by the FDA we are obligated to make an additional payment of $3.0 million to Bayer Schering under the terms of the Access Agreement. We also intend to file an sBLA to remove the requirement for a biodistribution scan from the Zevalin label in 2009.

We are currently focusing our efforts on Zevalin, OPAXIO, pixantrone and brostallicin. As of September 30, 2008, we had incurred aggregate net losses of approximately $1.3 billion since inception. We expect to continue to incur additional operating losses for at least the next year.

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.

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. Product sales are generally recorded upon shipment net of an allowance for estimated product returns and rebates. We analyze historical returns patterns for our products in determining an appropriate estimate for returns allowance. We may need to adjust our estimates if actual results vary which could have an impact on our earnings in the period of adjustment. If customers have product acceptance rights or product return rights, and we are unable to reasonably estimate returns related to that customer or market, we defer revenue recognition until such rights have expired. Our 2008 product sales relate to Zevalin which was acquired from Biogen in December 2007.

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.

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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.

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 Statement of Financial Accounting Standards, or 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.

Our 18.33%, 15.5%, 15%, 13.5%, 10%, 9% and 6.75% 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. 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.

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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 our restructuring activities, including estimates pertaining to employee separation costs, the related abandonment of excess facilities and impairment of fixed assets, and certain contract termination costs. Restructuring charges are recorded 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)*, 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.

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 September 30, 2008 and 2007

Product sales. Product sales for the three months ended September 30, 2008 relate to Zevalin, our commercial product acquired from Biogen in December 2007. We had no product sales during the comparable period in 2007.

License and contract revenue. License and contract revenue for the three months ended September 30, 2008 and 2007 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 September 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. There was no cost of product sold during the comparable period in 2007 as we acquired Zevalin in December 2007.

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

	Three Months Ended September 30,	
	2008	2007
Compounds under development:		
Pixantrone	$ 1,660	$ 4,585
Zevalin	3,026	
Brostallicin	535	772
OPAXIO		5,955
Other compounds	28	130
Operating expenses	5,561	6,583
Discovery research	516	541
Total research and development expenses	$ 11,326	$ 18,566

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 OPAXIO, pixantrone, brostallicin and Zevalin are approximately $216.3 million, $48.3 million, $7.8 million and $5.3 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 and Zevalin prior to our acquisitions of SM and Zevalin in July and December 2007, respectively, are also excluded from this amount.

Research and development expenses decreased to approximately $11.3 million for the three months ended September 30, 2008, from approximately $18.6 million for the three months ended September 30, 2007. Pixantrone costs decreased primarily due to a decrease in clinical development activity mainly related to a decrease in enrollment in our RAPID and EXTEND trials as well as the closure of our PIX303 clinical trial in the fourth quarter of 2007. 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. In September 2007, we announced that we reduced the enrollment target for the EXTEND trial and decided to conduct a full analysis, instead of an interim analysis as previously planned. We closed the PIX303 trial based on, among other considerations, our plans to refocus the Company s resources on obtaining pixantrone approval based on the EXTEND phase III trial before making additional substantial investments in alternative indications for pixantrone, as well as the changing competitive landscape in second line follicular NHL. Zevalin costs resulted from our acquisition of the product in December 2007 and primarily relate to clinical development activity including $2.0 million in expense related to the payment to Bayer Schering for access to the data from the FIT trial. Costs for our brostallicin program decreased primarily due to a reduction in clinical development activities related to phase I and phase II studies. Costs for our OPAXIO program decreased primarily due to an amendment to our contract with the GOG in August 2008 which resulted in a reduction in scope of the GOG0212 study and, accordingly, a reversal of accrued expenses. OPAXIO costs also decreased due to a reduction in our PGT307 trial, which was reduced in scope to U.S. sites only in early 2008, as well as a decrease in manufacturing activity. Operating expenses decreased primarily due to a reversal of accrued benefits during the three months ended September 30, 2008 resulting from a change in estimate, partially offset by an increase in advisory services related to clinical and quality activities.

Our lead drug candidates, OPAXIO, pixantrone 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

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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. Our bisplatinates and HIF1-α drug candidates 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 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.

We will be dependent on the successful completion of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing 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. We reported OPAXIO STELLAR 3 clinical trial results in March 2005 and STELLAR 2 and 4 results in May 2005, all of which missed their primary endpoints of superior overall survival. We have recently submitted an MAA for OPAXIO in the EU 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, however, we do not expect to receive a decision regarding approval of the MAA from the EMEA prior to the second half of 2009. If we do receive approval of that MAA in 2009, we would expect to receive cash inflows in 2009 through collaborative agreements or from sales of the product.

Due to the acquisition of Zevalin, we expect to incur additional costs associated with the implementation of sales and marketing support of Zevalin. In addition, under the terms of the Zevalin FIT trial access agreement with Bayer Schering, we made an initial payment to Bayer Schering of $2.0 million and beginning January 1, 2009, we will also pay royalties on net product sales until an aggregate of $11.5 million in royalties has been paid. An additional payment of $3.0 million will be made upon FDA approval of an sBLA for Zevalin based on the FIT trial results. We do not expect revenue generated from sales of Zevalin will be enough to fund our company-wide ongoing research, development, and operations for the next couple of years. We anticipate that funding to support our ongoing research, development and general operations will primarily come from public or private debt or equity financings, collaborations, milestones and licensing opportunities from current or future collaborators.

Selling, general and administrative expenses. Selling, general and administrative expenses decreased to approximately $7.8 million for the three months ended September 30, 2008, from approximately $8.9 million for the three months ended September 30, 2007. This is due to a $1.0 million decrease resulting from a reduced level of activities, primarily related to corporate communications and corporate development activities. We also had a decrease of approximately $0.8 million in compensation and benefits primarily related to a reversal of accrued benefits during the three months ended September 30, 2008 due to a change in estimate, as well as a $0.7 million decrease in finance and administration activities, including a decrease in expense related to our shareholder meetings. These decreases were offset by an increase of approximately $1.4 million in sales and marketing expenses due to the acquisition of Zevalin in December 2007 and subsequent expansion of our sales force as well as an increase in stock-based compensation of approximately $0.4 million for the period. We expect selling, general and administrative expenses to increase for the remainder of 2008 as compared to 2007 due to sales and marketing activities related to Zevalin.

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Amortization of purchased intangibles. Amortization for the three months ended September 30, 2008 increased to approximately $0.6 million from approximately $0.2 million for the three months ended September 30, 2007 primarily due to the amortization of intangible assets acquired in connection with our acquisition of Zevalin in December 2007 as well as accelerated amortization on the workforce intangible related to our Italian operations.

Acquired in-process research and development. Acquired in-process research and development for the three months ended September 30, 2007 relates to a one-time non-cash charge recorded in connection with our acquisition of SM in July 2007. This balance represents the estimated fair value of purchased technology that had not reached technological feasibility and had no alternative future use at the effective time of the acquisition.

Investment and other income. Investment and other income for the three months ended September 30, 2008 decreased to approximately $0.1 million as compared to $0.6 million for the three months ended September 30, 2007 primarily due to a lower average securities available-for-sale balance.

Interest expense. Interest expense increased to approximately $2.6 million for the three months ended September 30, 2008 from approximately $2.1 million for the three months ended September 30, 2007. This was due to an increase of approximately $1.7 million related to our 5.75% convertible senior notes issued in December 2007 and our 9%, 15% and 18.33% notes issued during 2008. This was offset by a decrease of $0.8 million in interest expense on our 5.75% convertible subordinated and senior subordinated notes due to the exchange of approximately $36.1 million of these notes for our 5.75% senior notes in December 2007, the cancellation of $9.1 million of these notes in exchange for shares of our common stock in February 2008 and repayment of the remaining amount upon maturity in June 2008. In addition, during the three months ended September 30, 2008 we reversed $0.4 million in interest expense accrued at June 30, 2008 for our 13.5% notes due to the repurchase of these notes in the third quarter of 2008.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs increased to approximately $11.1 million for the three months ended September 30, 2008 from approximately $0.3 million for the three months ended September 30, 2007. This increase was primarily due to the accelerated amortization of issuance costs and debt discount related to conversions of our 18.33% and 10% notes. For the three months ended September 30, 2008, amortization of the debt discount related to our 18.33% and 10% notes was approximately $5.5 million and $3.4 million, respectively, while the amortization of debt issue costs was approximately $0.5 million and $0.4 million respectively. The increase was also due to amortization of approximately $1.1 million related to the debt discount and debt issuance costs on our 5.75% convertible senior notes and our 9%, 13.5% and 15% notes.

Foreign exchange gain. The foreign exchange gain for the three months ended September 30, 2008 and 2007 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 $19.1 million for the three months ended September 30, 2008 is related to $15.5 million in payments made upon the conversion of $28.3 million of our 18.33% notes and $3.6 million in payments made upon the conversion of $9.0 million of our 10% notes.

Gain on derivative liabilities, net. The gain on derivative liabilities of $12.9 million for the three months ended September 30, 2008 is primarily due to gains of $6.5 million, $4.6 million and $3.4 million resulting from the change in the fair value of the derivative liabilities related to the embedded conversion options on our 18.33%, 15% and 10% notes, respectively. These gains were offset by a loss of $1.9 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant that was issued in connection with our 13.5% notes and Series E preferred stock financing and modified in July 2008 in connection with the issuance of our 18.33% notes. The gain on derivative liabilities for the three months ended September 30, 2007 was due to the change in the estimated fair value of our derivative liabilities on our 7.5% and 6.75% notes and did not change significantly for the period.

Loss on exchange of convertible notes. The loss on exchange of convertible notes of $10.3 million for the three months ended September 30, 2008 is due to the repurchase of approximately $17.5 million aggregate principal of our 13.5% notes in connection with the issuance of our 18.33% notes.

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Settlement expense. Settlement expense for the three months ended September 30, 2008 relates to payments made to Enable Capital Management LLC, or Enable, for release of all claims against us in connection with our alleged breach of contract related to certain of our preferred stock as discussed further in Note 11, *Legal Proceedings.*

Nine months ended September 30, 2008 and 2007

Product sales. Product sales for the nine months ended September 30, 2008 relate to Zevalin. We had no product sales during the comparable period in 2007.

License and contract revenue. License and contract revenue for the nine months ended September 30, 2008 and 2007 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

Cost of product sold. Cost of product sold for the nine months ended September 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. There was no cost of product sold during the comparable period in 2007 as we acquired Zevalin in December 2007.

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

	Nine Months Ended September 30,	
	2008	2007
Compounds under development:		
Pixantrone	$ 7,794	$ 11,493
Zevalin	5,201	
Brostallicin	3,623	772
OPAXIO	3,153	16,631
Other compounds	203	452
Operating expenses	21,447	19,342
Discovery research	1,617	1,678
Total research and development expenses	$ 43,038	$ 50,368

Research and development expenses decreased to approximately $43.0 million for the nine months ended September 30, 2008, from approximately $50.4 million for the nine months ended September 30, 2007. Pixantrone costs decreased primarily due to a decrease in enrollment in our RAPID and EXTEND trials as well as the closure of our PIX303 clinical trial in the fourth quarter of 2007. These decreases were partially offset by an increase in manufacturing activity. Zevalin costs resulted from our acquisition of the product in December 2007 and primarily relate to clinical development activity including $2.0 million in expense related to the payment to Bayer Schering for access to the data from the FIT trial. Costs for our brostallicin program increased as a result of our acquisition of SM in July 2007 and are primarily due to clinical development activities related to phase I and phase II studies. Costs for our OPAXIO program decreased primarily due to our PGT307 trial, which was reduced in scope to U.S. sites only in early 2008, reduced costs associated with our PIONEER trial which was suspended and closed in the fourth quarter of 2006 and incurred certain wrap-up costs in the first half of 2007, a decrease in the GOG0212 study related to the amendment to our contract with the GOG, as well as a decrease in manufacturing activity. Operating expenses increased primarily due to an increase in foreign currency rates associated with our Italian operations, the acquisition of SM in July 2007, and an increase in advisory services related to clinical and quality activities offset by a decrease due to a reversal of accrued benefits during the nine months ended September 30, 2008 resulting from a change in estimate.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $30.5 million for the nine months ended September 30, 2008, from approximately $24.6 million for the nine months ended September 30, 2007. This is attributed to a $4.6 million increase in sales and marketing expenses due to the acquisition of Zevalin in December 2007 and subsequent expansion of our sales force. There was also an increase in our stock-based compensation expense of approximately $1.5 million and we also had an increase in our legal expenses of approximately $1.0 million primarily due to our claim against the Lash Group, Inc.

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and Documedics Acquisition Co., Inc. In addition, we incurred $0.9 million in legal and consulting fees associated with the potential spin-off of certain assets in connection with the planned establishment of a separate joint venture. We expect to receive reimbursement for these fees in the event of the formation and capitalization of the new entity. These increases were offset by a decrease of approximately $1.3 million in finance and administration expenses primarily related to a decrease in expenses associated with our shareholder meetings as well as a decrease in certain taxes and insurance premiums. We also had a $0.5 million decrease in depreciation costs related to our Italian operations.

Amortization of purchased intangibles. Amortization for the nine months ended September 30, 2008 increased to approximately $1.5 million from approximately $0.6 million for the nine months ended September 30, 2007 primarily due to the amortization of intangible assets acquired in connection with our acquisition of Zevalin in December 2007 as well as accelerated amortization on the workforce intangible related to our Italian operations.

Acquired in-process research and development. Acquired in-process research and development for the nine months ended September 30, 2008 relates to adjustments to our one-time charge recorded in connection with our acquisition of Zevalin in December 2007. These adjustments resulted from changes in the estimated acquisition costs used in determining the total estimated purchase price of the acquisition. The amount for the nine months ended September 30, 2007 relates to a one-time non-cash charge recorded in connection with our acquisition of SM in July 2007.

Investment and other income. Investment and other income for the nine months ended September 30, 2008 decreased to approximately $0.5 million as compared to $2.1 million for the nine months ended September 30, 2007 primarily due to a lower average securities available-for-sale balance.

Interest expense. Interest expense increased to approximately $7.0 million for the nine months ended September 30, 2008 from approximately $6.1 million for the nine months ended September 30, 2007. This was due to an increase of approximately $2.7 million related to our 5.75% convertible senior notes issued in December 2007 and our 9%, 15% and 18.33% notes issued during 2008. These increases were offset by a decrease of $2.1 million in interest expense on our 5.75% convertible subordinated and senior subordinated notes.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs increased to approximately $52.3 million for the nine months ended September 30, 2008 from approximately $3.9 million for the nine months ended September 30, 2007. This increase was primarily due to the accelerated amortization of issuance costs and debt discount related to conversions of certain of our convertible notes issued in 2008. For the nine months ended September 30, 2008, amortization of the debt discount related to our 13.5%, 9%, 18.33% and 10% notes was approximately $23.4 million, $13.1 million, $5.5 million and $3.4 million, respectively, and the amortization of debt issue costs was approximately $2.0 million, $1.9 million, $0.5 million and $0.4 million, respectively. This amortization was primarily due to conversions of these notes during the nine months ended September 30, 2008. These increases were offset by a decrease of $2.9 million in amortization of the debt discount and issuance costs on our 7.5% notes primarily related to conversions of these notes during the nine months ended September 30, 2007.

Foreign exchange gain. The foreign exchange gain for the nine months ended September 30, 2008 and 2007 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 $52.5 million for the nine months ended September 30, 2008 is related to $22.4 million in payments made upon the conversion of $27.6 million of our 13.5% notes, $15.5 million made upon conversion of $28.3 million of our 18.33% notes, $11.0 million in payments made upon the conversion of $40.8 million of our 9% notes and $3.6 million made upon conversion of $9.0 million of our 10% notes. Make-whole interest expense of $2.3 million for the nine months ended September 30, 2007 is due to payments made related to the conversion of $15.3 million of our 7.5% notes.

Gain on derivative liabilities, net. The gain on derivative liabilities of $56.1 million for the nine months ended September 30, 2008 is primarily due to gains of $22.3 million, $12.0 million, $6.5 million, $4.5 million and $3.4 million resulting from the change in the estimated fair value of the derivative liabilities related to the interest

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embedded conversion option on our 13.5%, 9%, 18.33%, 15% and 10% notes, respectively. There was also a gain of $7.3 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant that was issued in connection with our 13.5% notes and Series E preferred stock financing and modified in June and July 2008 in connection with the issuance of our 15% and 18.33% notes. The amount of $3.6 million for the nine months ended September 30, 2007 primarily represents the change in the estimated fair value of our derivative liability related to the interest make-whole provision on our 7.5% notes.

Loss on exchange of convertible notes. The loss on exchange of convertible notes of $15.9 million for the nine months ended September 30, 2008 consists of a $10.3 million loss due to the repurchase of approximately $17.5 million aggregate principal of our 13.5% notes in connection with the issuance of our 18.33% in July and August 2008, 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 0.7 million shares of our common stock.

Write-off of financing arrangement costs. The write-off of financing arrangement costs of $2.4 million for the nine months ended September 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 is primarily due to significant uncertainty regarding our ability to pursue further financings under the agreement.

Settlement expense. Settlement expense for the nine months ended September 30, 2008 relates to payments made to Enable for release of all claims against us in connection with our alleged breach of contract related to certain of our preferred stock. The amount for the nine months ended September 30, 2007 relates to interest accrued on the $10.5 million payment to the USAO for release of all claims in connection with the investigation of our marketing practices relating to TRISENOX and related matters. Interest was accrued from the date of reaching an agreement in principle with the USAO in the fourth quarter of 2006 and the payment was made in April 2007.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2008, we had approximately $11.7 million in cash and cash equivalents, securities available-for-sale and interest receivable. In addition, in October 2008 we issued $24.7 million of 9.66% convertible senior notes, or 9.66% notes, for net proceeds, before fees and expenses, of $7.5 million after taking into account $7.2 million placed in escrow to fund make-whole payments and interest payments on the notes, our repurchase of $18.2 million of our 15% notes as well as $8.2 million in cash released from escrow related to the repurchased notes.

Net cash used in operating activities decreased to approximately $65.1 million during the nine months ended September 30, 2008, compared to approximately $85.0 million for the same period during 2007 primarily due to a decrease in cash payments made for operating expenses and an increase in cash collected from our sales of Zevalin. The significant increase in make-whole interest expense paid during the nine months ended September 30, 2008 is attributed to make-whole payments made on our 9%, 13.5%, 18.33% and 10% notes, which were paid out of restricted cash released from escrow upon conversion of these notes.

Net cash used in investing activities of approximately $494,000 for the nine months ended September 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 investing activities of approximately $10.3 million for the nine months ended September 30, 2007 was primarily due to proceeds from sales and maturities of securities available-for-sale offset by purchases of securities available-for-sale.

Net cash provided by financing activities of approximately $61.1 million for the nine months ended September 30, 2008 was primarily due to the issuances of our convertible senior notes. Proceeds from the issuance of 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 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

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approximately $19.6 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. Upon cancellation of the 9% notes, $1.4 million was released to us from the amount placed in escrow to fund make-whole payments. Proceeds from the issuance of our 15% notes were approximately $11.5 million, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. We received approximately $1.8 million in proceeds from the issuance of our 18.33% notes, net of issuance costs, restricted cash placed in escrow to fund make-whole payments and the repurchase of approximately $17.5 million of our 13.5% notes and warrants. Upon cancellation of the 13.5% notes and warrants, $6.5 million was released to us from the amount placed in escrow to fund make-whole payments. We received proceeds of approximately $10.5 million from the issuance of our 10% and 15.5% notes, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. In connection with these issuances, we made another deemed dividend payment of approximately $2.0 million to induce existing holders of our Series C preferred stock to convert their shares of preferred stock into common stock. We also received approximately $3.9 million in net proceeds from the issuance of common stock under our equity line of credit. 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. Net cash provided by financing activities of approximately $72.1 million for the nine months ended September 30, 2007 was primarily due to net proceeds of $18.6 million received from the sale of 20,000 shares of our Series A 3% convertible preferred stock and common stock warrants in February 2007, net proceeds of $34.8 million received from the sale of 37,200 shares of our Series B 3% convertible preferred stock and common stock warrants in April 2007 and net proceeds of $19.0 million received from the sale of 20,250 shares of our Series C 3% convertible preferred stock and common stock warrants in July 2007.

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 we expect to generate losses from operations for at least the next couple of years primarily due to research and development costs for Zevalin, OPAXIO, pixantrone, and brostallicin. Our existing cash and cash equivalents, securities available-for-sale and interest receivable, including the net proceeds raised in October as discussed above, is not sufficient to fund our planned operations through the end of the fourth quarter. This raises substantial doubt about our ability to continue as a going concern. Accordingly, we have implemented cost saving initiatives to reduce operating expenses 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. There is an additional $44.5 million in aggregate exercise price under the B unit warrant. However, no exercise of that additional aggregate exercise amount may be made unless and until both the purchaser of the B unit warrant and the Company agree to the exercise. Therefore, neither party can compel the exercise of the remainder of the B unit warrant. Additionally, we have an equity line of credit relationship under which we have remaining the lesser amount of approximately $8.0 million in gross proceeds or approximately 1.2 million shares of our common stock which, based on our stock price of $0.33 as of November 3, 2008, would be approximately $0.4 million in gross proceeds. 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 capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs.

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We may receive certain grants and subsidized loans from the Italian government and the EU through our Italian operations. However, to date such grants have not been significant and we may not receive such funding because the grants and subsidies are awarded at the discretion of the relevant authorities. However, our Italian branch will continue to apply for public financing when possible. In addition, 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; 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 September 30, 2008 (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**1 Year**	**2-3 Years**	**4-5 Years**	**After 5 Years**
18.33% Convertible senior notes (1)	$ 16,250	$	$ 16,250	$	$
15.5% Convertible senior notes (2)	14,211			14,211	
15% Convertible senior notes (3)	23,000		23,000		
9% Convertible senior notes (4)	5,585			5,585	
7.5% Convertible senior notes (5)	33,458		33,458		
6.75% Convertible senior notes (6)	7,000		7,000		
5.75% Convertible senior notes (7)	23,000			23,000	
4.0% Convertible senior subordinated notes (8)	55,150		55,150		
Interest on convertible notes (9)	44,003	15,644	25,666	2,693	
Convertible preferred stock (10)	11,052	11,052			
Operating leases:					
Facilities	24,720	6,157	11,932	6,587	44
Long-term obligations (11)	1,682	375	828	479	
Purchase commitments (12)	3,195	932	799	1,065	399
	$ 262,306	$ 34,160	$ 174,083	$ 53,620	$ 443

(1) The 18.33% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of approximately 126.582 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $7.90 per share.

(2) The 15.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 787.4 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $1.27 per share.

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(3) The 15% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 126.58228 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $7.90 per share.

(4) The 9% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 70.922 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $14.10 per share.

(5) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 11.96298 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $83.59 per share.

(6) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 9.50925 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $105.16 per share.

(7) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 33.33333 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $30.00 per share.

(8) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 1.85185 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $540.00 per share.

(9) $29.4 million of interest due on convertible notes is included in our restricted cash balance and is being held in an escrow account.

(10) Our convertible preferred stock is redeemable at the option of holders at any time after the two-year anniversary of the original issue date as follows: $550,000 of Series A preferred stock is redeemable in February 2009, $5,218,000 of Series B preferred stock is redeemable in April 2009, $4,284,000 of Series C preferred stock is redeemable in July 2009 and $1,000,000 of Series D preferred stock is redeemable in December 2009.

(11) Long-term obligations does not include $6.2 million of contingent consideration related to our acquisition of Zevalin, $1.2 million related to excess facilities charges and $0.9 million recorded as a long-term obligation for benefits owed to our Italian employees pursuant to Italian Law. The timing of the payments related to this obligation is unknown as the benefit is paid upon an employee s separation from the Company.

(12) This amount primarily relates Zevalin inventory purchase commitments pursuant to our supply agreement with Biogen that was entered into on December 21, 2007 in connection with the acquisition of U.S. rights to develop, market and sell Zevalin. Under the terms of the supply agreement, we are required to purchase from Biogen an amount of Zevalin every six months. We provide rolling forecasts of our supply requirements to Biogen in six-month increments for the next 24 months; however, under the terms of the agreement we are required to purchase a minimum of 150 packages, or 300 kits, for each six-month period in 2008, 2009 and 2010, and a minimum of 250 packages, or 500 kits, for each six-month period thereafter until the expiration of the term on June 9, 2014, unless earlier terminated. Each forecast for the next six-month period must be accompanied by a firm order.

Additional Milestone Activities

We have an amended agreement with PG-TXL Company L.P. 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. Currently, we expect to make a $1.0 million payment in the fourth quarter of 2008 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.

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

In connection with our acquisition of Zevalin, we may be required to pay Biogen up to $20.0 million in additional milestone payments based on positive trial outcomes and FDA approval for label expansion. This includes a $10.0 million payment that is due upon approval from the FDA to expand the labeling for the product with respect to an indolent NHL indication. If the FDA grants priority review of the sBLA that was submitted in September 2008, this payment could occur in the first half of 2009.

Pursuant to an acquisition agreement entered into with Cephalon, Inc. in June 2005, we may receive up to $100 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, we may receive up to $374 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.

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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 maintain 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 September 30, 2008 and December 31, 2007 was $1.2 million and $2.5 million, respectively. For each one percent change in interest rates, the change in the fair value of our securities available-for-sale would be immaterial.

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 remains the U.S. dollar, a significant portion of our consolidated costs now 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 (foreign funds). Based on the balance of foreign funds at September 30, 2008 of $0.2 million, an assumed 5%, 10% and 20% 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 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, 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 Chief Financial Officer, 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 Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

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(b) Changes in Internal Control over Financial Reporting

Due to the timing of our acquisitions of Systems Medicine, Inc. and our commercial product, Zevalin, both were excluded from the scope of our assessment of internal controls over financial reporting for the period ended September 30, 2008. We have begun to implement certain controls during 2008; however, we anticipate implementing additional controls related to these recent acquisitions. These changes could include implementing transactional controls at the subsidiary level and implementing additional controls surrounding revenue recognition and cash receipts related to product sales. In addition, during the second half of 2008, we have started to implement Oracle EBS for financial reporting. New controls will be implemented and tested in 2009 as a result of the new financial system integration.

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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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Recent Legal Proceedings

Based on language (the Disputed Language) contained in the Articles of Amendment to our Articles of Incorporation (the Amendments) filed in connection with the issuance of the Company s Series A, Series B and Series C Convertible Preferred Stock (the Preferred Stock), certain holders thereof (the Shareholders) asserted a right to consent (or not) to the transactions contemplated by the Exchange Agreements entered into by us and certain holders of our then existing convertible debt on December 12, 2007 (the Exchange). We are of the view that inclusion of the Disputed Language in the Amendments constitutes a scrivener s error without legal force or effect, and filed Articles of Correction with the Secretary of State of Washington in accordance with Section 23B.01.240 of the Revised Code of Washington. On January 2, 2008, Tang Capital Partners LP (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 Series B Preferred Stock. Tang alleges that our filing of Articles of Correction to the Articles of Amendment to the Amended and Restated Articles of Incorporation on or around December 11, 2007, materially and adversely altered the powers, preferences or rights conferred through its Securities Purchase Agreement, thereby constituting a Triggering Event. On September 23, 2008, Tang filed a motion with the court for issuance of a judgment in their favor, and there is not yet a court schedule on proceedings related to this motion. Tang seeks a judgment ordering CTI to redeem its Preferred Stock for 130% of the Stated Value of such stock of $3 million, plus interest at 18% per annum on this amount from approximately December 17, 2007 to the date of judgment, plus attorneys fees. As of this date, CTI estimates that the amount of such a judgment to which it is exposed if CTI does not prevail will be approximately $2.1 million comprised of alleged contractual penalties, interest and attorneys fees and an additional $3 million to redeem the principal value of the Preferred Stock. The interest and attorneys fees components may increase with time if the litigation continues.

Another holder of our Series C Preferred Stock, Enable Capital Management LLC (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 March 21, 2008, Enable filed an amended complaint, asserting an additional claim against us for breach of contract and breach of the covenant of good faith and fair dealing. Enable alleges that on or about March 4, 2008, we committed a further breach of our obligations by offering and/or paying consideration to certain holders of our preferred stock to induce those holders to convert their preferred stock into common stock without making the same offer to Enable. On September 29, 2008, in exchange for payments totaling $2,450,000, Enable entered into a release agreement with us to fully resolve this action.

On May 5, 2008, RHP Master Fund, Ltd. (RHP), a holder of our Series A Preferred Stock filed suit in the United States District Court for the Southern District of New York against us and certain officers and directors alleging breach of contract and violation of Washington Business Corporation Act by us and breach of fiduciary duty by the officer and director defendants. RHP alleges claims similar to those raised in Enable s amended complaint, namely that we breached our obligations to RHP by offering and paying consideration to certain holders of our Series A Preferred Stock to induce those holders to convert their preferred stock into common stock as part of the March 4, 2008 financing transaction without making the same offer to RHP. Following the filing of a motion to dismiss the complaint by the officer and director defendants, RHP filed an amended complaint on July 31, 2008. The amended complaint asserts the same causes of action as the original complaint. We dispute each of the claims asserted against us, and litigation is ongoing. At this time, we are not able to make a determination whether the likelihood of an unfavorable outcome is probable or remote.

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® (arsenic trioxide), seeking recovery of damages, including losses incurred by the Company in connection with our above referenced USAO investigation, defense and settlement of claims by the government 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 against The Lash Group. The parties have completed production of documents and fact witness depositions, and served expert

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reports. On June 19, 2008, the trial court entered judgment dismissing our claims for indemnification against The Lash Group on the legal ground that all False Claims Act (FCA) defendants are legally barred from filing such claims, notwithstanding that there has been no finding that the defendant engaged in any wrongdoing, and notwithstanding that the party sued may have been directly responsible for the conduct at issue in the FCA as a result of its erroneous advice, negligent services, and its own false and misleading statements about reimbursement to the government and physicians. We disagree with the Court s legal conclusion that negligent consultants may not be sued for indemnification pursuant to the express language of their contracts, and on July 19, 2008, we filed a Notice of Appeal with the Ninth Circuit Court of Appeals. We will seek a ruling that no law prohibits a defendant who settles FCA claims with the government from pursuing meritorious claims for contractual indemnification from responsible consultants. If successful, we intend to return to the United States District Court for trial, and seek more than $20 million in damages for liabilities and business losses that we contend were caused by Lash s negligent or reckless advice and its misleading communications concerning Medicare s obligation to reimburse doctors for TRISENOX. There is no guarantee that we will prevail on appeal or at trial.

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. We made the settlement payment of $10.6 million in April 2007, which included a settlement amount of $10.5 million and interest accrued on that amount since the date of reaching an agreement in principle. The settlement agreement did not address separate claims brought against us by the private party plaintiff. The private party plaintiff filed a petition for attorney s fees and costs in the approximate amount of $1.4 million on July 31, 2008. We have filed materials in opposition to this petition. There is no guarantee that we will partially or wholly prevail in opposing the petition for fees. At this time, no estimate of loss can be made.

Item 1A. Risk Factors

Factors Affecting Our Operating Results and Financial Condition

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of September 30, 2008, we had an accumulated deficit of approximately $1.3 billion. We are pursuing regulatory approval for OPAXIO, pixantrone and brostallicin and plan to seek regulatory approval for the expansion of approved uses of Zevalin. 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, will result in operating losses for the foreseeable future. We may never become profitable, even if we are able to commercialize products currently in development or otherwise.

Our debt and operating expenses exceed our net revenues.

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. We have a single drug we are marketing, Zevalin, and the net proceeds of sales of this drug are not sufficient to pay our debt and operating expenses on a current basis. We do not currently project that net revenues from sales of any of our products will be sufficient to cover our existing debt and operating expenses within the next twelve months. We need to raise capital to continue to fund our operations as our current cash resources would not fund us through the end of the fourth quarter. Unless we raise substantial additional capital, 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 need to raise additional funds and expect that we will need to continue to raise funds in the future, and funds may not be available on acceptable terms, or at all.

We have substantial operating expenses associated with the development of our product candidates and as of September 30, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately $11.7 million, and total current liabilities of approximately $39.7 million. We also have a substantial amount of debt outstanding: as of September 30, 2008, we had an aggregate principal balance of approximately $177.7 million in convertible notes, which does not take into account $24.7 million of 9.66% notes issued in

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October 2008 offset by conversions of $7.7 million of these notes, the repurchase of $18.2 million of our 15% notes and $14.2 million in conversion of our 15.5% notes. We also have an additional $44.5 million aggregate exercise price under our B unit warrant, however, no exercise of that amount may be made unless both the purchase of the B unit warrant and the Company agree to the exercise. Additionally, we have implemented an ongoing equity line of credit, under which the remaining amount available is the lesser of approximately $8.0 million in gross proceeds or approximately 1.2 million shares of our common stock which, based on our stock price of $0.33 as of November 3, 2008, would be approximately $0.4 million in gross proceeds. We expect that our existing cash and cash equivalents, securities available-for-sale and interest receivable, including proceeds received from our offering in October, will not provide sufficient working capital to fund our presently anticipated operations through the end of the fourth quarter, and we therefore need to raise additional capital.

We may seek to raise such 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. 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 OPAXIO, pixantrone, brostallicin, expanded uses of Zevalin and other products we may be developing. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the U.S., which may increase our costs and adversely affect our ability to obtain financing. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, shareholders may experience dilution of their proportionate ownership of us.

We recently announced a study data set cut-off for our phase III pivotal pixantrone trial and are awaiting top-line results which are critically important to us.

On November 3, 2008, we announced that we had closed the data set for preliminary analysis of the primary endpoint in the phase III EXTEND (PIX301) trial of pixantrone for patients with relapsed diffuse large B cell non-Hodgkin s lymphoma and had also provided notice to Novartis that the data set has been closed. We have an existing license and co-development agreement with Novartis for OPAXIO which also provides Novartis with an option to enter into an exclusive worldwide license to develop and commercialize pixantrone based upon agreed upon terms. The primary endpoint for the PIX301 study is complete remission (CR) and unconfirmed complete remission (uCR) in patients receiving either pixantrone or another single agent chemotherapeutic drug.

A third party contract research organization is currently reviewing this data and we expect them to provide us with preliminary top-line results shortly and to report such data in the fourth quarter. There can be no assurance that we will be able to complete our evaluation of or report data in such time frame. There can also be no assurance that the data, once reported, will be favorable or will be sufficient to demonstrate the safety and efficacy for purposes of obtaining FDA approval. If the primary endpoints of the PIX301 are not met, we will need to assess whether to continue to develop pixantrone. If the primary endpoints are met, there can be no assurance that such preliminary top-line results will not be affected by further analysis of the data, that we will have sufficient resources to continue to pursue FDA approval of pixantrone or that such results will be sufficient to support an NDA filing in 2009. Furthermore, there can be no assurance that Novartis would elect to exercise its option for pixantrone at such time or within the specified time period for doing so.

We may not be able to maintain the listing of our common stock on the Nasdaq Global Market, which would make it more difficult for investors to sell shares of our common stock, may trigger acceleration of our indebtedness and would require us to redeem our outstanding preferred stock.

Our common stock is listed on the Nasdaq Global Market. The Nasdaq Global Market has several quantitative and qualitative requirements companies must comply with to maintain this listing, including a $1.00 minimum bid price per share and $50 million minimum value of listed securities. On April 16, 2008, we received notice from the Nasdaq Stock Market (Nasdaq) that our common stock had a closing bid price below $1.00 for at least 30 consecutive business days and that, therefore, we were not in compliance with the listing standards of the Nasdaq Global Market. Pursuant to the Nasdaq Marketplace rules, we were granted a period of 180 calendar days from the date of notice, or until October 13, 2008, to regain compliance by again meeting the $1.00 minimum bid price for ten consecutive business days. We effected a 1-for-10 reverse stock split on August 31, 2008, and on September 23, 2008 we received a letter from Nasdaq stating that we had regained compliance with the $1.00 minimum bid requirement. However, our stock price is currently below $1.00 and there can be no assurance that we will be able to maintain compliance with the bid requirement. Nevertheless, on October 16, 2008, Nasdaq suspended the bid price requirement for all listed companies through January 16, 2009.

In addition, we received notice of deficiency from Nasdaq on September 5, 2008 because the market value of our listed securities had fallen below the $50 million minimum requirement for 10 consecutive business days. Accordingly, pursuant to the Nasdaq Marketplace Rules, we were granted a period of 30 calendar days to regain compliance with the market value of listed securities requirement. On October 7, 2008 we received a letter from Nasdaq stating that because we failed to regain compliance with the $50 million minimum value of listed securities requirement, our common stock would be subject to delisting unless we requested a hearing before a Nasdaq Listing Qualifications Panel (the

Panel). We timely requested a hearing. As a result, the delisting has been stayed pending a decision by the Panel following the hearing. However, there can be no assurances that the Panel will grant our request for continued listing on the Nasdaq Stock Market.

Additionally, we do not currently meet the requirements to transfer our securities listing to the Nasdaq Capital Market which requires, among other things, a $35 million minimum value of listed securities. The level of trading activity of our common stock may decline if it is no longer listed on the Nasdaq Global Market or Nasdaq Capital Market. Furthermore, our failure to maintain a listing on the Nasdaq Stock Market constitutes a triggering event for the redemption of our outstanding preferred stock and may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, if our common stock ceases to be

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listed for trading on the Nasdaq Stock Market for any reason, it may harm our stock price, increase the volatility of our stock price, make it more difficult to for investors to buy or sell shares of our common stock, and/or cause a highly damaging acceleration of indebtedness and would require us to redeem our outstanding shares of preferred stock. In addition, if we are not listed the Nasdaq Stock Market and/or if our public float remains below $75 million, we may 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 might 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 continued 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 have received a going concern opinion 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 report on our December 31, 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.

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 stock is traded on the MTA stock market in Milan, Italy and we are required to also comply with the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or 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 agencies regulate companies listed on Italy s public markets. Conducting our operations in a manner that complies with all 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 applicable regulatory regimes. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

In addition, under Italian law, we must publish a listing prospectus that has been approved by CONSOB prior to issuing common stock in any twelve-month period that exceeds 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 year. We filed our initial listing prospectus with CONSOB in April 2007 and worked with CONSOB to meet their 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. We continue to pursue the possibility of publishing a listing prospectus to cover other financing efforts under Italian law, however, at the present time we have not been successful in getting approval from the Italian regulators for such a listing prospectus. As a result, 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 as convertible preferred stock and convertible debt are not subject to the 10% limitation imposed by Italian law.

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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 based in Italy. We are subject to duties and risks arising from doing business in Italy, such as:

- Italian employment law, including collective bargaining agreements negotiated at the national level and over which we have no control;
- European data protection regulations, under which we will be unable to send private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices until our U.S. offices self-certify their adherence to the safe harbor framework established by the U. S. Department of Commerce in consultation with the European Commission;
- tariffs, customs, duties and other trade barriers; and
- capital controls, terrorism and other political risks.

We are also subject to the following operational challenges, among others, as a result of having a portion of our business and operations based in Italy:

- effectively pursuing the clinical development and regulatory approvals of all product candidates;
- successfully commercializing products under development;
- coordinating research and development activities to enhance introduction of new products and technologies;
- coalescing the Italian business culture with our own and maintaining employee morale; and
- maintaining appropriate uniform standards, controls, procedures and policies relating to financial reporting and employment related matters, and the conduct of development activities that comply with both U.S. and Italian laws and regulations.

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 the results of our operations.

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

As a result of 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, a portion of our consolidated financial obligations will arise in euros. In addition, 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.

In 2006, we identified material weaknesses in our internal control over financial reporting and we received an adverse opinion on internal control over financial reporting from our independent registered public accounting firm in connection with their annual internal control attestation process for fiscal year 2006.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis. We identified that as of December 31, 2006 we had material weaknesses in our European branch relative to the effectiveness of our internal control over financial reporting which were remedied during 2007.

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The existence of a material weakness is an indication that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we fail to maintain an effective system of internal controls, we may not be able to report our financial results accurately, which may deprive management of important financial information needed to manage the Company effectively, may cause investors to lose confidence in our reported financial information and may have an adverse effect on the trading price of our common stock.

We may not be successful in transferring certain of our operations to a new entity, which may mean that certain expenses incurred in connection with the proposed spin-off would not be reimbursed.

We currently expect to spin out certain of our operations into a new entity to be funded in part by outside investors, and have incurred legal fees and other costs in connection with that spin out. While we expect most of those fees to be repaid upon the funding of the new entity and the completion of the transfer of our related operations, there can be no assurance that the new entity will be funded or that we can complete the transfer of the related operations. If the new entity is not formed and the related operations are not transferred to that new entity, we will be required to pay all expenses we have incurred in connection with the spin out without reimbursement and may be required to continue to support such business operations in full.

If we are not able to successfully integrate recent and future acquisitions, our management s attention could be diverted, and efforts to integrate future acquisitions could consume significant resources.

The acquisitions of SM and of Zevalin, or any other future acquisition that we may undertake, involve numerous risks related to the integration of the acquired asset or entity into the Company after the acquisition is completed. These risks include the following:

- difficulties in integrating the operations, technologies, and products of the acquired companies;
- difficulties in implementing internal controls over financial reporting;
- diversion of management s attention from normal daily operations of the business;
- inability to maintain the key business relationships and the reputations of acquired businesses;
- entry into markets in which we have limited or no prior experience and in which competitors have stronger market positions;
- dependence on unfamiliar affiliates and partners;
- reduction in the development or commercialization of existing products due to increased focus on the development or commercialization of the acquired products;
- responsibility for the liabilities of acquired businesses;
- inability to maintain our internal standards, controls, procedures and policies at the acquired companies or businesses; and
- potential loss of key employees of the acquired companies.

In addition, if we finance or otherwise complete acquisitions by issuing equity or convertible debt securities, our existing shareholders may be diluted.

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If we are unable to expand label usage of Zevalin, or maintain or obtain improved reimbursement rates, we may not recognize the full value of the asset and there may be adverse effects on our expected financial and operating results.

We intend to seek expansion of the approved uses, or labeled uses, of Zevalin in the United States. However, we may be unable to obtain approval for such label expansion in full or in part. If we are not able to obtain approval for expansion of the labeled uses for Zevalin, or if we are otherwise unable to fulfill our marketing, sales and distribution plans for Zevalin, we may not recognize the full anticipated value of Zevalin. If we do not expand the approved uses of Zevalin, we may have insufficient net revenues to finance our current levels of debt and operations unless we are able to market and sell other products. We recently entered into an agreement with Bayer Schering for access to data from their first line indolent trial, or FIT trial. Although we submitted an sBLA based on the FIT trial data in September 2008, there can be no guarantee that such data will be adequate or suitable for approval of the sBLA by the FDA.

In 2007, the Centers for Medicare and Medicaid Services, or CMS, implemented new outpatient reimbursement rates to be put in place in 2008 for radiopharmaceuticals, including Zevalin. These new rates are below the acquisition costs of Zevalin. Congress passed legislation in late 2007 to delay the implementation of those new rates and stabilize reimbursement rates for the first six months of 2008 and subsequently passed legislation in July 2008 to extend that delay an additional 18 months to January 1, 2010, with the intention of giving drug manufacturers and CMS more time to reach an agreement that more adequately reflects hospitals costs associated with the therapy. However, there can be no guarantee that CMS will agree to a rate or methodology that provides an acceptable reimbursement on radiopharmaceuticals such as Zevalin. In the event that CMS does not agree to a reimbursement rate that is adequate to cover the acquisition costs of Zevalin, we may face immediate and significant difficulty in getting care providers to use Zevalin, which would have an adverse impact on our expected financial and operating results.

We may face difficulties in achieving broader market acceptance of Zevalin if we do not invest significantly in our sales and marketing infrastructure.

We currently market Zevalin using a direct sales force that we recently hired in connection with our acquisition of Zevalin from Biogen. U.S. sales of Zevalin by its prior owner either declined or remained flat over the past several years and we expect such sales to remain flat in 2008. We believe that our sales and marketing strategy, in conjunction with our efforts to obtain approval by the FDA for expanded uses of Zevalin, will increase sales of and revenue from Zevalin over the next few years. Our sales and marketing strategy intends to take advantage of the recent lowering of barriers to adoption, including greater economic incentives and practice efficiencies for Zevalin compared to rituximab, the recent adoption of positron emission tomography in community oncology practices, which facilitates use of Zevalin, and implementation of a Zevalin community access program, which targets facilitation of on-site ordering, receipt, and administration of Zevalin by the 100 largest community oncology group practices. However, implementation of the sales and marketing strategy will require an investment of resources and may not increase Zevalin revenues according to our forecasts. In addition, creation and expansion of an effective sales force may take time, and competition for sales and marketing personnel in our industry is intense. Therefore, we will need to effectively manage and expand our sales force, hire individuals with additional technical expertise, expand our distribution capacity or otherwise grow our sales and marketing infrastructure in order to achieve broader market acceptance and additional sales revenue from Zevalin. In addition to the factors just listed, if we do not effectively manage our sales force, our financial condition and operating results may suffer.

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 elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option related to pixantrone and we are able to reach a definitive agreement. Novartis is under no obligation to make such election or exercise such right and may never do so. In addition, even if Novartis

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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. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time on written notice to us.

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.

There are no guarantees that we will obtain regulatory approval to manufacture, market, or expand the marketing of 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 large 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. We have decided not to initiate an additional study, the PGT306 trial, for which we have submitted a special protocol assessment, or SPA, to conserve limited financial resources. 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 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. The MAA was accepted for review by the EMEA in April 2008, 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 will be 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. With the exception of Zevalin, none of our current products have received approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business and financial condition will be adversely affected.

Our marketed products, such as Zevalin, are and will be subject to extensive regulations regarding their promotion and commercialization. For instance, we are subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for our products that receive marketing approval. For example, federal statutes generally prohibit providing certain discounts and payments to physicians to encourage them to

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prescribe our product. Violations of such regulations or statutes may result in treble damages, criminal or civil penalties, fines or exclusion of CTI or its 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 our sales force is relatively new, 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 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, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement, and in connection with the acquisition of Zevalin, a commercially approved drug, we also entered into a corporate integrity agreement with the HHS-OIG that requires us to establish a compliance committee and compliance program and adopt a formal code of conduct. The USAO settlement does not address separate claims brought against the Company by the private party plaintiff in this matter, which generally relate to attorney s fees and employment related claims. In 2007, the United States District Court dismissed the private party plaintiff s employment claims as barred by applicable statutes of limitation. In July 2008, the private party plaintiff filed a petition seeking approximately $1.4 million in attorneys fees and costs. While we intend to oppose this petition, there can be no guarantee that we will partially or wholly prevail in such opposition to the petition for fees.

We rely on third parties for the manufacture and supply of Zevalin and for the manufacture and supply of radioactive isotopes used in the administration of Zevalin.

We currently rely on Biogen to manufacture and supply Zevalin to us through a long-term manufacturing agreement, and Biogen may, in turn, rely on other third-party manufacturers to fill its requirements for manufacturing Zevalin. If Biogen or any third party contract manufacturing organization, or CMO, or contract service provider, or CSP, upon which it relies does not produce or test and release Zevalin in sufficient quantities and on a timely and cost-effective basis, or if Biogen or any third party CMO or CSP does not obtain and maintain all required manufacturing approvals, our business could be harmed. In addition, we rely on MDS Nordion (MDS Canada) for the manufacture and supply of Yttrium-90, a radioactive isotope used in the administration of Zevalin therapy. MDS Nordion (MDS Canada) is currently our sole source of Yttrium-90, which must be manufactured and shipped in such a way as to ensure the appropriate potency of the isotope based on its radioactive half-life at the time of administration to the patient is valid. If MDS Nordion (MDS Canada) were to have problems with the manufacture or supply of Yttrium-90, our business could be materially impacted, and we may not be able to find an additional supplier of the isotope on acceptable terms or at all. We also rely on Coridien/Malinckrodt and GE for the manufacture and supply of Indium-111, a radioactive isotope used in the administration of Zevalin diagnostic for clinical purposes. Coridien/Malinckrodt and GE are currently our two qualified sources of Indium-111, which must be manufactured and shipped in such a way as to ensure the appropriate potency of the isotope based on its radioactive half-life at the time of administration of the diagnostic dose to the patient. If both companies were to have problems with the manufacture or supply of Indium-111, our business could be materially impacted, and we may not be able to find an additional supplier of the isotope on acceptable terms or at all.

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

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

- Zevalin currently competes with Bexxar®, which is marketed by GlaxoSmithKline, and any rituximab-containing chemotherapy regimen. Rituximab is marketed in the U.S. by Genentech and Biogen Idec. In addition, other companies such as Cephalon, Eli Lilly, Genta, Genmab, Favrille, and Genitope are developing products which could compete with Zevalin.

- 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 including, among others, Bristol-Myers Squibb Co. and others, which markets paclitaxel and generic forms of paclitaxel; Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which markets Tarceva ; Genentech and Roche, which markets Avastin , Eli Lilly, which markets Alimta®, and American Pharmaceutical Partners, which markets Abraxane . In addition, other companies such as NeoPharm Inc. and Telik, Inc. are also developing products which could compete with OPAXIO.

- Because pixantrone is intended to provide less toxic treatment to patients who have failed standard chemotherapy treatment, if pixantrone is brought 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 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, either alone or together with their collaborators and, in particular, the multinational pharmaceutical companies, have substantially greater financial resources and 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 products or eventual 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

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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. As discussed above, CMS proposed new rates for 2008 for Zevalin that, if implemented, would result in reimbursement rates below our acquisition cost of Zevalin. 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, with the exception of Zevalin, currently are in research or development, and have not received marketing approval.

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

be found ineffective or cause harmful side effects during preclinical testing or clinical trials,

fail to receive necessary regulatory approvals,

be difficult to manufacture on a scale necessary for commercialization,

be uneconomical to produce,

fail to achieve market acceptance, or

be precluded from commercialization by proprietary rights of third parties.

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

The intellectual property and assets related to Zevalin are subject to a security agreement with Biogen; if we were to default on certain payments or reimbursement owed to Biogen or certain third parties, those assets would be subject to foreclosure by Biogen and we could lose our ability to continue development, sales and marketing activities with respect to Zevalin.

On December 21, 2007, in connection with our purchase of Zevalin, we entered into a Security Agreement with Biogen granting a first priority security interest to Biogen in all of our right, title and interest (a) in and to the assets related to Zevalin that we purchased from Biogen, together with any other assets or rights related to any of such assets or otherwise used in the development, manufacture or commercialization of Zevalin,

and (b) under certain license, sublicense and supply agreements entered into in connection with our purchase of Zevalin. In the event we were to default on certain of our obligations under the Security Agreement, the Asset Purchase Agreement pursuant

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to which we continue to owe royalties and milestone payments to Biogen, or the related sublicense and service agreements, or in the event we were to make an application for, or consent to, the appointment of a receiver, trustee or liquidator of all or a substantial portion of our assets, transfer our assets as part of a general assignment or other arrangement for the benefit of creditors, become insolvent, file a voluntary or involuntary petition under the provisions of the United States Bankruptcy Code, or in the event of an attachment or execution upon, or seizure of, all or substantially all of our assets, Biogen may take any action with respect to the collateral under the Security Agreement that it deems necessary or advisable to accomplish the purposes of the Security Agreement. The Security Agreement will remain in effect until all obligations secured by that agreement have been satisfied. If Biogen were to foreclose on the collateral under this Security Agreement, it would have a material adverse impact on our business.

If any of our license agreements for intellectual property underlying Zevalin, OPAXIO, pixantrone, brostallicin, or any other products are terminated, we may lose our rights to develop or market that product.

We have licensed intellectual property, including patent applications relating to intellectual property for pixantrone, brostallicin and Zevalin. We have also in-licensed the intellectual property for our drug delivery technology relating to OPAXIO that 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 agreements, 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 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.

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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 on 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 but have not conducted an exhaustive search 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. We may not be able to successfully challenge the validity of these patents and could have 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 and therefore be unable to take certain corporate actions.

Our articles 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. 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 the Company s 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 and January 2008 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 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 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 quorum at future annual or special meetings of shareholders. 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 the Company. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452, 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 materially adverse effect on the Company.

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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 the securities 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.

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 a single source on a purchase order basis. 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 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 US 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 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, 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 finished products for pixantrone and brostallicin are both manufactured by a single vendor. The drug substance for Zevalin is produced under contract by Biogen and the drug product and finished product is manufactured and distributed at a contract manufacturer and contract distribution facility.

If we do not successfully develop additional products, we may be unable to generate significant revenue or become profitable.

We divested our commercial product, TRISENOX, in July 2005 and only acquired a new commercial product, Zevalin, in December 2007. Our ability to generate significant revenues from Zevalin is dependent in part on our ability to find new markets for the product, including through gaining wider acceptance and use of the drug by physicians and through FDA approval of expanded uses for the product. There is no guarantee that we will be successful in accomplishing either of these goals. OPAXIO, pixantrone, brostallicin and label expansions for Zevalin are currently in clinical trials and may not be successful. 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. 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 this and 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;

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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 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. Substantially all of our product candidates in clinical development are in-licensed from a third party, including Zevalin, OPAXIO, pixantrone, 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. On March 4, 2008, we submitted an MAA to the EMEA for OPAXIO. In April 2008, the EMEA accepted the MAA for review, however, we do not expect a regulatory decision on an MAA prior to the second half of 2009. Analysis of the data from our EXTEND trial is expected in the second half of 2008 and, if final study results are adequate, we could submit an NDA with the FDA in early 2009 with potential approval in the second half of 2009.

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 not be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Clinical testing may not show potential products to be safe and efficacious and potential products may not be approved for a specific indication. Further, 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. Data obtained from clinical trials are susceptible to varying interpretations. Government regulators and our collaborators may not agree with our interpretation of our clinical trial results. In addition, 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. 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.

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If we fail to commence or complete, need to perform more or larger clinical trials than planned or experience delays in any of our present or planned clinical trials, 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.

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 novel 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 may not develop into commercial products.

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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, marketing and sale of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering marketing and sales of Zevalin as well as 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 Zevalin or any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

Adverse events related to our products can negatively impact our product sales and results from operations.

Our commercial product, Zevalin, has the possibility of causing significant side effects in patients, and deaths associated with an infusion reaction symptom complex, though rare, have occurred within 24 hours of infusions of rituximab, a component of Zevalin. In addition, Yttrium-90 Zevalin administration often results in severe and prolonged cytopenias in most patients, while severe cutaneous and mucocutaneous reactions have also been reported. While side effects are common in oncology drugs, adverse events such as these could negatively impact sales of Zevalin, which in turn could negatively impact our results from operations.

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.

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 October 31, 2008, our stock price has ranged from a low of $0.29 to a high of $35.50. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

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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 2008 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;
- 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 the Company 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.

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

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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 6. Exhibits

(a) Exhibits

3.1	Registrant s Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on January 29, 2008).
3.2	Registrant s Amended and Restated Bylaws (Incorporated by reference to appendix H to the Registrant s Registration Statement on Form S-4 (No. 333-106906).
4.1	Indenture, dated October 22, 2008 between Cell Therapeutics, Inc. and U.S. Bank National Association, as trustee, including Form of Global Note (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on October 24, 2008).
10.1	Securities Purchase Agreement, dated October 21, 2008 between Cell Therapeutics, Inc. and BAM Opportunity Fund LP (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on October 24, 2008).
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: November 7, 2008

By: /s/ James A. Bianco, M.D.
James A. Bianco, M.D.

Chief Executive Officer

Dated: November 7, 2008

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

Executive Vice President, Finance and Administration

(Principal Financial Officer, Chief Accounting Officer)