

CELL THERAPEUTICS INC  
Form 10-Q  
May 12, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**  
**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended: March 31, 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**  
(State or other jurisdiction of

incorporation or organization)

**501 Elliott Avenue West, Suite 400**

**Seattle, Washington**  
(Address of principal executive offices)

**(206) 282-7100**

(Registrant's telephone number, including area code)

**91-1533912**  
(I.R.S. Employer Identification No.)

**98119**  
(Zip 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  No

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

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

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

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 May 8, 2008
Common Stock, no par value	116,102,874

---

**Table of Contents**

**CELL THERAPEUTICS, INC.**

**TABLE OF CONTENTS**

	<b>PAGE</b>
<b>PART I - FINANCIAL INFORMATION</b>	
ITEM 1: Financial Statements	
<u>Condensed Consolidated Balance Sheets at March 31, 2008 and December 31, 2007</u>	3
<u>Condensed Consolidated Statements of Operations Three Months Ended March 31, 2008 and 2007</u>	4
<u>Condensed Consolidated Statements of Cash Flows Three Months Ended March 31, 2008 and 2007</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
ITEM 2: <u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	18
ITEM 3: <u>Quantitative and Qualitative Disclosures About Market Risk</u>	30
ITEM 4: <u>Controls and Procedures</u>	30
<b>PART II - OTHER INFORMATION</b>	
ITEM 1: <u>Legal Proceedings</u>	32
ITEM 1A: <u>Risk Factors</u>	32
ITEM 4: <u>Submission of Matters to a Vote of Security Holders</u>	49
ITEM 5: <u>Other Information</u>	49
ITEM 6: <u>Exhibits</u>	50
<b><u>Signatures</u></b>	51

**Table of Contents****CELL THERAPEUTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except share amounts)

	March 31, 2008 (unaudited)	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,603	\$ 15,798
Restricted cash	6,165	
Securities available-for-sale	1,725	2,548
Interest receivable	13	46
Accounts receivable, net	1,926	51
Inventory, net	341	290
Prepaid expenses and other current assets	3,777	3,904
Total current assets	27,550	22,637
Property and equipment, net	5,336	6,025
Goodwill	17,064	17,064
Other intangibles, net	15,788	15,957
Other assets	12,898	11,830
Total assets	\$ 78,636	\$ 73,513
<b>LIABILITIES AND SHAREHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 7,558	\$ 6,595
Accrued expenses	28,762	26,034
Current portion of deferred revenue	80	80
Current portion of long-term obligations	821	1,020
Current portion of convertible senior subordinated notes	7,964	16,907
Current portion of convertible subordinated notes	2,760	2,910
Total current liabilities	47,945	53,546
Deferred revenue, less current portion	378	398
Long-term obligations, less current portion	9,700	9,879
9% convertible senior notes	16,953	
7.5% convertible senior notes	32,315	32,220
6.75% convertible senior notes	6,921	6,922
5.75% convertible senior notes	23,467	23,287
Convertible senior subordinated notes	55,150	55,150
Total liabilities	192,829	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 March 31, 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 March 31, 2008 and December 31, 2007, respectively	4,031	11,881

Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

Series C 3% Convertible Preferred Stock, \$1,000 stated value, 20,250 shares designated; 6,284 and 8,284 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	4,725	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 March 31, 2008 and December 31, 2007, respectively	734	2,938
Shareholders' deficit:		
Common stock, no par value:		
Authorized shares - 200,000,000		
Issued and outstanding shares - 94,631,098 and 62,444,239 at March 31, 2008 and December 31, 2007, respectively	1,040,975	979,295
Accumulated other comprehensive loss	(1,058)	(4,007)
Accumulated deficit	(1,164,017)	(1,109,413)
Total shareholders' deficit	(124,100)	(134,125)
Total liabilities and shareholders' deficit	\$ 78,636	\$ 73,513

See accompanying notes.

**Table of Contents****CELL THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)****(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>		
Product sales	\$ 3,374	\$
License and contract revenue	20	20
<b>Total revenues</b>	<b>3,394</b>	<b>20</b>
<b>Operating expenses:</b>		
Cost of product sold	890	
Research and development	15,855	15,286
Selling, general and administrative	11,174	8,130
Amortization of purchased intangibles	397	207
Acquired in-process research and development	36	
<b>Total operating expenses</b>	<b>28,352</b>	<b>23,623</b>
Loss from operations	(24,958)	(23,603)
<b>Other income (expense):</b>		
Investment and other income, net	260	703
Interest expense	(12,929)	(3,916)
Foreign exchange gain (loss)	(2,237)	447
Make-whole interest expense	(7,781)	(2,310)
Gain on derivative liabilities	11,744	2,708
Loss on exchange of convertible notes	(2,295)	
Settlement expense		(143)
<b>Other expense, net</b>	<b>(13,238)</b>	<b>(2,511)</b>
Loss before minority interest	(38,196)	(26,114)
Minority interest in net loss of subsidiary	32	
Net loss	(38,164)	(26,114)
Preferred stock beneficial conversion feature		(2,594)
Preferred stock dividends	(242)	(31)
Deemed dividends on conversion of preferred stock	(16,198)	
Net loss attributable to common shareholders	\$ (54,604)	\$ (28,739)
Basic and diluted net loss per common share	\$ (0.77)	\$ (0.76)
Shares used in calculation of basic and diluted net loss per common share	71,074	37,588

See accompanying notes.



**Table of Contents****CELL THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)****(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (38,164)	\$ (26,114)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	36	
Depreciation and amortization	1,569	1,395
Minority interest in net loss of subsidiary	(32)	
Equity-based compensation expense	884	318
Non-cash loss on exchange of convertible notes	2,295	
Non-cash gain on derivative liabilities	(11,744)	(2,708)
Non-cash interest expense	10,944	1,995
Other	(56)	(60)
Changes in operating assets and liabilities:		
Restricted cash	7,781	
Interest receivable	33	101
Accounts receivable, net	(1,876)	(11)
Inventory	(50)	
Prepaid expenses and other current assets	184	928
Other assets	271	(595)
Accounts payable	869	344
Accrued expenses	3,199	1,302
Deferred revenue	(20)	(20)
Excess facilities obligations	(236)	(640)
Other long-term obligations	(69)	34
Total adjustments	13,982	2,383
Net cash used in operating activities	(24,182)	(23,731)
<b>Investing activities</b>		
Cash paid for acquisition of Zevalin	(420)	
Purchases of securities available-for-sale	(1,011)	(15,835)
Proceeds from sales of securities available-for-sale	1,607	
Proceeds from maturities of securities available-for-sale	235	15,335
Purchases of property and equipment	(242)	(191)
Net cash provided by (used in) investing activities	169	(691)
<b>Financing activities</b>		
Proceeds from sale of common stock, net of offering costs	1,183	
Proceeds from issuance of 9% convertible senior notes, net of issuance costs	49,543	
Restricted cash from issuance of 9% convertible senior notes	(13,947)	
Deemed dividends on conversion of preferred stock	(16,198)	
Transaction costs related to exchange of convertible subordinated and senior subordinated notes	(278)	



Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

Proceeds from issuance of Series A 3% convertible preferred stock and warrants, net		18,754
Payment of additional offering costs related to December 2007 issuance of common stock and warrants	(473)	
Payment of dividends on preferred stock	(251)	
Payment of offering costs related to Series D 7% preferred stock and warrants	(44)	
Repayment of long-term obligations	(127)	(34)
Net cash provided by financing activities	19,408	18,720
Effect of exchange rate changes on cash and cash equivalents	2,410	(401)
Net decrease in cash and cash equivalents	(2,195)	(6,103)
Cash and cash equivalents at beginning of period	15,798	17,129
Cash and cash equivalents at end of period	\$ 13,603	\$ 11,026
<b>Supplemental disclosure of cash flow information</b>		
Cash paid during the period for interest	\$ 7,849	\$ 2,322
Cash paid for taxes	\$	\$
<b>Supplemental disclosure of noncash financing and investing activities</b>		
Conversion of Series A 3% convertible preferred stock to common stock	\$ 4,771	\$
Conversion of Series B 3% convertible preferred stock to common stock	\$ 7,850	\$
Conversion of Series C 3% convertible preferred stock to common stock	\$ 1,504	\$
Conversion of Series D 7% convertible preferred stock to common stock	\$ 2,203	\$
Conversion of 9% convertible senior notes to common stock	\$ 28,820	\$
Conversion of 7.5% convertible senior notes to common stock	\$	\$ 7,912
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.

**Table of Contents**

**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.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of March 31, 2008 and for the three months ended March 31, 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 month period ended March 31, 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.

*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) 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 March 31, 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.

All intercompany transactions and balances are eliminated in consolidation.

*Reverse Stock-Split*

On April 15, 2007, we effected a one-for-four reverse stock split of our common stock. All impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the stock split. Impacted amounts include shares of common stock authorized and outstanding, share issuances, shares underlying stock options and warrants, shares reserved and loss per share.

---

**Table of Contents**
*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 couple of years 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 \$15.3 million as of March 31, 2008. In addition, as discussed in Note 9, *Subsequent Events*, we issued securities for net proceeds, before fees and expenses, of \$22.9 million in April 2008 and can require the same purchaser to complete a second closing of that offering of at least \$5.0 million prior to July 4, 2008 provided that we have enough shares authorized to issue additional shares. Even with this additional financing, these amounts are not sufficient to fund our planned operations for the next twelve months as well as repay approximately \$10.7 million in principal due on our convertible subordinated and senior subordinated notes in June 2008 which raises substantial doubt about our ability to continue as a going concern. Accordingly, we have commenced a cost savings initiative but will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. In April 2008, we issued a warrant, the B unit warrant, to purchase up to \$67.5 million in convertible debt and common stock warrants which may be exercised any time prior to April 30, 2009. We can compel the purchaser of the B unit warrant to exercise that warrant if we reach certain milestones and satisfy certain conditions prior to April 30, 2009, including maintaining a stock price of at least \$0.87 per share for 20 trading days within a thirty-day period, receiving positive results from our PIX301 trial or submitting an sBLA for additional uses of Zevalin, and other conditions. We may not satisfy these conditions, in which case we will not be able to compel the exercise of the B unit warrant. In 2006, we entered into a Step-Up Equity Financing Agreement with Société Générale pursuant to which we can request Société Générale to provide limited amounts of equity funding to us from time to time, provided we have met certain conditions under that agreement prior to requesting such equity funding. The maximum aggregate amount that can be raised under the terms of that financing agreement is \$60 million, which is equal to approximately \$94.8 million as of March 31, 2008. To date, we have made one equity issuance to Société Générale for approximately \$0.9 million. However, additional funding, including any obtained under the Step-Up Equity Financing Agreement, 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. 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 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 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.

## **Table of Contents**

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. 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. 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 March 31, 2008 consists of finished goods inventory for Zevalin.

### *Accounts Receivable*

Our accounts receivable balance includes trade receivables related to Zevalin as of March 31, 2008 and is net of an allowance for product returns totaling approximately \$56,000 for the period. We analyze historical returns patterns for our products in determining an appropriate estimate for 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 March 31, 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.

### *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.

## **Table of Contents**

### *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 \$7.5 million and \$7.2 million as of March 31, 2008 and December 31, 2007, respectively, of which \$6.7 million and \$6.5 million is included in *other assets* and \$0.8 million and \$0.7 million is included in *prepaid expenses and other current assets* as of March 31, 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 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 March 31, 2008 and 2007, options, warrants, unvested share awards and rights, convertible debt and convertible preferred stock aggregating 55,910,079 and 10,544,313, 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.

Our 6.75% convertible senior notes, or 6.75% notes, contain a feature that provides for a make-whole payment upon any conversion of these notes. The payment is equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion upon any conversion of these notes. This make-whole feature represents an embedded derivative which is required to be accounted for separately from the related debt securities. The fair value of this derivative is calculated based on a discounted cash flow model.

Our 7.5% convertible senior notes, or 7.5% 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. The payment is equal to \$225 per \$1,000 principal amount of the notes less any interest amounts paid prior

---

**Table of Contents**

to the date of automatic conversion or repurchase. This make-whole feature also represents an embedded derivative that must be accounted for separately from the related debt securities. The fair value of this derivative 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.

Our 9% convertible senior notes, or 9% notes, include a feature that calls for make-whole payments upon any conversion of these notes. The payment is equal to \$270 per \$1,000 principal amount of the notes less any interest amounts paid prior to the date of conversion. This make-whole feature also represents an embedded derivative that must be accounted for separately from the related debt securities. We use assistance from an independent valuation specialist to measure the fair value of the make-whole feature. The fair value of this derivative 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 our 6.75%, 7.5% and 9% notes are included in *gain on derivative liabilities* 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.

The interest make-whole provision of the 5.75% convertible senior notes represents an embedded derivative. At the issuance of the 5.75% notes, the interest make-whole feature was found to have no value.

*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.

## Table of Contents

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.

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 Standard 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 be added 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 Standard 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 Standard 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.

**Table of Contents****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 \$35.2 million and \$26.3 million for the three month periods ended March 31, 2008 and 2007, respectively.

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

	March 31, 2008	December 31, 2007
Foreign currency translation adjustment	\$ (1,061)	\$ (4,010)
Net unrealized gain on securities available-for-sale	3	3
<b>Accumulated other comprehensive loss</b>	<b>\$ (1,058)</b>	<b>\$ (4,007)</b>

**3. Convertible Preferred Stock**

During the three months ended March 31, 2008, 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:

	Shares of Preferred Stock Converted	Shares of Common Stock Issued
Series A 3% convertible preferred stock	6,300	941,703
Series B 3% convertible preferred stock	10,162	1,509,948
Series C 3% convertible preferred stock	2,000	512,820
Series D 7% convertible preferred stock	3,000	1,148,324

As of March 31, 2008 and December 31, 2007, we had \$242,000 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 March 31, 2007, we recorded a beneficial conversion feature charge related to the effective conversion price for the Series A preferred stock of approximately \$2.6 million. This was recorded as a dividend expense 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. For more information regarding the triggering events, 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.

**4. Convertible Senior Notes***9% Convertible Senior Notes*

In March 2008, we issued approximately \$51.7 million aggregate principal amount of our 9% notes. We recorded issuance costs related to the 9% notes of approximately \$2.2 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 7,326,950 shares of common stock at an exercise price of \$1.41 per share. The warrants will not be exercisable until July 2, 2008 and will expire on the third anniversary of the date on which they become exercisable. 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 4.1 million shares of common stock, induced by an aggregate cash payment of approximately \$16.2 million, which is recorded as deemed dividends in the current period pursuant to the provisions of EITF



## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

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 \$33.2 million after deducting the cash inducement, related expenses and commissions. In addition, \$13.9 million of this amount was restricted and held in escrow to fund potential make-whole payments as described below.

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 709.22 shares of common stock per \$1,000 principal amount of the notes, which is

**Table of Contents**

subject to adjustments in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$1.41 per share. Subject to certain conditions, the notes will automatically convert if, at any time after March 4, 2009 and prior to maturity, the closing price per share of our common stock has exceeded 150% 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 interest payment equal to \$270 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.

As of March 31, 2008, a total of \$28.8 million of our 9% notes had been converted into approximately 20.4 million shares of common stock. In connection with the conversion of the notes, we made make-whole interest payments of approximately \$7.8 million. As of March 31, 2008, approximately \$6.2 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. In April 2008, \$5.3 million of the 9% notes and 744,682 of related warrants were cancelled pursuant to a securities purchase agreement as discussed further in Note 9, *Subsequent Events*.

The interest make-whole provision 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 interest make-whole feature 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 \$9.2 million for the period ended March 31, 2008 primarily related 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 period ended March 31, 2008 was \$11.7 million and is included in *gain on derivative liabilities*. At March 31, 2008, the fair value of the derivative was \$1.3 million, which was recorded in *9% convertible senior notes*.

*7.5% Convertible Senior Notes*

The interest make-whole 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. Accordingly, we recorded interest expense of \$0.1 million and \$1.4 million for the three months ended March 31, 2008 and 2007 respectively. The expense recorded for the three months ended March 2007 was primarily related to accelerated accretion due to note conversions. The change in the estimated fair value for the three months ended March 31, 2007 was \$2.7 million and was included in *gain on derivative liabilities*. As of March 31, 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 months ended March 31, 2008.

For the three months ended March 31, 2007, \$7.9 million of our 7.5% notes were converted into 946,510 shares of common stock. In connection with the conversion of \$6.2 million of these notes during the three months ended March 31, 2007 and \$7.4 million of our 7.5% notes on April 2, 2007, we made discretionary interest make-whole payments of approximately \$2.3 million which is included in *make-whole interest expense* for the three months ended March 31, 2007.

**Table of Contents***6.75% Convertible Senior Notes*

The interest make-whole provision 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. Accordingly, we recorded interest expense of \$20,000 for the three months ended March 31, 2008 and 2007. The estimated fair value of the derivative liability was approximately \$0.1 million at March 31, 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 March 31, 2008 and 2007 was \$22,000 and \$28,000, respectively, and is recorded in gain on derivative liabilities.

*5.75% Convertible Senior Notes*

In accordance with the provisions in EITF 96-19, *Debtor's Accounting for a Modification or Exchange of Debt Instruments*, 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 for the three months ended March 31, 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 0.1 million and 6.7 million shares of our common stock, respectively. The exchange was accounted for in accordance with provisions in Accounting Principles Board No. 26, *Early Extinguishment of Debt* and FASB Technical Bulletins 80-1, *Early Extinguishment of Debt through Exchange for Common or Preferred Stock*. 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, including a write-off of approximately \$14,000 of unamortized issuance costs relating to the extinguished notes.

As of March 31, 2008, approximately \$2.7 million of our 5.75% convertible subordinated notes and approximately \$8.0 million of our 5.75% convertible senior subordinated notes are included in our current liabilities. These notes are due in June 2008.

**5. 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 months ended March 31, 2008, which was allocated as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
Research and development	\$ 258	\$ 189
Selling, general and administrative	633	129
Stock-based compensation expense included in operating expenses	\$ 891	\$ 318

**Table of Contents**

There were no options granted during the three months ended March 31, 2008. For options granted during the three months ended March 31, 2007, fair value was estimated at the date of grant using the Black-Scholes pricing model, with the following weighted average assumptions:

	<b>Three Months Ended March 31, 2007</b>
Risk-free interest rates	4.5%
Expected dividend yield	None
Expected life (in years)	4.2
Expected volatility	73%

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.

**6. Financing Agreement**

In January 2008, we sold 800,000 shares to Société Générale under our Step-Up Equity Financing Agreement. These shares were sold in a registered offering at an issue price of 1.07, or approximately \$1.59, per share and 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.

**7. Restructuring Activities**

During 2005, we reduced our workforce in the U.S. and Europe and terminated our aircraft lease. In conjunction with our workforce reduction 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 three months ended March 31, 2008 (in thousands):

	<b>Excess Facilities Charges</b>	<b>Employee Separation Costs</b>
Balance at December 31, 2007	\$ 1,548	\$ 9
Adjustments	69	1
Payments	(306)	(5)
Balance at March 31, 2008	\$ 1,311	\$ 5



**Table of Contents**

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 \$69,000 and \$32,000 for the three months ended March 31, 2008 and 2007, respectively, which is 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 March 31, 2008 and December 31, 2007 respectively, approximately \$0.3 million and \$0.5 million of the liability for restructuring activities is included in *current portion of long-term obligations* and approximately \$1.0 million is included in *long-term obligations, less current portion* as of both dates.

**8. Legal Proceedings****Recent Legal Proceedings**

Based on language (the *Disputed Language*) contained in the Articles of Amendment to the Company's 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 the Company and certain holders of its then existing convertible debt on December 12, 2007 (the *Exchange*). The Company is 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 the Company 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 the Company's 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, and as a result, Tang is entitled to redemption of its Preferred Stock in consideration for 130% of its Stated Value, plus other available relief, if any. Another holder of 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 CTI for breach of contract and breach of the covenant of good faith and fair dealing. Enable alleges that on or about March 4, 2008, CTI committed a further breach of its obligations by offering and/or paying consideration to certain holders of CTI preferred stock to induce those holders to convert their preferred stock into common stock without making the same offer to Enable. Additional holders of our preferred stock may assert claims similar to those asserted by Tang and Enable. CTI disputes each of the claims asserted against it and intends to defend itself vigorously. 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, 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.

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.

**Table of Contents****9. Subsequent Events**

On April 29, 2008, we entered into a Securities Purchase Agreement, or purchase agreement, with a single institutional investor. Pursuant to the purchase agreement, we issued units consisting of \$36.0 million aggregate principal amount of our 13.5% Convertible Senior Notes due 2014, or 13.5% notes, 9,000 shares of the Company's Series E 13.5% Convertible Exchangeable Preferred Stock, or Series E preferred stock, with an aggregate stated value of \$9.0 million, warrants to purchase 28,481,012 shares of our common stock at an exercise price of \$0.95 per share, or A warrants, and a warrant to purchase additional securities, or B unit warrant, as described in more detail below. The purchase price equates, on an as-converted-to-common stock basis, to approximately \$1.14 for each of the 56,962,025 shares of our common stock underlying the 13.5% notes and the Series E preferred stock. This transaction was completed on April 30, 2008. The investor also exchanged, and we subsequently cancelled, \$5.3 million aggregate principal amount of our 9% notes due 2012, along with all warrants issued in connection with such 9% notes, as part of the consideration paid for the securities. In addition, the amount related to make-whole payments that would otherwise be payable on conversion of that cancelled note will be remitted to us from the escrow account when the account is closed in March 2009. Interest on the note from the date of issuance until the date of cancellation will be paid to the holder in cash.

The total purchase price for the securities was approximately \$64.6 million. Of this amount, \$5.3 million was credited to the investor upon surrender of the investor's 9% notes, as described above, and \$36.5 million was deposited into an escrow account to be used to make interest payments and make-whole payments, as described below. After taking into account these amounts, the net amount of cash received was approximately \$22.9 million.

The Series E preferred stock carries a 13.5% cumulative annual dividend rate, and is convertible into common stock at \$0.79 per share. In addition, on or after May 31, 2008 and prior to October 31, 2008, the holder has the optional right to exchange all, but not less than all, of the 9,000 shares of Series E Preferred issued in this transaction for an aggregate principal amount of 13.5% notes equal to the stated value of the Series E preferred stock plus any accrued and unpaid dividends.

The 13.5% notes will bear an annual interest rate of 13.5% and be convertible into common stock at a conversion price of \$0.79. Interest on the notes is payable, at our option, in cash, common stock or some combination thereof, subject to certain conditions. If not converted or repurchased prior to maturity, the notes mature on April 30, 2014. Upon conversion of the notes or upon exercise by the holder of a one-time right to require early redemption of the notes (which may be exercised in May 2011), we will be required to pay a make-whole amount to the holders of the converted or redeemed notes equal to \$810 per \$1,000 principal amount of the converted or redeemed notes less any interest paid on such notes prior to the conversion or redemption date, or make-whole payment. An amount adequate to pay the make-whole payments on the notes will be held in escrow for a period of one year. At the end of one year, all funds remaining in escrow will be released to us.

The 13.5% notes will automatically convert if, at any time after April 30, 2009 and prior to maturity, the closing price of our common stock has exceeded \$1.58 for at least 20 trading days within any 30 consecutive trading day period, subject to certain conditions, or triggering event. The amount of notes that shall automatically convert on a triggering event shall equal the lesser of (i) the value of ten (10) times the volume weighted average price of our common stock during the 20-day period when the stock price exceeded \$1.58, multiplied by the average daily trading volume of our common stock during such 20 day period and rounded down to the nearest \$1,000, and (ii) one-half of the principal amount of the notes that have been authenticated under the Indenture as of the date of the automatic conversion notice. Once a triggering event has occurred, a new 30 trading day period for which an automatic conversion may be triggered shall commence. However, such automatic conversions shall occur only if our shareholders have previously approved the automatic-conversion provisions of the notes.

The A warrants will not be exercisable until our shareholders have approved an amendment to our Amended and Restated Articles of Incorporation to increase the authorized shares of common stock of the Company and the necessary amendment to the articles has been filed with the Secretary of State of the State of Washington. The A warrants will expire on the fifth anniversary of the date on which they become exercisable. We have the ability, upon certain other conditions being met and upon achieving certain product milestones, to accelerate the termination date of the A warrants.

The B unit warrant consists of a warrant to purchase 67,500 units consisting of 12.5% Convertible Senior Notes and additional A warrants, with an exercise price equal to \$1,000 per unit. The total aggregate exercise price of the B unit warrant of approximately \$67.5 million represents 150% of the aggregate value of the 13.5% notes and the Series E preferred stock. The B unit warrant is exercisable at any time after April 30, 2008 and will expire on or prior to April 30, 2009. The conversion/exercise price of the notes/warrants underlying the B unit warrant is \$0.79 per share of common stock. Subject to certain other conditions being met, including an \$0.87 stock price, and our achievement of certain product milestones, 90 days after the B unit warrant becomes exercisable, we may force the holder to exercise all of the B unit warrant. We also have the ability, upon certain similar conditions being met and our achievement of certain product milestones, to accelerate the termination date of the B unit warrant.

Under the purchase agreement, we also have the right to require the investor to either make an \$8.0 million exercise of the B unit warrant or buy \$5.0 million of common stock/A warrants units, depending on our common stock market price at the time, on or before June 14, 2008 or, if

Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

we do not have enough shares authorized for the issuance as of June 14, 2008, then such deadline will be extended until July 4, 2008.



**Table of Contents****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

---

**Table of Contents**

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 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 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 2010. A potential interim analysis, based on the number of events in the database, is planned for 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 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, 97 of whom are currently evaluable according to Histological Intent to Treat, or HITT, criteria. An analysis of the data is expected in the second half of 2008 and, if final study results are adequate, we could submit an NDA with the FDA in early 2009 with potential approval in the second half of 2009. 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. Three deaths occurred in the pixantrone arm versus none in the control arm. Based on subsequent follow-up, we believe this discrepancy is probably due to the early nature of the data. 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

## **Table of Contents**

of Cancer, or EORTC. Additionally, we initiated a phase II myxoid liposarcoma trial in 2007. Brostallicin also has demonstrated synergy with new targeted agents as well as established treatments in preclinical trials; consequently, we have begun a multi-arm combination study with brostallicin and other agents, including Avastin (bevacizumab). This study is being conducted in conjunction with U.S. Oncology at multiple sites in the United States with the first combinations expected to be completed in 2008.

We are developing Zevalin for additional indications. 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 March 2008, Bayer Schering received a positive opinion from the European Committee for Medicinal Products for Human Use, or CHMP, recommending Zevalin as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma in Europe. Upon a favorable review by the European Commission, Bayer Schering could receive marketing authorization for this indication of Zevalin later this year. While we do not currently have any rights to use or access the data from the FIT trial, we have been negotiating with Bayer Schering for access to those results and expect to reach a final agreement with them regarding that data in the near future. If we are successful in obtaining access to the FIT trial results and the data is suitable for FDA filing, we plan to submit a supplemental biologics license application, or sBLA, for Zevalin consolidation of first remission in advanced stage follicular NHL in the second half of 2008. We also intend to file an sBLA to remove the requirement for a biodistribution scan from the Zevalin label in 2008.

We are currently focusing our efforts on Zevalin, OPAXIO, pixantrone, and brostallicin, and have no immediate plans to conduct any further clinical studies on CT-2106 (polyglutamate camptothecin), or any other early-stage drug candidates.

As of March 31, 2008, we had incurred aggregate net losses of approximately \$1.2 billion since inception. We expect to continue to incur additional operating losses for at least the next couple of years.

## **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.

## **Table of Contents**

### *License and Contract Revenue*

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

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

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

### *Impairment of Long-lived Assets*

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

### *Valuation of Goodwill*

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

### *Derivatives Embedded in Certain Debt Securities*

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

Our 6.75% convertible senior notes, or 6.75% notes, contain a feature that provides for a make-whole payment upon any conversion of these notes. The payment is equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion upon any conversion of these notes. This make-whole feature represents an embedded derivative which is required to be accounted for separately from the related debt securities. The fair value of this derivative is calculated based on a discounted cash flow model.

---

## Table of Contents

Our 7.5% convertible senior notes, or 7.5% 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. The payment is equal to \$225 per \$1,000 principal amount of the notes less any interest amounts paid prior to the date of automatic conversion or repurchase. This make-whole feature also represents an embedded derivative that must be accounted for separately from the related debt securities. The fair value of this derivative 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. As of December 31, 2006, we determined that we would make additional discretionary make-whole payments to certain investors during 2007. These additional payments constituted modifications to the terms of the agreement and were included in the valuation model as of December 31, 2006. All additional planned discretionary make-whole payments were made during the three months ended March 31, 2007.

Our 9% convertible senior notes, or 9% notes, include a feature that calls for a make-whole payment upon any conversion of these notes. The payment is equal to \$270 per \$1,000 principal amount of the notes less any interest amounts paid prior to the date of conversion. This make-whole feature also represents an embedded derivative that must be accounted for separately from the related debt securities. We use assistance from an independent valuation specialist to measure the fair value of the make-whole feature. The fair value of this derivative 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 our 6.75%, 7.5% and 9% notes are included in *gain on derivative liabilities* 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.

The interest make-whole provision of the 5.75% convertible senior notes, or 5.75% senior notes, represents an embedded derivative. At the issuance of the 5.75% notes, the interest make-whole feature was found to have no value.

### *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.

**Table of Contents**

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 March 31, 2008 and 2007**

**Product sales.** Product sales for the three months ended March 31, 2008 relate to Zevalin, our commercial product acquired from Biogen in December 2007. There were no product sales during the comparable period in 2007.

**License and contract revenue.** License and contract revenue for the three months ended March 31, 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 March 31, 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 there were no product sales during this period.

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

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Compounds under development:		
Pixantrone	\$ 2,368	\$ 3,242
OPAXIO	1,643	4,673
Brostallicin	1,305	
Zevalin	1,175	
Other compounds	106	270
Operating expenses	8,603	6,666
Discovery research	655	435
<b>Total research and development expenses</b>	<b>\$ 15,855</b>	<b>\$ 15,286</b>

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 \$214.8 million, \$42.9 million, \$5.5 million and \$1.3 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.

---

**Table of Contents**

Research and development expenses increased to approximately \$15.9 million for the three months ended March 31, 2008, from approximately \$15.3 million for the three months ended March 31, 2007. Pixantrone costs decreased primarily due to the closure of our PIX303 clinical trial in the fourth quarter of 2007 as well as a decrease in enrollment in our RAPID trial. 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. 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. Costs for our OPAXIO program decreased primarily due to reduced costs associated with our PIONEER trial which was suspended and closed in the fourth quarter of 2006 and incurred certain wrap-up costs in the first quarter of 2007 as well as a decrease in manufacturing activity. Costs incurred for brostallicin resulted from our acquisition of SM in July 2007 and are primarily due to clinical development activities related to phase I and phase II studies. Zevalin costs resulted from our acquisition of the product in December 2007 and primarily relate to clinical development activity. Operating expenses increased primarily due to an increase in personnel costs related to severance charges incurred during January 2008 related to our reduction in force, the acquisition of SM in July 2007 and an increase in foreign currency rates associated with our Italian operations.

Our lead drug candidates, OPAXIO, pixantrone and brostallicin are currently in clinical trials, and we are developing Zevalin for additional indications. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. Regulatory agencies, including the FDA and EMEA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the availability and proximity of patients with the relevant condition. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. Our bisplatinates and HIF1- drug candidates are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates.

Our products will be successful only if:

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

- our product candidates, if developed, are approved.

We will be dependent on the successful completion of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing research, development and commercial activities for these and other product candidates. We also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products.

Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost. We reported OPAXIO STELLAR 3 clinical trial results in March 2005 and STELLAR 2 and 4 results in May 2005, all of which missed their primary endpoints of superior overall survival. We have recently submitted an MAA for OPAXIO in the EU for first-line treatment of patients with advanced NSCLC who are PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our STELLAR clinical trials, however, we do not expect to receive a decision regarding approval of the MAA from the EMEA prior to the second half of 2009. If we do receive approval of that MAA in 2009, we would expect to receive cash inflows in 2009 through collaborative agreements or from sales of the product.

---

**Table of Contents**

Due to the acquisition of Zevalin, we expect to incur additional costs associated with the implementation of sales and marketing support of Zevalin. In addition, we are negotiating with Bayer Schering, which holds the rights to Zevalin outside the United States, for access to the data from recently published results of their Phase III first line indolent trial of Zevalin, known as the FIT trial, which we do not currently have any rights to use or access. While we expect to reach a final agreement with Bayer Schering regarding access to that data in the near future, if for some reason we are not successful with that negotiation, or if the results of the FIT trial prove to be inadequate for us to submit an sBLA for expanded approved indications of Zevalin, we will need to perform additional clinical trials of our own in order to seek label expansions of Zevalin. We expect to incur additional costs related to obtaining those rights from Bayer Schering and/or the additional clinical trials that may be required to expand approved indications of Zevalin. As a result, any revenue generated by sales of Zevalin may not be enough to fund our company-wide ongoing research, development, and operations for the next couple of years. We anticipate that funding to support our ongoing research, development and general operations will primarily come from public or private debt or equity financings, collaborations, milestones and licensing opportunities from current or future collaborators.

***Selling, general and administrative expenses.*** Selling, general and administrative expenses increased to approximately \$11.2 million for the three months ended March 31, 2008, from approximately \$8.1 million for the three months ended March 31, 2007. This increase is attributed to a \$1.4 million increase in our corporate development activities primarily related to an increase in financial advisory services and strategic activities. Our sales and marketing expenses increased \$1.3 million due to the acquisition of Zevalin in December 2007. Our compensation and benefits related to general and administrative activities increased approximately \$0.6 million due to the acquisition of SM, an increase in bonus expense and severance costs incurred during 2008 related to our reduction in force. In addition, stock-based compensation increased approximately \$0.5 million. These increases were offset by a decrease of approximately \$0.7 million in finance and administration expenses primarily related to a decrease in expenses associated with our shareholder meetings, our reverse stock split that occurred in 2007 and other external financial reporting activities. We expect selling, general and administrative expenses to continue to increase in 2008 as compared to 2007 due to the development of sales and marketing activities related to Zevalin.

***Amortization of purchased intangibles.*** Amortization for the three months ended March 31, 2008 increased to approximately \$0.4 million from approximately \$0.2 million for the three months ended March 31, 2007 primarily due to the amortization of intangible assets acquired in connection with our acquisition of Zevalin in December 2007.

***Acquired in-process research and development.*** Acquired in-process research and development for the three months ended March 31, 2008 relates to adjustments to our one-time charge recorded in connection with our acquisition of Zevalin in December 2007. These adjustments resulted from changes in the estimated acquisition costs used in determining the total estimated purchase price of the acquisition.

***Investment and other income.*** Investment and other income for the three months ended March 31, 2008 decreased to approximately \$0.3 million as compared to \$0.7 million for the three months ended March 31, 2007 primarily due to a lower average securities available-for-sale balance.

***Interest expense.*** Interest expense increased to approximately \$12.9 million for the three months ended March 31, 2008 from approximately \$3.9 million for the three months ended March 31, 2007. This increase was due to \$9.2 million in accretion of the debt discount, \$1.3 million in amortization of debt issuance costs and \$0.2 million in interest expense on our 9% notes which were issued in March 2008; the amount of accretion on the debt discount and amortization of debt issuance costs was primarily related to conversions of these notes during the three months ended March 31, 2008. In addition, there was an increase of \$0.2 million in the accretion of the debt discount and \$0.3 million in interest expense related to our 5.75% senior notes. These increases were offset by a \$1.3 million decrease in the accretion on our debt discount and a \$0.4 million decrease in the amortization of debt issuance costs related to our 7.5% notes primarily related to conversions of these notes during the three months ended March 31, 2007. In addition, interest expense on our 5.75% convertible subordinated



**Table of Contents**

and senior subordinated notes decreased approximately \$0.6 million due to the exchange of approximately \$36.1 million of these notes for our 5.75% senior notes in December 2007 and the cancellation of \$9.1 million of these notes in exchange for shares of our common stock in February 2008.

**Foreign exchange gain (loss).** The foreign exchange loss for the three months ended March 31, 2008 is due to fluctuations in currency exchange rates, primarily related to payables in our U.S. based companies that are denominated in foreign currencies. The foreign exchange gain for the three months ended March 31, 2007 is due to fluctuations in foreign currency exchange rates, primarily related to payables in our European branch denominated in foreign currencies.

**Make-whole interest expense.** Make-whole interest expense of \$7.8 million for the three months ended March 31, 2008 is related to payments made upon the conversion of \$28.8 million of our 9% notes. Make-whole interest expense of \$2.3 million for the three months ended March 31, 2007 is due to payments made related to the conversion of \$6.2 million of our 7.5% notes during the three months ended March 31, 2007 and the conversion of \$7.4 million of our 7.5% notes on April 2, 2007.

**Gain on derivative liabilities.** The gain on derivative liabilities of \$11.7 million for the three months ended March 31, 2008 primarily represents the change in the estimated fair value of our derivative liability related to the interest make-whole provision on our 9% notes. The amount of \$2.7 million for the three months ended March 31, 2007 primarily represents the change in the estimated fair value of our derivative liability related to the interest make-whole provision on our 7.5% notes. While we had a derivative liability related to our 6.75% notes for each of these periods, the change in the estimated fair value was not significant.

**Loss on exchange of convertible notes.** We recorded a loss of approximately \$2.3 million for the three months ended March 31, 2008 due to the extinguishment of approximately \$9.1 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately 6.8 million shares of our common stock. The loss includes approximately \$14,000 of write-off of unamortized issuance costs attributed to the extinguished notes.

**Settlement expense.** Settlement expense for the three months ended March 31, 2007 relates to interest accrued on the \$10.5 million payment to the USAO for release of all claims in connection with the investigation of our marketing practices relating to TRISENOX and related matters. Interest was accrued from the date of reaching an agreement in principle with the USAO in the fourth quarter of 2006 and the payment was made in April 2007.

**LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2008, we had approximately \$15.3 million in cash and cash equivalents, securities available-for-sale and interest receivable. In addition, in April we sold \$36.0 million in aggregate principal amount of our 13.5% Convertible Senior Notes, or 13.5% notes, due 2014, 9,000 shares of the Company's Series E 13.5% Convertible Exchangeable Preferred Stock, or Series E preferred stock, with an aggregate stated value of \$9.0 million and warrants to purchase certain securities in the future for an aggregate purchase price of approximately \$64.6 million. Of that purchase price, funds for approximately \$5.3 million were used to surrender existing 9% notes and \$36.5 million was deposited into an escrow account to be used for interest and make-whole payments on the notes issued in the offering. After these payments, net proceeds from the transaction were approximately \$22.9 million before fees and expenses. We have the right to require the purchaser of our 13.5% notes and Series E preferred stock to purchase at least \$5.0 million in additional securities prior to June 14, 2008, provided that if we do not have adequate authorized shares available on that date, the deadline for such additional closing may be extended to July 4, 2008.

Net cash used in operating activities increased slightly to approximately \$24.2 million during the three months ended March 31, 2008, compared to approximately \$23.7 million for the same period during 2007 primarily due an increase in cash paid for interest, an increase in our loss from operations and a decrease in our investment income offset by a decrease in restricted cash used to fund interest make-whole payments during the three months ended March 31, 2008. For the three months ended March 31, 2008, our net loss included \$7.8 million in make-whole interest payments related to conversions of our 9% notes. For the three months ended March 31, 2007, our net loss included \$2.3 million in make-whole interest payments related to conversions of our 7.5% notes.

---

**Table of Contents**

Net cash provided by investing activities of approximately \$0.2 million for the three months ended March 31, 2008 was primarily due to proceeds from sales and maturities of securities available-for-sale offset by purchases of securities available-for-sale, cash paid for acquisition costs related to our purchase of Zevalin in December 2007 and purchases of property and equipment. Net cash used in investing activities of approximately \$0.7 million for the three months ended March 31, 2007 was primarily due to purchases of securities available-for-sale and property and equipment offset by proceeds from maturities of securities available-for-sale.

Net cash provided by financing activities of approximately \$19.4 million for the three months ended March 31, 2008 was primarily related to proceeds from the issuance of our 9% notes, net of issuance costs, restricted cash placed in escrow to fund make-whole payments and a deemed dividend payment to induce existing holders of our Series A, B, C, and D convertible preferred stock to convert their shares of preferred stock into common stock. Net cash provided by financing activities for the three months ended March 31, 2007 was primarily due to net proceeds of \$18.8 million received from the sale of 20,000 shares of our Series A 3% convertible preferred stock and common stock warrants in February 2007.

We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred net losses since inception and we expect to generate losses from operations for at least the next couple of years primarily due to research and development costs for Zevalin, OPAXIO, pixantrone, and brostallicin. Our existing cash and cash equivalents, securities available-for-sale and interest receivable, including the approximately \$22.9 million in net proceeds raised in April 2008 as discussed above, is not sufficient to fund our planned operations for the next twelve months as well as repay approximately \$10.7 million in principal due on our convertible subordinated and senior subordinated notes in June 2008. This raises substantial doubt about our ability to continue as a going concern. Accordingly, we implemented a cost savings initiative in March 2008 and plan to reduce the Company's projected net cash operating expenses to a forecasted \$77 million in 2008. However, we will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. In connection with the sale of our 13.5% notes and Series E preferred stock, we issued a B unit warrant to purchase up to \$67.5 million in 12.5% convertible notes and common stock warrants. If we achieve certain milestones and certain conditions are met, we can compel the exercise of that warrant in full prior to its termination date of April 30, 2009. In 2006, we entered into a Step-Up Equity Financing Agreement with Société Générale pursuant to which we can request Société Générale to provide limited amounts of equity funding to us from time to time, provided we have met certain conditions under that agreement prior to requesting such equity funding. The maximum aggregate amount that can be raised under the term of that financing agreement is 60 million, which is equal to approximately \$94.8 million as of March 31, 2008. To date, we have made one equity issuance to Société Générale for approximately 0.9 million. However, we may not be able to request further funding from Société Générale under the Financing Agreement or meet the conditions to compel exercise of the B unit warrant and additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs.

We may receive certain grants and subsidized loans from the Italian government and the EU through our Italian operations. However, to date such grants have not been significant and we may not receive such funding because the grants and subsidies are awarded at the discretion of the relevant authorities. However, our Italian branch will continue to apply for public financing when possible. In addition, our future capital requirements will depend on many factors, including:

results of our clinical trials;

success in acquiring or divesting products, technologies or businesses;

progress in and scope of our research and development activities; and

competitive market developments.

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



**Table of Contents**

The following table includes information relating to our contractual obligations as of March 31, 2008 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
9% Convertible senior notes (1)	\$ 22,835	\$	\$	\$ 22,835	\$
7.5% Convertible senior notes (2)	33,458			33,458	
6.75% Convertible senior notes (3)	7,000		7,000		
5.75% Convertible senior notes (4)	23,250			23,250	
5.75% Convertible senior subordinated notes (5)	7,964	7,964			
4.0% Convertible senior subordinated notes (6)	55,150		55,150		
5.75% Convertible subordinated notes (7)	2,760	2,760			
Interest on convertible notes	19,012	6,653	11,204	1,155	
Operating leases:					
Facilities	28,569	6,245	12,322	9,449	553
Long-term obligations (8)	1,984	466	794	724	
Purchase commitments (9)	2,503	80	692	1,065	666
	\$ 204,485	\$ 24,168	\$ 87,162	\$ 91,936	\$ 1,219

- (1) The 9% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 709.22 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$1.41 per share.
- (2) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 119.6298 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$8.36 per share.
- (3) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 95.0925 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$10.52 per share.
- (4) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 333.3333 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$3.00 per share.
- (5) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 25 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$40.00 per share.
- (6) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 18.5185 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$54.00 per share.
- (7) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of 7.353 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$136.00 per share.
- (8) Long-term obligations does not include \$6.2 million of contingent consideration related to our acquisition of Zevalin, \$1.3 million related to excess facilities charges and \$1.0 million recorded as a long-term obligation for benefits owed to our Italian employees pursuant to

Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

Italian Law. The timing of the payments related to this obligation is unknown as the benefit is paid upon an employee's separation from the Company.

**Table of Contents**

- (9) We purchase Zevalin inventory from Biogen pursuant to a supply agreement that we entered into with Biogen on December 21, 2007 in connection with the acquisition of U.S. rights to develop, market and sell Zevalin. Under the terms of the supply agreement, we are required to purchase from Biogen an amount of Zevalin every six months. We provide rolling forecasts of our supply requirements to Biogen in six-month increments for the next 30 months; however, under the terms of the agreement we are required to purchase a minimum of 150 packages, or 300 kits, for each six-month period in 2008, 2009 and 2010, and a minimum of 250 packages, or 500 kits, for each six-month period thereafter until the expiration of the term on June 9, 2014, unless earlier terminated. Each forecast for the next six-month period must be accompanied by a firm order.

*Additional Milestone Activities*

We have an amended agreement with PG-TXL Company L.P. which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL's polymer technology. Pursuant to this agreement we are required to pay a \$0.5 million milestone payment that became due upon the acceptance of our MAA for review by the EMEA in March 2008 and is accrued for as of March 31, 2008. We may also be required to pay up to \$14.4 million in additional milestone payments under this agreement including a \$3.0 million payment upon approval of the MAA filing by the EMEA, which may occur in the second half of 2009. The timing of the remaining milestone payments under the amended agreement is based on trial commencements and completions and regulatory and marketing approval with the FDA and EMEA.

Under a license agreement entered into for brostallicin, we may be required to pay up to \$80 million in milestone payments, based on the achievement of certain product development results. Due to the early stage of development that brostallicin is in, we are not able to determine whether the clinical trials will be successful and therefore cannot make a determination that the milestone payments are reasonably likely to occur at this time.

Pursuant to an acquisition agreement entered into with Cephalon, Inc. in June 2005, we may receive up to \$100 million in payments upon achievement by Cephalon of specified sales and development milestones related to TRISENOX. However, the achievement of any such milestones is uncertain at this time.

Under our agreement with Novartis Pharmaceutical Company Ltd., or Novartis, if Novartis elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option to develop and commercialize pixantrone, we may receive up to \$374 million in registration and sales related milestone payments. Novartis is under no obligation to make such election or exercise such right and may never do so. Additionally, even if Novartis exercises such rights, any milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals, which we may never receive.

**Table of Contents****Item 3. Quantitative and Qualitative Disclosures About Market Risk***Interest Rate Market Risk*

We are exposed to market risk related to changes in interest rates that could adversely affect the value of our investments. We maintain a short-term investment portfolio consisting of interest bearing securities with an average maturity of less than one year. These securities are classified as available-for-sale. These securities are interest bearing and thus subject to interest rate risk and will fall in value if market interest rates increase. Since we generally hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected significantly by a sudden change in market interest rates related to our securities portfolio. The fair value of our securities available-for-sale at March 31, 2008 and December 31, 2007 was \$1.7 million and \$2.5 million, respectively. For each one percent change in interest rates, the fair value of our securities available-for-sale would change by approximately \$6,000 and \$12,000 as of March 31, 2008 and December 31, 2007, respectively.

*Foreign Exchange Market Risk*

We are exposed to risks associated with foreign currency transactions insofar as we use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Although our reporting currency remains the U.S. dollar, a significant portion of our consolidated costs now arise in euros, which we translate into U.S. dollars for purposes of financial reporting, based on exchange rates prevailing during the applicable reporting period. In addition, the reported carrying value of our euro-denominated assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Accordingly, changes in the value of the U.S. dollar relative to the euro might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might harm our reported results and accounts from period to period.

We have foreign exchange risk related to foreign-denominated cash and cash equivalents and interest receivable (foreign funds). Based on the balance of foreign funds at March 31, 2008 of \$1.6 million, an assumed 5%, 10% and 20% negative currency exchange movement would result in fair value declines of \$0.1 million, \$0.2 million and \$0.3 million.

**Item 4. Controls and Procedures****(a) Evaluation of Disclosure Controls and Procedures**

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

Our management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

**Table of Contents**

(b) Changes in Internal Controls

Due to the timing of our acquisitions of Systems Medicine, Inc. and our commercial product, Zevalin, both were excluded from the scope of our assessment of internal controls over financial reporting for the period ended March 31, 2008. However, during 2008 we anticipate implementing additional controls related to these recent acquisitions. These changes could include implementing transactional controls at the subsidiary level, revenue recognition and cash receipts controls related to product sales in addition to implementing a more sophisticated accounting system.

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



**Table of Contents****PART II - OTHER INFORMATION****Item 1. Legal Proceedings**  
**Recent Legal Proceedings**

Based on language (the "Disputed Language") contained in the Articles of Amendment to the Company's 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 the Company and certain holders of its then existing convertible debt on December 12, 2007 (the "Exchange"). The Company is 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 the Company 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 the Company's 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, and as a result, Tang is entitled to redemption of its Preferred Stock in consideration for 130% of its Stated Value, plus other available relief, if any. Another holder of 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 CTI for breach of contract and breach of the covenant of good faith and fair dealing. Enable alleges that on or about March 4, 2008, CTI committed a further breach of its obligations by offering and/or paying consideration to certain holders of CTI preferred stock to induce those holders to convert their preferred stock into common stock without making the same offer to Enable. Additional holders of our preferred stock may assert claims similar to those asserted by Tang and Enable. CTI disputes each of the claims asserted against it and intends to defend itself vigorously. 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, seeking recovery of damages, including losses incurred by the Company in connection with our 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.

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.

**Item 1A. Risk Factors**  
**Factors Affecting Our Operating Results and Financial Condition**

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of March 31, 2008, we had an accumulated deficit of approximately \$1.2 billion. We are pursuing regulatory approval for OPAXIO and pixantrone and plan to seek regulatory approval for the expansion of approved uses of Zevalin and eventually hope to seek regulatory approval for brostallicin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities, expenses which, together with projected general and administrative expenses, will result in operating losses for the foreseeable future. We may never become profitable, even if we are able to commercialize products currently in development or otherwise.

**Table of Contents**

*Our debt and operating expenses exceed our net revenues.*

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. We have a single drug we are marketing, Zevalin, and the net proceeds of sales of this drug are not sufficient to pay our debt and operating expenses on a current basis. We do not currently project that net revenues from sales of any of our products will be sufficient to cover our existing debt and operating expenses within the next twelve months. Unless we raise substantial additional capital, we will not be able to repay this debt or the interest, liquidated damages or other payments that may become due with respect to our debt. Approximately \$10.7 million of this debt is due in June 2008. Prior to this debt becoming due, we may engage in one or more restructuring transactions which could involve, among other things, an effective increase in interest rates, alteration of terms or other arrangements which may be adverse to the value of our common stock and preferred stock.

*We need to raise additional funds immediately and expect that we will need to continue to raise funds in the future, and funds may not be available on acceptable terms, or at all.*

In 2007, we were able to raise capital through the sale of preferred stock and common stock, and raised a total of \$91.0 million in gross proceeds; we have subsequently raised an additional \$1.3 million in gross proceeds from an equity offering under our Step-Up Equity Financing Agreement with Société Générale in January 2008 and approximately \$35.5 million in proceeds from a convertible debt offering, net of inducement payments for conversions of convertible preferred stock, in March 2008 (approximately \$13.9 million of this amount was restricted and being held in escrow to fund potential make-whole payments on conversion of such debt, of which \$7.8 million had been paid as of March 31, 2008). In addition, we received approximately \$22.9 million from the sale of convertible debt and preferred stock in April 2008, net of amounts reserved for interest and make-whole payments and the cancellation of an outstanding convertible note issued in March 2008 which was tendered as partial consideration, and have the right to compel the purchaser of such debt and preferred stock to purchase at least \$5.0 million in additional securities on or before June 14, 2008, provided that if we do not have adequate authorized shares for such an offering at that time, the deadline may be postponed until July 4, 2008. However, we have substantial operating expenses associated with the development of our product candidates and as of March 31, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately \$15.3 million, and total current liabilities of approximately \$47.9 million. We also have a substantial amount of debt outstanding, including an aggregate principal balance of approximately \$169.7 million in convertible notes as of May 2, 2008, of which \$10.7 million is due in June 2008. Furthermore, as a result of our preferred stock financings in 2007, we may be obligated to redeem such preferred stock starting in February 2009. We expect that our existing cash and cash equivalents, securities available-for-sale and interest receivable, including proceeds received from our offerings through April 2008, will not provide sufficient working capital to fund our presently anticipated operations for the next 12 months and repay our notes due in June 2008, and we will therefore need to raise additional capital.

We may raise such capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. In connection with the sale of convertible debt and preferred stock in April 2008, we issued a B unit warrant to purchase up to \$67.5 million in additional debt securities and common stock warrants. If we achieve certain milestones and meet certain conditions, we can compel the exercise of that B unit warrant in full prior to its expiration on April 30, 2009. In addition, we have a Step-Up Equity Financing Agreement with Société Générale pursuant to which we can request Société Générale to provide limited amounts of equity funding to us from time to time, provided we have met certain conditions under that agreement prior to requesting such equity funding. The maximum aggregate amount that can be raised under the term of that financing agreement is 60 million, which is equal to approximately \$94.8 million as of March 31, 2008. To date, we have made one equity issuance to Société Générale for approximately 0.9 million. However, we may not meet the conditions necessary to request additional funding from Société Générale under the Financing Agreement and we may not be able to achieve the milestones necessary to compel the exercise of the B unit warrant, and additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to OPAXIO, pixantrone, brostallicin, expanded uses of Zevalin and other products we may be developing. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the U.S., which may increase our costs and adversely affect our ability to obtain financing. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, shareholders may experience dilution of their proportionate ownership of us.

**Table of Contents**

*We have received a going concern opinion on our December 31, 2007 consolidated financial statements*

Due to our need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their report on our December 31, 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our common stock and we may have a more difficult time obtaining necessary financing.

*We may be unable to obtain a quorum for meetings of our shareholders and therefore be unable to take certain corporate actions.*

Our bylaws require that a quorum, consisting of a majority of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our shareholders. A substantial number of our common shares are held by Italian institutions and under Italian laws and regulations, it is difficult to communicate with the beneficial holders of those shares to obtain votes. In 2006, we scheduled two annual meetings of shareholders but were unable to obtain quorum at either meeting. Following that failure to obtain quorum, we contacted certain depository banks in Italy where significant numbers of shares of our common stock were held and asked them to cooperate by making a book entry transfer of their share positions at Monte Titoli to their U.S. correspondent bank, who will then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks contacted agreed to make the share transfer pursuant to these arrangements as of the record date of the meeting, subject to the relevant beneficial owner taking no action to direct the voting of such shares. Under Rule 452 of the New York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as the uncontested election of directors, an amendment to the Company's articles of incorporation to increase authorized shares that are to be used for general corporate purposes, and the ratification of our auditors, in the event that the broker receives no voting instruction from the beneficial owner. As a result of this custody transfer, we were able to hold a special meeting of the shareholders in April 2007, an annual meeting of the shareholders in September 2007 and another special meeting of the shareholders in January 2008. However, obtaining a quorum at future meetings depends in part upon the willingness of the Italian depository banks to continue participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to participate in custody transfer arrangements in the future. We are continuing to explore other alternatives to achieve quorum for our meetings, however, we cannot be certain that we will find an alternate method if we are unable to continue to use the custody transfer arrangements. As a result, we may be unable to obtain quorum at future annual or special meetings of shareholders. If we are unable to obtain a quorum at our shareholder meetings and thus fail to get shareholder approval of corporate actions, such failure could have a materially adverse effect on the Company. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, such failure could have a materially adverse effect on the Company.

*We could fail in financing efforts if we fail to receive shareholder approval when needed.*

We are required under the Nasdaq Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20% of our total shares of common stock outstanding before the issuance of the securities at a discount to the greater of book or market value in an offering that is not deemed to be a public offering by Nasdaq. Funding of our operations in the future may require issuance of additional equity securities that would comprise more than 20% of our total shares of common stock outstanding, but we might not be successful in obtaining the required shareholder approval for such an issuance, particularly in light of the difficulties we have experienced in obtaining a quorum and holding shareholder meetings as outlined above.

---

**Table of Contents**

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

Our stock is traded on the MTA stock market in Milan, Italy and we are required to also comply with the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or CONSOB, which is the public authority responsible for regulating the Italian securities market and the Borsa Italiana, which ensures the development of the managed market in Italy. Collectively these agencies regulate companies listed on Italy's public markets. Conducting our operations in a manner that complies with all applicable laws and rules requires us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all applicable regulatory regimes. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

In addition, under Italian law, we must publish a listing prospectus that has been approved by CONSOB prior to issuing common stock in any twelve-month period that exceeds 10% of the number of shares of common stock outstanding at the beginning of that period. We have attempted to publish a listing prospectus in Italy to cover our general offerings for the past year. We filed our initial listing prospectus with CONSOB in April 2007 and worked with CONSOB to meet their requirements to publish that listing prospectus for the remainder of 2007. We were finally able to publish a listing prospectus in January 2008, however, that listing prospectus was limited to shares to be issued to Société Générale under the Step-Up Equity Financing Agreement we entered into with Société Générale in 2006. We continue to pursue the possibility of publishing a listing prospectus to cover other financing efforts under Italian law, however, at the present time we have not been successful in getting approval from the Italian regulators for such a listing prospectus. As a result, we are required to raise money using alternative forms of securities; for example, we may use convertible preferred stock and convertible debt in lieu of common stock as convertible preferred stock and convertible debt are not subject to the 10% limitation imposed by Italian law.

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

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

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

*If we are not able to successfully identify and complete valuable acquisition opportunities, we may not achieve the anticipated growth we would otherwise achieve were such acquisitions accomplished.*

We have in the past and may in the future seek to further expand our product portfolio through acquisitions of other complementary businesses or technologies or marketed products. For example, in July 2007, we acquired SM, a privately held oncology company, and gained worldwide rights to brostallicin, a DNA minor groove binding agent with proven anti-tumor activity which is currently in phase II clinical studies. Additionally, in December 2007, we acquired Zevalin from Biogen Idec, or Biogen, for development, marketing and sale in the United States. Mergers and acquisitions are inherently risky, and we cannot assure that we will be able to complete future acquisitions, or that our acquisitions will be successful. The successful execution of our acquisition strategy will depend, in part, on our ability to identify, negotiate, complete and integrate such acquisitions and, if necessary, obtain satisfactory debt or equity financing to fund those acquisitions. Failure to manage and successfully integrate acquired businesses could harm our business.

## **Table of Contents**

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

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

difficulties in integrating the operations, technologies, and products of the acquired companies;

difficulties in implementing internal controls over financial reporting;

diversion of management's attention from normal daily operations of the business;

inability to maintain the key business relationships and the reputations of acquired businesses;

entry into markets in which we have limited or no prior experience and in which competitors have stronger market positions;

dependence on unfamiliar affiliates and partners;

reduction in the development or commercialization of existing products due to increased focus on the development or commercialization of the acquired products;

responsibility for the liabilities of acquired businesses;

inability to maintain our internal standards, controls, procedures and policies at the acquired companies or businesses; and

potential loss of key employees of the acquired companies.

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

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

We intend to seek expansion of the approved uses, or labeled uses, of Zevalin in the United States. However, we may be unable to obtain approval for such label expansion in full or in part. If we are not able to obtain approval for expansion of the labeled uses for Zevalin, or if we are otherwise unable to fulfill our marketing, sales and distribution plans for Zevalin, we may not recognize the full anticipated value of Zevalin. If we do not expand the approved uses of Zevalin, we may have insufficient net revenues to finance our current levels of debt and operations unless we are able to market and sell other products. While we are negotiating with Bayer Schering for access to data from their first line indolent trial, or FIT trial, and expect to reach a final agreement with them on access to that data in the near future, we currently have no rights to that data, and there is no assurance that Bayer Schering will agree to give us access to their data on reasonable terms or at all. In addition, even if we are able to use the data from Bayer Schering's FIT trial, there can be no guarantee that such data will be adequate or suitable for submission to the FDA in support of a supplemental biologics license application for additional approved uses of Zevalin, or that the FDA will approve such supplemental biologics license application.



---

**Table of Contents**

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

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

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

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

We have entered into a License and Co-Development agreement related to OPAXIO and pixantrone with Novartis International Pharmaceutical Ltd., or Novartis, pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize pixantrone. We will not receive any royalty or milestone payments under this agreement unless Novartis elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option related to pixantrone and we are able to reach a definitive agreement. Novartis is under no obligation to make such election or exercise such right and may never do so. In addition, even if Novartis exercises such rights, any royalties and milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals and the attainment of certain sales levels. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels.

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

There are no guarantees that we will obtain regulatory approval to manufacture, market or expand the marketing of any of our drug candidates. Obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

## **Table of Contents**

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

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

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA in Europe for OPAXIO for first-time treatment of patients with advanced NSCLC who are PS2 on March 4, 2008 based on results of the STELLAR trials, however a successful regulatory outcome from the EMEA is not assured as the EMEA's final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the MAA.

*We are subject to extensive government regulation.*

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

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. With the exception of Zevalin, none of our current products have received approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. If our products are not approved in a timely manner to provide revenues to defray our debt and operating expenses, or if they are not approved at all, our business and financial condition will be adversely affected.

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

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



---

**Table of Contents**

compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort to maintain compliance. Failure to comply with FDA, EMEA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of \$10.5 million and entered into a settlement agreement with the United States Attorney's Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement, and in connection with the acquisition of Zevalin, a commercially approved drug, we also entered into a corporate integrity agreement with the HHS-OIG that required us to establish a compliance committee and compliance program and adopt a formal code of conduct. The USAO settlement does not address separate claims brought against the Company by the private party plaintiff in this matter, which generally relate to attorney's fees and employment related claims. In 2007, the United States District Court dismissed the private party plaintiff's employment claims as barred by applicable statutes of limitation, and the private party plaintiff has advised us that he intends to seek a court order awarding approximately \$1 million in attorneys' fees. We are not able to reasonably estimate the potential cost of any award that may be made pursuant to this claim.

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

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

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

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

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

---

**Table of Contents**

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

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

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

Many of our competitors, either alone or together with their collaborators and, in particular, the multinational pharmaceutical companies, have substantially greater financial resources and development and marketing teams than us. In addition, many of our competitors, either alone or together with their collaborators, have significantly greater experience than we do in developing, manufacturing and marketing products. As a result, these companies' products might come to market sooner or might prove to be more effective, less expensive, have fewer side effects or be easier to administer than ours. In any such case, sales of our products or eventual products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

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

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

challenging the prices charged for health care products and services,

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

denying or limiting coverage for products that are approved by the FDA but are considered experimental or investigational by third-party payors,

refusing in some cases to provide coverage when an approved product is used for disease indications in a way that has not received FDA marketing approval, and

denying coverage altogether.

The trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities.



---

## Table of Contents

Even if we succeed in bringing any of our proposed products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. As discussed above, CMS proposed new rates for 2008 for Zevalin that, if implemented, would result in reimbursement rates below our acquisition cost of Zevalin. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

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

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. All of our compounds, with the exception of Zevalin, currently are in research or development, and have not received marketing approval.

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

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

fail to receive necessary regulatory approvals,

be difficult to manufacture on a scale necessary for commercialization,

be uneconomical to produce,

fail to achieve market acceptance, or

be precluded from commercialization by proprietary rights of third parties.

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

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

On December 21, 2007, in connection with our purchase of Zevalin, we entered into a Security Agreement with Biogen granting a first priority security interest to Biogen in all of our right, title and interest (a) in and to the assets related to Zevalin that we purchased from Biogen, together with any other assets or rights related to any of such assets or otherwise used in the development, manufacture or commercialization of Zevalin, and (b) under certain license, sublicense and supply agreements entered into in connection with our purchase of Zevalin. In the event we were to default on certain of our obligations under the Security Agreement, the Asset Purchase Agreement pursuant to which we continue to owe royalties and milestone payments to Biogen, or the related sublicense and service agreements, or in the event we were to make an application for, or consent to, the appointment of a receiver, trustee or liquidator of all or a substantial portion of our assets, transfer our assets as part of a general assignment or other arrangement for the benefit of creditors, become insolvent, file a voluntary or involuntary petition under the provisions of the United States Bankruptcy Code, or in the event of an attachment or execution upon, or seizure of, all or substantially all of our assets, Biogen may take any action with respect to the collateral under the Security Agreement that it deems necessary or advisable to

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

accomplish the purposes of the Security Agreement. The Security Agreement will remain in effect until all obligations secured by that agreement have been satisfied. If Biogen were to foreclose on the collateral under this Security Agreement, it would have a material adverse impact on our business.

## **Table of Contents**

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

We have licensed intellectual property, including patent applications relating to intellectual property for pixantrone, brostallicin and Zevalin. We have also in-licensed the intellectual property for our drug delivery technology relating to OPAXIO that uses polymers that are linked to drugs, known as polymer-drug conjugates. Some of our product development programs depend on our ability to maintain rights under these licenses. Each licensor has the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we default under any license agreements, we may lose our right to market and sell any products based on the licensed technology.

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

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

obtain patent protection for our products or processes both in the United States and other countries,

protect trade secrets, and

prevent others from infringing on our proprietary rights.

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

The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. Third parties may independently develop such know-how or otherwise obtain access to our technology. While we require our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

---

**Table of Contents**

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

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

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

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

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

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

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by US and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. One of our products under development, OPAXIO, has a complex manufacturing process, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredients and finished products for pixantrone and brostallicin are both manufactured by a single vendor. The drug substance for Zevalin is produced under contract by Biogen and the drug product and finished product is manufactured and distributed at a contract manufacturer and contract distribution facility.

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

We divested our commercial product, TRISENOX, in July 2005 and acquired a new commercial product, Zevalin, in December 2007. Our ability to generate significant revenues from Zevalin is dependent in part on our ability to find new markets for the product, including through gaining wider acceptance and use of the drug by physicians and through FDA approval of expanded uses for the product. There is no guarantee that we will be successful in accomplishing either of these goals. OPAXIO, pixantrone, brostallicin and label expansions for Zevalin are currently in clinical trials and may not be successful. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. We will need to commit significant time and resources to develop this and additional product candidates. Our product candidates will be successful only if:

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

**Table of Contents**

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

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

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

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

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Substantially all of our product candidates in clinical development are in-licensed from a third party, including Zevalin, OPAXIO, pixantrone, and brostallicin.

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

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

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors. On March 4, 2008, we submitted an MAA to the EMEA for OPAXIO which was accepted for review by that agency in March 2008, however, we do not expect a regulatory decision on the MAA prior to the second half of 2009. Analysis of the data from our EXTEND trial is expected in the second half of 2008 and, if final study results are adequate, we could submit an NDA with the FDA in early 2009 with potential approval in the second half of 2009.

We may not obtain authorization to permit product candidates that are in the preclinical development phase to enter the human clinical testing phase. Authorized preclinical or clinical testing may not be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Clinical testing may not show potential products to be safe and efficacious and potential products may not be approved for a specific indication. Further, the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials. Data obtained from clinical trials are susceptible to varying interpretations. Government regulators and our collaborators may not agree with our interpretation of our clinical trial results. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

We have limited experience in conducting clinical trials. We expect to continue to rely on third parties, such as contract research organizations, academic institutions and/or cooperative groups, to conduct, oversee and monitor clinical trials as well as to process the clinical results and manage test requests, which may result in delays or failure to complete trials if the third parties fail to perform or to meet the applicable standards.



## Table of Contents

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

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

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the Gynecologic Oncology Group to perform a phase III trial of OPAXIO in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX, however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

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

collaborative arrangements may not be on terms favorable to us;

disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;

we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;

partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;

agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;

business combinations or significant changes in a partner's business strategy might adversely affect that partner's willingness or ability to complete its obligations to us; and

the terms and conditions of the relevant agreements may no longer be suitable.

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

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

We base several of our product candidates upon novel technologies that we are using to develop drugs for the treatment of cancer. These technologies have not been proven. Furthermore, preclinical results in animal studies may not predict outcomes in human clinical trials. Our

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

product candidates may not be proven safe or effective. If these technologies do not work, our drug candidates may not develop into commercial products.

**Table of Contents**

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

A portion of our business is based in Italy. We are subject to duties and risks arising from doing business in Italy, such as:

Italian employment law, including collective bargaining agreements negotiated at the national level and over which we have no control;

European data protection regulations, under which we will be unable to send private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices until our U.S. offices self-certify their adherence to the safe harbor framework established by the U. S. Department of Commerce in consultation with the European Commission;

tariffs, customs, duties and other trade barriers; and

capital controls, terrorism and other political risks.

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

effectively pursuing the clinical development and regulatory approvals of all product candidates;

successfully commercializing products under development;

coordinating research and development activities to enhance introduction of new products and technologies;

coalescing the Italian business culture with our own and maintaining employee morale; and

maintaining appropriate uniform standards, controls, procedures and policies relating to financial reporting and employment related matters, and the conduct of development activities that comply with both U.S. and Italian laws and regulations.

We may not succeed in addressing these challenges, risks and duties, any of which may be exacerbated by the geographic separation of our operations in the United States and in Italy. These risks related to doing business in Italy could harm the results of our operations.

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

Our business exposes us to potential product liability risks inherent in the testing, manufacturing, marketing and sale of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering marketing and sales of Zevalin as well as product use in our clinical trials for our product candidates, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will provide adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of Zevalin or any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

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

Our commercial product, Zevalin, has the possibility of causing significant side effects in patients, and deaths associated with an infusion reaction symptom complex, though rare, have occurred within 24 hours of infusions of rituximab, a component of Zevalin. In addition, Yttrium-90 Zevalin administration often results in severe and

## **Table of Contents**

prolonged cytopenias in most patients, while severe cutaneous and mucocutaneous reactions have also been reported. While side effects are common in oncology drugs, adverse events such as these could negatively impact sales of Zevalin, which in turn could negatively impact our results from operations.

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

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

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

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

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

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

## **Risks Related To the Securities Markets**

*Our stock price is extremely volatile, which may affect our ability to raise capital in the future and may subject the value of your investment in our securities to sudden decreases.*

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve month period ended April 30, 2008, our stock price has ranged from a low of \$0.47 to a high of \$5.66. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

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

announcements by us or others of results of preclinical testing and clinical trials and regulatory actions;

announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

**Table of Contents**

our issuance of additional debt, equity or other securities, which we need to pursue in 2008 to generate additional funds to cover our current debt and operating expenses;

our quarterly operating results;

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts' recommendations;

changes in health care policies and practices;

economic and other external factors; and

general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. For example, in the case of our company, beginning in March 2005, several class action lawsuits were instituted against CTI and certain directors and officers of CTI and a derivative action lawsuit was filed against CTI's full board of directors. While these lawsuits were dismissed with prejudice, as a result of these types of lawsuits, we could incur substantial legal fees and our management's attention and resources could be diverted from operating our business as we respond to the litigation. We maintain significant insurance to cover these risks for the Company and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, and there is no guarantee that the insurance will cover any specific claim that we may face in the future, or that it will be adequate to cover all potential liabilities and damages,

*Our common stock is listed on the Nasdaq Global Market and we may not be able to maintain that listing, which may make it more difficult for investors to sell shares of our common stock.*

Our common stock is listed on the Nasdaq Global Market. The Nasdaq Global Market has several quantitative and qualitative requirements companies must comply with to maintain this listing, including a \$1.00 minimum bid price per share and \$50 million minimum value of listed securities. On April 16, 2008, we received notice from the Nasdaq Stock Market that our common stock had a closing bid price below \$1.00 for at least 30 consecutive business days and therefore we are not in compliance with the listing standards of the Nasdaq Global Market. Under the current Nasdaq Global Market rules, we have a period of 180 days from the date of notice, or until October 13, 2008, to attain compliance by again meeting the \$1.00 minimum bid price for a minimum of 10 consecutive business days. If we are unable to meet that compliance criteria before October 13, 2008, we may have the option to transfer to the Nasdaq Capital Market, assuming we meet all other initial listing

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-Q

qualifications for the Nasdaq Capital Market, where we can receive an additional 180 days to regain compliance. If we are ultimately unable to attain compliance with the minimum bid price we may be delisted. In addition, if we fail to maintain the minimum value of listed securities, we may have to transfer to the Nasdaq Capital Market or may be delisted. The level of trading activity of our common stock may decline if it is no longer listed on the Nasdaq Global Market or Nasdaq Capital Market. Furthermore, our failure to maintain a listing on the Nasdaq market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such date. As such, if our common stock ceases to be listed for trading on the Nasdaq Global Market or Nasdaq Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult to for investors to sell shares of our common stock.

## **Table of Contents**

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

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

a classified board so that only approximately one third of the board of directors is elected each year;

elimination of cumulative voting in the election of directors;

procedures for advance notification of shareholder nominations and proposals;

the ability of our board of directors to amend our bylaws without shareholder approval; and

the ability of our board of directors to issue shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as the board of directors may determine.

In addition, as a Washington corporation, we are subject to Washington law which imposes restrictions on some transactions between a corporation and certain significant shareholders.

These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

### **Item 4. Submission of Matters to a Vote of Security Holders.**

(a) On January 28, 2008, we held a Special Meeting of Shareholders, or Special Meeting. Each share of Common stock was entitled to one vote per share, each share of Series A 3% Preferred Stock was entitled to approximately 149.5 votes per share, each share of Series B Preferred Stock was entitled to approximately 148.6 votes per share, each share of Series C 3% Preferred Stock was entitled to approximately 220.8 votes per share and each share of Series D 7% Preferred Stock was entitled to approximately 383.1 votes per share.

(b) Not applicable.

(c) At the Special Meeting, our shareholders approved the proposal to amend and restate our articles of incorporation to increase the number of authorized shares from 110 to 210 million and to increase the number of authorized shares of common stock from 100 to 200 million. With respect to this proposal, there were 36,102,185 votes cast for the proposal, 1,270,992 votes cast against the proposal and 154,822 abstentions.

The foregoing matters are described in detail in the Company's proxy statement dated December 21, 2007 for the Special Meeting. No other matters were voted on at the Special Meeting.

(d) Not applicable.

### **Item 5. Other Information**

(a) We have set the date of our Special Meeting in Lieu of Annual Meeting to be June 19, 2008 this year. As a result, any shareholder proposals to be included in the Special Meeting in Lieu of Annual Meeting under Rule 14a-8 of the Securities Exchange Act of 1934 must be received by us a reasonable amount of time prior to the date we prepare the proxy materials. We have already filed our preliminary proxy statement and



intend to prepare and mail our definitive proxy statement no later than May 23, 2008.

**Table of Contents**

**Item 6. Exhibits**

(a) Exhibits

- 10.1 Severance Agreement and General Release between the Registrant and Scott C. Stromatt, M.D. dated April 3, 2008.
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**SIGNATURES**

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

**CELL THERAPEUTICS, INC.**

(Registrant)

Dated: May 12, 2008

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

Dated: May 12, 2008

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

(Principal Financial Officer, Chief Accounting Officer)