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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CELL THERAPEUTICS, INC.

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 pro