

CELL THERAPEUTICS INC

Form 10-Q

August 09, 2007

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

**For the quarterly period ended: June 30, 2007**

**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**

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**CELL THERAPEUTICS, INC.**

**(Exact name of registrant as specified in its charter)**

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**Washington**  
**(State or other jurisdiction of**

**incorporation or organization)**

**501 Elliott Avenue West, Suite 400**

**91-1533912**  
**(I.R.S. Employer**

**Identification No.)**

**98119**

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Seattle, Washington  
(Address of principal executive offices)

(206) 282-7100

(Zip Code)

(Registrant's telephone number, including area code)

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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 ☐

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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 July 31, 2007
Common Stock, no par value	49,965,313

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(In thousands, except share amounts)

	June 30, 2007 (unaudited)	December 31, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,026	\$ 17,129
Securities available-for-sale	35,413	36,708
Interest receivable	363	570
Accounts receivable, net	162	183
Prepaid expenses and other current assets	10,486	9,948
Total current assets	54,450	64,538
Property and equipment, net	6,478	7,915
Goodwill	17,064	17,064
Other intangibles, net	1,278	1,663
Other assets	10,311	10,641
Total assets	\$ 89,581	\$ 101,821
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 1,035	\$ 639
Accrued expenses	16,883	28,567
Current portion of deferred revenue	80	80
Current portion of long-term obligations	1,982	2,816
Current portion of derivative liability		2,270
Current portion of convertible senior subordinated notes	27,407	
Current portion of convertible subordinated notes	28,490	
Total current liabilities	75,877	34,372
Deferred revenue, less current portion	438	478
Long-term obligations, less current portion	4,155	4,667
7.5% convertible senior notes	32,039	45,916
6.75% convertible senior notes	6,931	6,945
Convertible senior subordinated notes	55,150	82,557
Convertible subordinated notes		28,490
Total liabilities	174,590	203,425
Commitments and contingencies		
Preferred stock, no par value:		
Authorized shares 10,000,000		
Series A 3% Convertible Preferred Stock, \$1,000 stated value, 20,000 shares designated; 6,850 and 0 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	5,188	
Series B 3% Convertible Preferred Stock, \$1,000 stated value, 37,200 shares designated; 15,380 and 0 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	11,884	
Shareholders' deficit:		
Common stock, no par value:		

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Authorized shares 100,000,000

Issued and outstanding shares 43,332,181 and 36,397,230 at June 30, 2007 and December 31, 2006, respectively

	917,301	860,691
Accumulated other comprehensive loss	(1,634)	(1,187)
Accumulated deficit	(1,017,748)	(961,108)

Total shareholders' deficit	(102,081)	(101,604)
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Total liabilities and shareholders' deficit	\$ 89,581	\$ 101,821
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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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Revenues:				
License and contract revenue	\$ 20	\$ 20	\$ 40	\$ 40
Total revenues	20	20	40	40
Operating expenses:				
Research and development	16,516	15,164	31,802	30,928
Selling, general and administrative	7,590	8,199	15,720	18,762
Amortization of purchased intangibles	212	199	419	388
Total operating expenses	24,318	23,562	47,941	50,078
Loss from operations	(24,298)	(23,542)	(47,901)	(50,038)
Other income (expense):				
Investment and other income	738	694	1,441	1,236
Interest expense	(3,678)	(4,708)	(7,594)	(13,336)
Foreign exchange gain	387	821	834	1,112
Make-whole interest expense		(4,374)	(2,310)	(24,540)
Gain on derivative liabilities	906	2,659	3,614	6,083
Gain on exchange of convertible notes		7,978		7,978
Settlement expense	(17)		(160)	(883)
Other income (expense), net	(1,664)	3,070	(4,175)	(22,350)
Net loss	(25,962)	(20,472)	(52,076)	(72,388)
Preferred stock beneficial conversion feature	(1,789)		(4,383)	
Preferred stock dividends	(150)		(181)	
Net loss attributable to common shareholders	\$ (27,901)	\$ (20,472)	\$ (56,640)	\$ (72,388)
Basic and diluted net loss per common share	\$ (0.65)	\$ (0.78)	\$ (1.41)	\$ (2.97)
Shares used in calculation of basic and diluted net loss per common share	42,713	26,150	40,165	24,335

See accompanying notes.

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

	<b>Six Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Operating activities</b>		
Net loss	\$ (52,076)	\$ (72,388)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,693	3,234
Equity-based compensation expense	554	2,502
Loss on disposition of property and equipment		76
Amortization (accretion) of investment premium (discount)	(115)	134
Non-cash gain on convertible notes		(7,978)
Non-cash gain on derivative liabilities	(3,614)	(6,083)
Non-cash interest expense	3,575	9,257
Non-cash rent benefit	(96)	(8)
Loss on sale of investment securities	1	
Changes in operating assets and liabilities:		
Restricted cash		859
Interest receivable	207	(32)
Accounts receivable, net	21	1,346
Prepaid expenses and other current assets	(376)	784
Other assets	(358)	417
Accounts payable	405	(2,371)
Accrued expenses	(11,958)	(1,799)
Deferred revenue	(40)	(40)
Excess facilities obligations	(1,297)	(1,391)
Other long-term obligations	62	(276)
Total adjustments	(10,336)	(1,369)
Net cash used in operating activities	(62,412)	(73,757)
<b>Investing activities</b>		
Purchases of securities available-for-sale	(26,488)	(16,961)
Proceeds from sales of securities available-for-sale	5,485	
Proceeds from maturities of securities available-for-sale	22,377	18,488
Purchases of property and equipment	(733)	(348)
Proceeds from sale of property and equipment		511
Net cash provided by investing activities	641	1,690
<b>Financing activities</b>		
Proceeds from issuance of Series A 3% convertible preferred stock and warrants, net	18,608	
Proceeds from issuance of Series B 3% convertible preferred stock and warrants, net	34,920	
Proceeds from issuance of 7.5% convertible senior notes, net		31,177
Release of restricted cash related to 6.75% convertible senior notes		24,712

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Mandatory redemptions of 6.75% convertible senior notes		(2,655)
Proceeds from common stock sold via the employee stock purchase plan		17
Payment of dividends on preferred stock	(34)	
Repayment of long-term obligations	(55)	(57)
Net cash provided by financing activities	53,439	53,194
Effect of exchange rate changes on cash and cash equivalents	(771)	(468)
Net decrease in cash and cash equivalents	(9,103)	(19,341)
Cash and cash equivalents at beginning of period	17,129	50,022
Cash and cash equivalents at end of period	\$ 8,026	\$ 30,681

### Supplemental disclosure of cash flow information

Cash paid during the period for interest	\$ 6,529	\$ 29,055
Cash paid for taxes	\$	\$

### Supplemental disclosure of noncash financing and investing activities

Conversion of Series A 3% convertible preferred stock to common stock	\$ 9,959	\$
Conversion of Series B 3% convertible preferred stock to common stock	\$ 16,860	\$
Conversion of 7.5% convertible senior notes to common stock	\$ 15,294	\$ 7,375
Conversion of 6.75% convertible senior notes to common stock	\$	\$ 68,645
Conversion of convertible senior subordinated notes to common stock	\$	\$ 4
Extinguishment of 5.75% convertible senior subordinated notes in exchange for 7.5% convertible senior notes	\$	\$ 39,518
Extinguishment of 5.75% convertible subordinated notes in exchange for 7.5% convertible senior notes	\$	\$ 1,150
Issuance of 7.5% convertible senior notes in exchange for 5.75% subordinated and senior subordinated notes	\$	\$ 33,156

See accompanying notes.



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**CELL THERAPEUTICS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**1. Description of Business and Summary of Significant Accounting Policies**

*Description of Business*

Cell Therapeutics, Inc., or CTI or the Company, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics; an area with significant market opportunity that we believe is not adequately served by existing therapies. Our operations are primarily conducted in the United States and Italy.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of June 30, 2007 and for the three and six months ended June 30, 2007 and 2006 has been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the Company's financial position at such date and the operating results and cash flows for such periods. Operating results for the three and six month periods ended June 30, 2007 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 financial statements and the related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2006 included in our Form 10-K.

The balance sheet at December 31, 2006 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements.

*Reverse Stock-Split*

On April 15, 2007, we effected a one-for-four reverse stock split of our common stock (see Note 3, *Capital 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.

*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 several years primarily due to research and development costs for XYOTAX, pixantrone and CT-2106. *Cash and cash equivalents, securities available-for-sale and interest receivable* are approximately \$43.8 million as of June 30, 2007. In addition, in July 2007, we closed a Series C 3% convertible preferred stock and common stock warrant financing generating proceeds of approximately \$19.0 million, net of placement agency fees. We have approximately \$55.9 million in principal due on our convertible subordinated and senior subordinated notes in June 2008 and this net amount is not sufficient to repay these notes and to fund our planned operations for the next twelve months which raises substantial doubt about our ability to continue as a going concern. We plan to restructure these notes. However, we may be unable to do this on favorable terms or at all. Accordingly, we will need to raise additional

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funds and are currently exploring alternative sources of equity or debt financing. While we have a \$60 million (approximately \$80 million) Step-Up Equity Financing Agreement with Société Générale which we may be able to utilize to provide additional equity funding, additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

### *License and Contract Revenue*

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

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

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

### *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. Research and development costs are expensed as incurred. Generally, in instances where we enter into agreements with third parties for research and development activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

### *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 impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values.

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### *Value Added Tax Receivable*

Our European subsidiary is 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 \$10.8 million and \$10.6 million as of June 30, 2007 and December 31, 2006, respectively, of which \$5.7 million and \$5.5 million is included in *other assets* and \$5.1 million and \$5.1 million is included in *prepaid expenses and other current assets* as of June 30, 2007 and December 31, 2006, respectively. This receivable balance typically has a three to five 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 share is calculated based on the net loss 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 earnings per 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 June 30, 2007 and 2006, options, warrants, unvested share awards and rights, convertible debt and convertible preferred stock aggregating 16,041,550 and 11,790,155, 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 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, includes 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 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 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.

Changes in the estimated fair value of the derivative liabilities related to both our 6.75% and 7.5% notes are included in *gain on derivative liabilities* and will be calculated until the relevant feature expires or all of the relevant notes are converted or repurchased.

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### *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 in accordance with SFAS No. 52, *Foreign Currency Translation*.

### *Recently Issued Accounting Pronouncements*

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which provides guidance on how to measure assets and liabilities that use fair value. This statement clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 will apply whenever another generally accepted accounting principle requires, or permits, assets or liabilities to be measured at fair value but does not expand the use of fair value to any new circumstances. This statement will also require additional disclosures in both annual and quarterly reports. SFAS 157 is effective for fiscal years beginning after November 2007, and will be adopted by us beginning January 1, 2008. We are currently evaluating the potential impact this statement may have on our financial statements, but do not believe the impact of adoption will be material.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – Including an Amendment of FASB Statement No. 115*, or SFAS 159. The Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected would be reported in earnings at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements in order to facilitate comparisons between entities choosing different measurement attributes for similar types of assets and liabilities. SFAS 159 does not affect existing accounting requirements for certain assets and liabilities to be carried at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the requirements of SFAS 159 and have not yet determined the impact on the financial statements.

In June 2007, the EITF reached a consensus on Issue 07-3, which focuses 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. EITF 07-3 is effective for periods beginning after December 15, 2007. Further, the EITF has Issue 07-1 currently under consideration. 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 collaboration agreement should be presented in the income statement and certain related disclosure questions. We are currently evaluating the requirements of these issues and have not yet determined the impact on the financial statements.

### *Reclassifications*

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

## **2. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income or loss. SFAS No. 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 \$26.2 million and \$20.2 million for the three month periods ended June 30, 2007 and 2006, respectively. Total comprehensive loss was \$52.5 million and \$71.8 million for the six month periods ended June 30, 2007 and 2006, respectively.

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

	June 30, 2007	December 31, 2006
Foreign currency translation adjustment	\$ (1,616)	\$ (1,203)
Net unrealized gain (loss) on securities available-for-sale	(18)	16
Accumulated other comprehensive loss	\$ (1,634)	\$ (1,187)

**3. Capital Stock***3% Convertible Preferred Stock***Series A**

In February 2007, we issued 20,000 shares of our Series A 3% Convertible Preferred Stock, or Series A preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 3%, payable quarterly. The Series A preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted, which is initially \$1,000 per share, by the conversion price, which is initially \$6.69 (post-split). The initial conversion price is subject to adjustment in certain events. The Series A preferred stock will vote on an as-converted basis with the common stock.

In connection with the Series A preferred stock issuance, we issued warrants to purchase an additional 1,494,766 shares of our common stock at an exercise price of \$6.44 per post-split share. At issuance, the warrants maintained a provision that would not allow them to become exercisable until an increase in the number of authorized shares was obtained from our shareholders. We obtained shareholder approval to increase the number of authorized shares of common stock from 200 million (50 million post-split) to 400 million (100 million post-split) and on April 16, 2007 we filed amended and restated articles of incorporation effecting that increase. The warrants became exercisable on that date and will terminate two years after the date they became exercisable, or April 16, 2009.

The holders of Series A preferred stock have the right to require us to redeem all or a portion of the Series A preferred stock shares, payable in common stock, upon the occurrence of certain triggering events for a redemption amount equal to the greater of (a) 130% of the stated value or (b) the product of (1) the volume weighted average price of the common stock on the trading day preceding the conversion and (2) the stated value divided by the conversion price; plus all accrued and unpaid dividends or other payments on such shares. In addition, at any time after the two-year anniversary of the original issue date, holders of Series A preferred stock have the right to require us to redeem any of their outstanding Series A preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. With respect to our accounting for the preferred stock, because redemption is at the option of the holder of the Series A preferred stock and is not certain to occur, it is considered contingently redeemable and is not classified as a liability under the scope of SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. In addition, EITF Topic D-98, *Classification and Measurement of Redeemable Securities*, states that Rule 5-02.28 of Regulation S-X requires securities with redemption features that are not solely within the control of the issuer to be recorded outside of permanent equity. As the Series A preferred stock shares include certain redemption features that may be triggered by events or actions that are outside our control, we have classified these shares as mezzanine equity.

The net proceeds from the issuance of the Series A preferred stock of approximately \$18.6 million were allocated between the fair value of the warrants and the Series A preferred stock. Using the Black-Scholes option pricing model, we calculated the relative fair value of the warrants to purchase 1,494,766 shares of our common stock to be approximately \$3.5 million. This relative fair value has been recorded as a reduction of the mezzanine equity balance for the Series A preferred stock and an addition to common stock. Additionally, we calculated a beneficial conversion feature charge related to the conversion price for the Series A preferred stock to common stock

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of approximately \$2.6 million. As the Series A preferred stock can be converted immediately, the amount of the beneficial conversion feature was immediately accreted and resulted in a deemed dividend. This charge was recorded as a dividend expense included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

As of June 30, 2007, 13,150 shares of Series A preferred stock had been converted into 1,965,619 shares of common stock. As of that date we had approximately \$51,000 of Series A preferred stock dividends accrued which were paid in July 2007.

### **Series B**

In April 2007, we issued 37,200 shares of our Series B 3% convertible preferred stock, or Series B preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 3%, payable quarterly. The Series B preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted, which is initially \$1,000 per share, by the conversion price, which is initially \$6.73. The initial conversion price is subject to adjustment in certain events. The Series B preferred stock will vote on an as-converted basis with the common stock.

In connection with the Series B preferred stock issuance, we issued warrants to purchase an additional 2,763,731 shares of our common stock at an exercise price of \$6.48 per share. The warrants will become exercisable on October 16, 2007 and will terminate two years from this date.

The holders of Series B preferred stock have the right to require us to redeem all or a portion of the Series B preferred stock shares, payable in common stock, upon the occurrence of certain triggering events for a redemption amount equal to the greater of (a) 130% of the stated value or (b) the product of (1) the volume weighted average price of the common stock on the trading day preceding the conversion multiplied by (2) the stated value divided by the conversion price; plus all accrued and unpaid dividends or other payments on such shares. In addition, at any time after the two-year anniversary of the original issue date and subject to the prior rights of the Series A preferred stock, holders of Series B preferred stock have the right to require us to redeem any of their outstanding Series B preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. Based on these redemption features, which are comparable to the redemption features of our Series A preferred stock, we have classified these shares as mezzanine equity in accordance with the guidance discussed above in the Series A preferred stock.

The net proceeds from the issuance of the Series B preferred stock of approximately \$34.8 million were allocated between the fair value of the warrants and the Series B preferred stock. Using the Black-Scholes option pricing model, we calculated the relative fair value of the warrants to purchase 2,763,731 shares of our common stock to be approximately \$6.1 million. This relative fair value has been recorded as a reduction of the mezzanine equity balance for the Series B preferred stock and an addition to common stock. Additionally, we calculated a beneficial conversion feature charge related to the conversion price for the Series B preferred stock to common stock of approximately \$1.8 million. As the Series B preferred stock can be converted immediately, the amount of the beneficial conversion feature was immediately accreted and resulted in a deemed dividend. This charge was recorded as a dividend expense included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

As of June 30, 2007, 21,820 shares of Series B preferred stock had been converted into 3,242,190 shares of common stock. As of that date we had approximately \$96,000 of Series B preferred stock dividends accrued which were paid in July 2007.

### **Series C**

In July 2007, we issued 20,250 shares of our Series C 3% convertible preferred stock, or Series C preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 3%, payable quarterly. We also issued warrants to purchase an additional 2,596,148 shares of our common stock at an exercise price of \$4.53 per share. The warrants will not be exercisable until six months after the date of issuance and will terminate on the second anniversary of the date upon which they become exercisable.

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The Series C preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted which is \$1,000 per share, by the conversion price, which is initially \$3.90. The initial conversion price is subject to adjustment in certain events. The Series C preferred stock will vote on an as-converted basis with the common stock.

As of July 31, 2007, 9,443 shares of Series C preferred stock had been converted into 2,421,276 shares of common stock.

### *Authorized Shares*

On April 10, 2007, we held a special meeting whereby shareholders approved an increase to the number of authorized shares of our common stock from 200 million to 400 million. After the effect of our one-for-four reverse stock split as discussed below, total authorized shares are 110 million and total authorized shares of our common stock are 100 million.

### *Reverse Stock Split*

In February 2007, our board of directors approved a one-for-four reverse stock split of our common stock, and a proportionate reduction of the authorized number of shares of our common stock. On April 15, the reverse stock split became effective. As a result of the reverse stock split, every four shares of our issued and outstanding common stock were automatically combined into one issued and outstanding share. Fractional shares calculated in the split were rounded down to the nearest share and no fractional shares were issued. In lieu of fractional shares, shareholders received cash at a rate of \$6.81 per whole post-split share. The reverse stock split affected all of the holders of our common stock uniformly and did not affect any shareholder's percentage of ownership interest. Any shares of our common stock or shares of common stock underlying options, warrants, convertible preferred stock and convertible debt were proportionately reduced and the exercise prices of any warrants or options and the conversion prices of any convertible debt were proportionately increased in accordance with the terms of the related agreements. All impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the reverse stock split.

## **4. Aequus BioPharma, Inc.**

In May 2007, we formed Aequus BioPharma, Inc., or Aequus, a 70% majority owned subsidiary. We entered into a license agreement with Aequus whereby Aequus gained rights to our Genetic Polymer technology which Aequus will continue to develop. The Genetic Polymer technology may speed the manufacture, development, and commercialization of follow-on and novel protein-based therapeutics.

Minority interests are not reflected in our balance sheet as losses are fully absorbed by CTI with no obligation of reimbursement by the minority shareholders until profits are generated by Aequus. As of June 30, 2007, Aequus had incurred approximately \$131,000 in operating expenses in support of its research and development efforts. Our President and Chief Executive Officer, James A. Bianco, M.D. and our Executive Vice President, Chief Medical Officer, Jack W. Singer, M.D. are both minority shareholders of Aequus, each owning a 5% equity share of the company. Additionally, both Dr. Bianco and Dr. Singer are members of Aequus' board of directors and each have entered into a consulting agreement with Aequus.

In May 2007, we also entered into an agreement to fund Aequus up to \$2.0 million in cash in exchange for a convertible promissory note that becomes due and payable in five years and earns interest at a rate of 6% per annum. The note can be converted into equity at any time prior to its maturity upon CTI's demand, or upon other triggering events. The number of shares of Aequus equity securities to be issued upon conversion of this note is equal to the quotient obtained by dividing (i) the outstanding balance of the note by (ii) 100% of the price per share of the equity securities. As of June 30, 2007, we have funded Aequus with an initial payment of \$0.5 million. Additional payments of up to \$1.5 million will be made upon the achievement of certain milestones. In addition, we have entered into a services agreement to provide certain administrative and research and development services to Aequus. The amounts charged for these services, if unpaid by Aequus within 30 days, will be considered additional principal advanced under the promissory note.

**Table of Contents****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 No. 123(R), *Share-Based Payment (Revised 2004)*, or SFAS 123(R), for the three and six months ended June 30, 2007, which was allocated as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Research and development	\$ 123	\$ 508	\$ 312	\$ 1,079
Selling, general and administrative	113	697	242	1,423
Stock-based compensation expense included in operating expenses	\$ 236	\$ 1,205	\$ 554	\$ 2,502

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Risk-free interest rates	4.9%	5.1%	4.7%	4.9%
Expected dividend yield	None	None	None	None
Expected life (in years)	2.8	2.7	3.5	3.2
Expected volatility	76%	74%	76%	74%

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. Convertible Senior Notes***7.5% Convertible Senior Notes*

For the three and six months ended June 30, 2007, \$7.4 million and \$15.3 million of our 7.5% notes were converted into 0.9 million shares and 1.8 million shares of common stock, respectively. We had \$33.5 million and \$48.8 million principal amount of our 7.5% notes outstanding as of June 30, 2007 and December 31, 2006, respectively. In connection with the conversion of \$6.2 million of these notes during the three months ended March



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31, 2007 and \$7.4 million of 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 six months ended June 30, 2007. There was no make-whole interest expense for the three months ended June 30, 2007. In May 2006, we made a discretionary make-whole payment of \$1.7 million related to the conversion of approximately \$7.4 million of the 7.5% notes which is included in *make-whole interest expense* for the three and six months ended June 30, 2006.

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. At the issuance of the 7.5% notes, the interest make-whole feature was estimated to have a fair value of approximately \$3.7 million and the initial recorded value of the 7.5% notes was reduced by this allocation. In addition, at December 31, 2006, we recorded an increase to the derivative balance of \$1.8 million which represents the change in value as a result of the modification of the terms of the make-whole interest provision related to certain investors. 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 \$1.3 million and \$0.5 million for the three months ended June 30, 2007 and 2006, respectively, and interest expense of \$2.7 million and \$0.5 million for the six months ended June 30, 2007 and 2006, respectively. The expense recorded for the three and six months ended June 30, 2007 was primarily related to accelerated accretion due to note conversions. The estimated fair value of the derivative liability is adjusted quarterly for changes in the estimated market value. The change in the estimated fair value was \$0.9 million and \$2.1 million for the three months ended June 30, 2007 and 2006, respectively, and was \$3.6 million and \$2.1 million for the six months ended June 30, 2007 and 2006, respectively. These amounts were included in *gain on derivative liabilities*. At June 30, 2007, the fair value of the derivative was \$10,000 and was recorded in *7.5% convertible senior notes*. At December 31, 2006, the fair value of the derivative was \$3.6 million, \$2.3 million of which was recorded in *current portion of derivative liability* and \$1.3 million of which was recorded in *7.5% convertible senior notes*.

### *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 and \$0.6 million for the three months ended June 30, 2007 and 2006, respectively and interest expense of \$39,000 and \$3.9 million for the six months ended June 30, 2007 and 2006, respectively. The expense recorded for the three and six months ended June 30, 2006 was primarily related to accelerated accretion due to note conversions. The estimated fair value of the derivative liability was \$0.2 million at June 30, 2007 and December 31, 2006 and was recorded in *6.75% convertible senior notes*. The change in the estimated fair value was \$26,000 and \$0.6 million for the three months ended June 30, 2007 and 2006, respectively, and was \$53,000 and \$4.0 million for the six months ended June 30, 2007 and 2006, respectively. These amounts were included in *gain on derivative liabilities*.

### *5.75% Convertible Subordinated and Senior Subordinated Notes*

As of June 30, 2007, \$28.5 million of our 5.75% convertible subordinated notes and \$27.4 million of our 5.75% convertible senior subordinated notes were reclassified to current liabilities from long-term liabilities. These notes are due in June 2008.

## **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.

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The following table summarizes the changes in the liability for restructuring activities during the six months ended June 30, 2007 (in thousands):

	Excess Facilities Charges	Employee Separation Costs
Balance at December 31, 2006	\$ 3,951	\$ 27
Adjustments	22	
Payments	(1,319)	(9)
Balance at June 30, 2007	\$ 2,654	\$ 18

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 No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, 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 estimated sublease income. We reversed expenses of approximately \$10,000 and \$118,000 for the three months ended June 30, 2007 and 2006, respectively. For the six months ended June 30, 2007 and 2006 we recorded additional restructuring expense of approximately \$22,000 and \$338,000, respectively. These amounts are included in *selling, general and administrative* expense. The adjustments to restructuring expense 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 periodically evaluate our existing needs, the current and estimated future values of our subleases, and other future commitments to determine whether we should record additional excess facilities charges or adjustments to such charges. As of June 30, 2007 and December 31, 2006 respectively, approximately \$1.5 million and \$2.6 million of the liability for restructuring activities is included in *current portion of long-term obligations* and approximately \$1.1 million and \$1.4 million is included in *long-term obligations, less current portion*.

**8. Legal Proceedings**

In April 2007, we entered into a settlement agreement with the United States Attorney's Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior business practices relating to TRISENOX® (arsenic trioxide). Pursuant to this settlement agreement, we made a single payment of \$10.6 million to the USAO, which included a settlement amount of \$10.5 million and interest accrued on that amount since the date of reaching an agreement in principle, in return for a release of all government claims in connection with a qui tam action brought by a private plaintiff and related matters. This settlement does not address separate claims brought against the Company by the private party plaintiff in such matters, which generally relate to attorney's fees and employment related claims. We believe that the private party plaintiff's claims related to wrongful termination are not meritorious.

As of December 31, 2006, \$10.5 million related to the USAO litigation matter was included in *accrued expenses*. As of March 31, 2007, this amount was increased by approximately \$0.1 million to \$10.6 million. We made the settlement payment of \$10.6 million in April 2007.

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, 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.

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**9. Subsequent Events**

On July 24, 2007, we entered into a definitive merger agreement with Systems Medicine, Inc., or SMi, a privately held oncology company. On July 31, 2007, we completed the acquisition of SMi in a stock for stock merger valued at \$20 million in which 4,211,856 shares of CTI common stock were issued in exchange for outstanding SMi ordinary shares. Of the total shares issued, 421,186 remain subject to an escrow account. The total cost of the merger is estimated to be approximately \$20 million, before related transaction costs which are yet to be determined. Pursuant to the terms of the acquisition agreement, if certain FDA regulatory approval milestones are met, the stockholders of SMi could also receive a maximum of \$15 million in additional consideration, payable in either cash or shares of our common stock at our election. Under the agreement, SMi will continue to operate as a wholly-owned subsidiary of CTI.

SMi applies a systems biology approach to drug development, combining pharmacogenomics and bioinformatics with experienced preclinical, clinical, and regulatory expertise to find and exploit a specific cancer's context-of-vulnerability. SMi holds worldwide rights to use, develop, import and export Brostallicin, a DNA minor groove binding agent that has demonstrated anti-tumor activity and a favorable safety profile in clinical trials.

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

*The following discussion should be read in conjunction with the 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 XYOTAX, paclitaxel poliglumex, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. As announced in March and May, 2005, our STELLAR 2, 3, and 4 phase III clinical studies for XYOTAX did not meet their primary endpoints of superior overall survival. However, we believe a pooled analysis of STELLAR 3 and 4 demonstrates a statistically significant survival advantage among women receiving XYOTAX 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 XYOTAX and carboplatin, known as the PGT202 trial, supporting the potential benefit observed in the STELLAR first-line trials. We believe the lack of safe and effective treatments for women with advanced first-line NSCLC who are performance status 2, or PS2, represents an unmet medical need. In December, 2005, we initiated a phase III clinical trial, known as the PIONEER, or PGT305, study, for XYOTAX as first-line monotherapy in PS2 women with NSCLC. In November 2006, we suspended enrollment in the PIONEER trial to allow data related to recently enrolled patients to mature and to assess the differences in early cycle deaths observed between arms of the study. In December 2006, we agreed with the recommendation of the Data Safety Monitoring Board to close the PGT305 PIONEER lung cancer clinical trial and took patients off both treatment arms. The decision was due, in part, to the diminishing utility of the PIONEER trial given our plans to submit a new protocol to the U.S. Food and Drug Administration, or FDA. In early 2007, we submitted two new protocols under a Special Protocol Assessment, or SPA, to the FDA. The new trials, known as PGT306 and PGT307, focus exclusively on NSCLC in women with pre-menopausal estrogen levels, the subset of patients where XYOTAX demonstrated the greatest potential survival advantage in the STELLAR trials. We anticipate initiating enrollment on the PGT307 trial in the second half of 2007. Based on discussions related to the SPA for the PGT306 Phase III study, 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 XYOTAX in the NSCLC setting. In Europe, we plan to submit a marketing authorization application, or MAA, in the first half of 2008, 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 basis for this filing has been reviewed by the Scientific Advice Working Party, or SAWP, at the European Medicines Agency, or EMEA; 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.

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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 PIX 301 study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study will continue. Pixantrone is also being studied in a phase II/III study, known as RAPID or PIX203, in which pixantrone is substituted for doxorubicin in the R-CHOP regimen compared to the standard R-CHOP 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. The study, which is targeting enrollment of 280 patients, is expected to complete enrollment in 2009. We plan to meet with the FDA to discuss using data from the EXTEND (PIX301) and RAPID (PIX203) clinical trials to expedite submission of an NDA related to pixantrone. In addition, a protocol for a phase III trial of pixantrone in indolent NHL, the PIX303 trial, has been submitted under the SPA provision with the FDA. This study, which is expected to start in the second half of 2007, will evaluate the combination of fludarabine, pixantrone, and rituximab, or FP-R, versus fludarabine and rituximab, or F-R, in patients who have received at least one prior treatment for relapsed or refractory indolent NHL. The target enrollment for the trial is 300 patients. In May 2007, we received fast track designation from the FDA for pixantrone for the treatment of relapsed or refractory indolent NHL.

We also are developing CT-2106, polyglutamate camptothecin, which is in the phase II component of a phase I/II trial in combination with 5FU/LV for the treatment of colorectal cancer relapsing following FOLFOX therapy. Due to resource constraints, we are currently focusing our efforts on near-term products in our pipeline, XYOTAX and pixantrone, and have no immediate plans to conduct additional CT-2106 studies.

As of June 30, 2007, we had incurred aggregate net losses of approximately \$1,017.7 million since inception. We expect to continue to incur additional operating losses for at least the next several 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 consolidated financial statements and require our most difficult, subjective or complex judgments in the preparation of our consolidated financial statements.

### *License and Contract Revenue*

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

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

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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, 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 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 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, includes 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 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 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.

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Changes in the estimated fair value of the derivative liabilities related to both our 6.75% and 7.5% notes are included in *gain on derivative liabilities* and will be calculated until the relevant feature expires or all of the relevant notes are converted or repurchased.

### *Restructuring Charges*

We have recorded charges in connection with our restructuring activities, including estimates pertaining to employee separation costs, the related abandonment of excess facilities and impairment of fixed assets, and certain contract termination costs. Restructuring charges are recorded in accordance with SFAS No. 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 No. 123(R), *Share-Based Payment (Revised 2004)*, or SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006.

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available in U.S. Treasury securities at maturity with an equivalent term. We have not declared or paid any dividends 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.

## **RESULTS OF OPERATIONS**

### **Three months ended June 30, 2007 and 2006.**

***License and contract revenue.*** License and contract revenue for the three months ended June 30, 2007 and 2006 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

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

	Three Months Ended	
	June 30, 2007	2006
Compounds under development:		
XYOTAX	\$ 6,003	\$ 5,490
Pixantrone	3,666	2,498
Other compounds	52	75
Operating expenses	6,093	6,707
Discovery research	702	394
<b>Total research and development expenses</b>	<b>\$ 16,516</b>	<b>\$ 15,164</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 XYOTAX and pixantrone are approximately \$203.1 million and \$30.8 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.

Research and development expenses increased to approximately \$16.5 million for the three months ended June 30, 2007, from approximately \$15.2 million for the three months ended June 30, 2006. Costs for our XYOTAX program increased primarily due to costs associated with an increase in manufacturing activity as well as start-up costs associated with our PGT307 trial, in which we anticipate initiating enrollment in the second half of 2007. These increases were partially offset by a decrease in costs associated with our PIONEER trial which was suspended and closed in the fourth quarter of 2006. Pixantrone costs increased due to an increase in costs associated with our EXTEND and RAPID trials, primarily related to increased patient enrollment and sites, and start-up costs associated with our PIX303 trial. These increases were partially offset by a decrease in costs associated with the wrap-up of our phase I trials. Operating expenses decreased primarily due to a decrease in stock-based compensation expense primarily related to the vesting of options and restricted stock during 2006 as well as a reduction in personnel costs in CTI (Europe).

Our lead drug candidates, XYOTAX and pixantrone are currently in clinical trials. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. Regulatory agencies, including the FDA and EMEA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the availability and proximity of patients with the relevant condition. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. Many of our 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;





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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 our research and development of 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 XYOTAX 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. Approval in the EU would be targeted approximately 15 months following the submission of an MAA, which is planned for the first half of 2008 based on non-inferiority analyses.

We may not generate revenue from the sale of commercial drugs for at least the next couple of years, if ever. Without revenue generated from commercial sales, we anticipate that funding to support our ongoing research, development and general operations will primarily come from public or private debt or equity financings, collaborations, milestones and licensing opportunities from current or future collaborators.

***Selling, general and administrative expenses.*** Selling, general and administrative expenses decreased to approximately \$7.6 million for the three months ended June 30, 2007, from approximately \$8.2 million for the three months ended June 30, 2006. This decrease is primarily attributed to a \$0.5 million decrease in stock-based compensation expense primarily related to the vesting of options and restricted stock during 2006 and a \$0.4 million decrease in sales and marketing expenses due to a shift in focus to clinical development from pre-marketing activities. We expect selling, general and administrative expenses to continue to be consistent in 2007 as compared to 2006.

***Amortization of purchased intangibles.*** Amortization for the three months ended June 30, 2007 and 2006 is related to the amortization of our assembled workforce asset in CTI (Europe).

***Investment and other income.*** Investment and other income for both the three months ended June 30, 2007 and 2006 was approximately \$0.7 million. While this amount remained consistent between periods, the impact on interest income of having a higher securities available-for-sale balance for the three months ended June 30, 2007 as compared to June 30, 2006, was offset by lower prevailing interest rates on these investments and a decrease in other miscellaneous income of approximately \$59,000.

***Interest expense.*** Interest expense decreased to approximately \$3.7 million for the three months ended June 30, 2007 from approximately \$4.7 million for the three months ended June 30, 2006. This change is mainly due to a \$0.9 million decrease in the amortization of debt issuance costs primarily associated with accelerated amortization related to conversions of our 6.75% convertible senior notes, or 6.75% notes, during the three months ended June 30, 2006. In addition, interest expense on our 5.75% convertible subordinated and senior subordinated notes decreased approximately \$0.2 million due to the exchange of a portion of these notes for our 7.5% convertible senior notes, or 7.5% notes, in April 2006. Interest expense on our 7.5% and 6.75% notes also decreased approximately \$0.2 million due to conversions of these notes in 2007 and 2006. These decreases were offset by a net increase of \$0.2 million in accretion of the debt discount on our 7.5% and 6.75% notes. Interest expense on our 7.5% notes increased \$0.8 million primarily due to accelerated accretion on the additional debt discount recorded in December 2006 resulting from note conversions during the three months ended June 30, 2007 while our 6.75% notes decreased \$0.6 million primarily associated with accelerated accretion due to conversions of these notes during the three months ended June 30, 2006.

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**Foreign exchange gain.** The foreign exchange gain for the three months ended June 30, 2007 and 2006 is due to fluctuations in foreign currency exchange rates, primarily related to payables denominated in foreign currencies.

**Make-whole interest expense.** Make-whole interest expense of \$4.4 million for the three months ended June 30, 2006 is related to payments made upon the conversion of \$8.9 million of our 6.75% notes and \$7.4 million of our 7.5% notes.

**Gain on derivative liabilities.** The gain on derivative liabilities of \$0.9 million for the three months ended June 30, 2007 primarily represents the change in the estimated fair value of our derivative liability related to the interest make-whole provision on our 7.5% notes. The estimated fair value of the derivative liability related to our interest make-whole provision on our 6.75% notes did not change significantly during this period. The amount of \$2.7 million for the three months ended June 30, 2006 represents the change in the estimated fair value of the derivative liabilities on our 6.75% and 7.5% notes of \$0.6 million and \$2.1 million, respectively.

**Gain on exchange of convertible notes.** During the three months ended June 30, 2006, we recorded a gain of \$8.0 million due to the extinguishment of approximately \$40.7 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately \$33.2 million aggregate principal of our 7.5% notes. The gain is net of accrued interest of \$0.9 million and issuance costs of \$0.4 million attributable to the exchanged notes.

**Six months ended June 30, 2007 and 2006.**

**License and contract revenue.** License and contract revenue for the six months ended June 30, 2007 and 2006 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

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

	Six Months Ended	
	June 30, 2007	2006
Compounds under development:		
XYOTAX	\$ 10,676	\$ 11,584
Pixantrone	6,908	5,291
Other compounds	322	555
Operating expenses	12,759	12,710
Discovery research	1,137	788
<b>Total research and development expenses</b>	<b>\$ 31,802</b>	<b>\$ 30,928</b>

Research and development expenses increased to approximately \$31.8 million for the six months ended June 30, 2007, from approximately \$30.9 million for the six months ended June 30, 2006. Costs for our XYOTAX program decreased primarily due to costs associated with our PIONEER trial which was suspended and closed in the fourth quarter of 2006. This decrease was partially offset by start-up costs associated with our PGT307 trial. Pixantrone costs increased due to an increase in costs associated with our RAPID trial, primarily related to increased patient enrollment and the cost for comparator drug, and start-up costs associated with our PIX303 trial.

**Selling, general and administrative expenses.** Selling, general and administrative expenses decreased to approximately \$15.7 million for the six months ended June 30, 2007, from approximately \$18.8 million for the six months ended June 30, 2006. This decrease is primarily attributed to a \$1.1 million decrease in our corporate development expenses mainly related to legal expenses associated with our litigation with Micromet which was settled in May 2006. There was also a \$1.0 million decrease in stock-based compensation expense primarily related to the vesting of options and restricted stock during 2006 and a \$0.8 million decrease in sales and marketing expenses due to a shift in focus to clinical development from pre-marketing activities. In addition, restructuring charges decreased approximately \$0.3 million primarily due to adjustments related to our excess facilities for



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changes in our estimate of the timing and amount of cash flows. These decreased costs were partially offset by a \$0.6 million increase in financial and administrative charges primarily related to our special and annual shareholder meetings and financial reporting activities.

***Amortization of purchased intangibles.*** Amortization for the six months ended June 30, 2007 and 2006 is related to the amortization of our assembled workforce asset in CTI (Europe).

***Investment and other income.*** Investment and other income for the six months ended June 30, 2007 and 2006 was approximately \$1.4 million and \$1.2 million, respectively. This increase is due to a higher average securities available-for-sale balance offset slightly by lower prevailing interest rates on our investments during the six months ended June 30, 2007 compared to the six months ended June 30, 2006.

***Interest expense.*** Interest expense decreased to approximately \$7.6 million for the six months ended June 30, 2007 from approximately \$13.3 million for the six months ended June 30, 2006. This change is primarily due to a \$4.0 million decrease in the amortization of debt issuance costs primarily associated with accelerated amortization related to conversions of our 6.75% notes during the six months ended June 30, 2006. In addition, there was a net decrease of \$1.7 million in accretion of the debt discount on our 7.5% and 6.75% notes. Our 6.75% notes decreased \$3.9 million primarily due to accelerated accretion related to conversions of these notes during the six months ended June 30, 2006 while our 7.5% notes increased \$2.2 million primarily associated with accelerated accretion resulting from increased conversions of these notes during the six months ended June 30, 2007 as compared to the six months ended June 30, 2006. Interest expense on our 5.75% convertible subordinated and senior subordinated notes also decreased approximately \$0.7 million due to exchanges of these notes for our 7.5% notes in April 2006. These decreases were offset by an increase in interest expense on our 6.75% notes and 7.5% notes of \$0.4 million and \$0.3 million, respectively.

***Foreign exchange gain.*** The foreign exchange gain for the six months ended June 30, 2007 and 2006 is due to fluctuations in foreign currency exchange rates, primarily related to payables denominated in foreign currencies.

***Make-whole interest expense.*** Make-whole interest expense of \$2.3 million for the six months ended June 30, 2007 is due to payments made related to the conversion of \$15.3 million of our 7.5% notes. Make-whole interest expense of \$24.5 million for the six months ended June 30, 2006 is related to payments made upon the conversion of \$68.6 million of our 6.75% notes and \$7.4 million of our 7.5% notes.

***Gain on derivative liabilities.*** The gain on derivative liabilities of \$3.6 million for the six months ended June 30, 2007 primarily represents the change in the estimated fair value of our derivative liability related to the interest make-whole provision on our 7.5% notes. The estimated fair value of the derivative liability related to our interest make-whole provision on our 6.75% notes did not change significantly during this period. The amount of \$6.1 million for the six months ended June 30, 2006 represents the change in the estimated fair value of our derivative liabilities on our 6.75% and 7.5% notes of \$4.0 million and \$2.1 million, respectively.

***Gain on exchange of convertible notes.*** During the six months ended June 30, 2006, we recorded a gain of \$8.0 million due to the extinguishment of approximately \$40.7 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately \$33.2 million aggregate principal amount of our 7.5% notes. The gain is net of accrued interest of \$0.9 million and issuance costs of \$0.4 million attributable to the exchanged notes.

***Settlement expense.*** Settlement expense for the six months ended June 30, 2007 relates to interest accrued on the \$10.5 million payment to the USAO for release of all claims in connection with the investigation of our promotional 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. Settlement expense for the six months ended June 30, 2006 relates to the amount due under the settlement of our dispute with Micromet AG in May 2006 and is net of payables previously due to Micromet.

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### LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2007, we had approximately \$43.8 million in cash and cash equivalents, securities available-for-sale and interest receivable.

Net cash used in operating activities decreased to approximately \$62.4 million during the six months ended June 30, 2007, compared to approximately \$73.8 million for the same period during 2006 primarily due to a decrease in our net loss. For the six months ended June 30, 2007, our net loss included \$2.3 million in make-whole interest payments related to conversions of our 7.5% notes. For the six months ended June 30, 2006, our net loss included \$24.5 million in make-whole interest payments related to conversions of our 6.75% and 7.5% notes. Additionally, the decrease in our net loss was partially offset by a decrease in our accrued expenses balance.

Net cash provided by investing activities totaled approximately \$0.6 million and \$1.7 million during the six months ended June 30, 2007 and 2006, respectively. The net cash provided by investing activities during these periods was primarily due to proceeds from sales and maturities of securities available-for-sale offset by purchases of securities available-for-sale.

Net cash provided by financing activities totaled approximately \$53.4 million and \$53.2 million during the six months ended June 30, 2007 and 2006, respectively. The net cash provided by financing activities for the six months ended June 30, 2007 was primarily due to net proceeds of \$18.6 million received from the sale of 20,000 shares of our Series A 3% convertible preferred stock and common stock warrants in February 2007 and net proceeds of \$34.9 million received from the sale of 37,200 shares of our Series B 3% convertible preferred stock and common stock warrants in April 2007. The net cash provided by financing activities during the six months ended June 30, 2006 was primarily due to \$31.2 million in net proceeds received from the issuance of our 7.5% notes as well as \$24.7 million of restricted cash related to the issuance of our 6.75% convertible senior notes that was released from escrow upon conversion of a portion of these notes.

We expect to generate losses from operations for at least the next several years due to research and development costs for XYOTAX, pixantrone and CT-2106.

We have prepared our condensed 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 several years primarily due to research and development costs for XYOTAX and pixantrone and CT-2106. We have approximately \$55.9 million in principal due on our convertible subordinated and senior subordinated notes in June 2008 and our existing *cash and cash equivalents, securities available-for-sale and interest receivable* is not sufficient to repay these notes and to fund our planned operations for the next twelve months. These factors, among others, raise substantial doubt about our ability to continue as a going concern. We plan to restructure these notes. However, we may be unable to do this on favorable terms or at all. We will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. While we have a \$60 million (approximately \$80 million) Step-Up Equity Financing Agreement with Société Générale which we may be able to utilize to provide additional equity funding, additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs.

Periodically, we may receive certain grants and subsidized loans from the Italian government and the EU through CTI (Europe). 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. 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;

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

competitive market developments.

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

The following table includes information relating to our contractual obligations as of June 30, 2007 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
7.5% Convertible senior notes (1)	\$ 33,458	\$	\$	\$ 33,458	\$
6.75% Convertible senior notes (2)	7,000			7,000	
5.75% Convertible senior subordinated notes (3)	27,407	27,407			
4.0% Convertible senior subordinated notes (4)	55,150			55,150	
5.75% Convertible subordinated notes (5)	28,490	28,490			
Interest on convertible notes	20,910	8,279	10,376	2,255	
Operating leases:					
Facilities	31,272	7,361	10,994	10,960	1,957
Long term obligations (6)	2,475	461	750	1,159	105
	\$ 206,162	\$ 71,998	\$ 22,120	\$ 109,982	\$ 2,062

- (1) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of approximately 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.
- (2) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of approximately 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.
- (3) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of approximately 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.
- (4) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of approximately 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.
- (5) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of approximately 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.
- (6) Long-term obligations does not include \$2.7 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 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.

The remaining amount of milestone payments we may be required to pay pursuant to the amended agreement with PG-TXL Company L.P. is \$14.9 million. The timing of these payments is based on trial commencements and completions and regulatory and marketing approval with the FDA and EMEA.

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### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

#### *Interest Rate Market Risk*

We are exposed to market risk related to changes in interest rates that could adversely affect the value of our investments. We maintain a short-term investment portfolio consisting of interest bearing securities with an average maturity of less than one year. These securities are classified as available-for-sale. These securities are interest bearing and thus subject to interest rate risk and will fall in value if market interest rates increase. Since we generally hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected significantly by a sudden change in market interest rates related to our securities portfolio. The fair value of our securities available-for-sale at June 30, 2007 and December 31, 2006 was \$35.4 million and \$36.7 million, respectively. For each one percent change in interest rates, the fair value of our securities available-for-sale would change by approximately \$120,000 and \$135,000 as of June 30, 2007 and December 31, 2006, 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 June 30, 2007 of \$3.7 million, an assumed 5%, 10% and 20% negative currency exchange movement would result in fair value declines of \$0.2 million, \$0.4 million and \$0.7 million.

### **Item 4. Controls and Procedures**

#### **(a) Evaluation of Disclosure Controls and Procedures**

Our management evaluated, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this quarterly report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are, to the best of their knowledge, not effective based on the material weaknesses in internal control over financial reporting described in our Annual Report on Form 10-K for the period ended December 31, 2006.

#### *Remediation of Material Weaknesses*

During the six months ended June 30, 2007, to remedy the material weaknesses in our internal control over financial reporting, we implemented enhanced review and approval procedures that are designed to help ensure we accurately record accounts payable and accrued expense balances in CTI (Europe), and trained personnel in key finance positions in CTI (Europe) regarding the enhanced procedures and appropriate levels of oversight and review.

We continue to identify other controls, procedures, and resources to improve both the preparation and review of payables and accruals in CTI (Europe). The control deficiencies will be fully remediated when in the opinion of our management, the revised control processes have been operating for a sufficient period of time to provide reasonable assurance as to their effectiveness.



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(b) Changes in Internal Control over Financial Reporting

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.

*Other Financial Information*

With respect to the unaudited condensed consolidated financial statements of Cell Therapeutics, Inc. for the six-month period ended June 30, 2007, included herein, Stonefield Josephson, Inc. ( "Stonefield Josephson" ) reported that they have applied limited procedures in accordance with professional standards for a review of such information. However, their report dated August 9, 2007 appearing below, states that they did not audit and they do not express an opinion on that unaudited financial information. Stonefield Josephson has not carried out any significant or additional audit tests beyond those which would have been necessary if their report had not been included. Accordingly, the degree of reliance on their report on such information should be restricted in light of the limited nature of the review procedures applied. Stonefield Josephson is not subject to the liability provisions of Section 11 of the Securities Act of 1933 ( "the Act" ) for their report on the unaudited condensed consolidated financial statements because that report is not a report or a part of a registration statement prepared or certified by Stonefield Josephson within the meaning of Sections 7 and 11 of the Act.

*Report of Independent Registered Public Accounting Firm*

Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of Cell Therapeutics, Inc. as of June 30, 2007, and the related condensed consolidated statements of operations for the six months ended June 30, 2007 and condensed consolidated statements of cash flows for the six months ended June 30, 2007. These interim financial statements are the responsibility of the Company's management.

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

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

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the condensed consolidated financial statements, the Company has substantial monetary liabilities in excess of monetary assets as of June 30, 2007, including approximately \$55.9 million of convertible subordinated notes and senior subordinated notes which mature in June 2008. The Company's ability to satisfy these obligations upon maturity raises substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are described in Note 1. These condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event the Company cannot continue in existence.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2006, and the related consolidated statements of operations, shareholders' deficit, and cash flows for the year then ended (not presented herein); and in our reports dated March 16, 2007, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2006, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Stonefield Josephson, Inc.  
Stonefield Josephson, Inc.  
Los Angeles, Ca

August 9, 2007

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**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

In April 2007, we entered into a settlement agreement with the United States Attorney's Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior business practices relating to TRISENOX. The USAO's investigation related to our promotional practices relating to TRISENOX. Pursuant to the settlement agreement, we made a single payment of \$10.6 million to the USAO, which included a settlement amount of \$10.5 million and interest accrued on that amount since the date of reaching an agreement in principle, in return for a release of all government claims in connection with a qui tam action brought by a private party plaintiff and related matters. In addition, we have agreed to provide notice to the Office of the Inspector General of the Department of Health and Human Services, or OIG-HHS, prior to manufacturing, marketing, selling or distributing any product reimbursed by government programs or upon acquiring any product or any company that manufactures, markets, sells or distributes a product reimbursed by government programs. We have further agreed to enter into a corporate integrity agreement with the OIG-HHS in the event we intend to manufacture, market, sell or distribute any product reimbursed by government programs prior to April 16, 2012. The settlement agreement disclaimed any admission of wrongdoing by the Company. This settlement does not address separate claims brought against the Company by the private party plaintiff in such matters, which generally relate to attorney's fees and employment related claims. We believe that the private party plaintiff's claims related to wrongful termination are not meritorious.

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, 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.

**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 June 30, 2007, we had an accumulated deficit of approximately \$1,017.7 million. We are pursuing regulatory approval for XYOTAX and pixantrone and will need to conduct research, development, testing and regulatory compliance 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.

*We have a substantial amount of debt.*

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. Unless we generate substantial sales from one of our potential products or raise substantial additional capital, we may not be able to repay this debt or the interest, liquidated damages or other payments with respect to our debt. 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 exchanges involving the issuance of additional shares of common stock or other arrangements which may dilute or be adverse to the value of our common stock.

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*We expect to need to raise additional funds in the near future, and they may not be available on acceptable terms, or at all.*

We recently sold shares of our Series A 3% convertible preferred stock, Series B 3% convertible preferred stock and Series C 3% convertible preferred stock in three separate offerings, pursuant to which we raised an aggregate of approximately \$77.5 million in gross proceeds. However, we expect that our existing cash and cash equivalents, securities available for sale and interest receivable, including amounts received from the preferred stock issuances, will not be sufficient to fund our operations at current levels for the next twelve months and accordingly, we expect that we will need to raise additional funds. We are exploring alternatives to raise additional capital through public or private equity financings, partnerships, debt financings, bank borrowings or other sources, including but not limited to the Step-Up Equity Financing Agreement we entered into with Société Générale in June 2006. In particular, we will need to raise additional funds to complete the phase III clinical trials for XYOTAX and pixantrone.

We may raise such capital through public or private equity financings, partnerships, debt financings or restructurings, bank borrowings or other sources. 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 XYOTAX, pixantrone 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, such as the Step-Up Equity Financing Agreement, may require us to meet additional regulatory requirements in Italy and the U.S., which may increase our costs and adversely affect our ability to obtain financing. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, shareholders may experience dilution of their proportionate ownership of us.

*We may not receive the regulatory approvals required for us to raise funds using the Step-Up Equity Financing Agreement.*

In June 2006, we announced that we had entered into a Step-Up Equity Financing Agreement with Société Générale, pursuant to which we had the option, subject to the satisfaction of certain conditions, to issue shares of our common stock to Société Générale. We are required to file and obtain an authorization for the publication of an Italian Listing Prospectus prior to being able to issue any shares under this agreement, and any delays or restrictions relating to this could potentially impair our ability to raise funds through this agreement. We will not be able to raise funds by issuing shares to Société Générale pursuant to this agreement if we are unable to satisfy this condition, and we may be unable to raise necessary funds from other sources.

*We may be unable to obtain a quorum for our annual meeting of shareholders and therefore 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 quorum was not present at our annual meeting of shareholders scheduled for June 23, 2006 or at our rescheduled annual meeting scheduled for November 30, 2006, in Milan. While we were able to obtain quorum at a special meeting of shareholders on April 10, 2007, with the sole purpose being to increase the number of authorized shares of common stock, we may be unable to obtain quorum at our annual meeting of shareholders. If we are unable to obtain a quorum at our annual shareholder meeting and thus fail to get shareholder approval of corporate actions, such failure could have a materially adverse effect on the Company. It is possible that even if we are able to obtain a quorum for our annual meeting of the shareholders we may still not receive enough votes to approve the proxy proposals and 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 shareholder approval for purposes of complying with the Nasdaq Marketplace Rules. We could require such approval to raise additional funds, but might not be successful in obtaining any such required shareholder approval.

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

Our stock is traded on the MTAX market and we are required to also comply with the rules and regulations of CONSOB and Borsa Italiana, which collectively 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 regulatory regimes. Compliance with Italian listing requirements may delay additional issuances of our common stock and we are taking appropriate steps to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

*We have identified material weaknesses in our internal control over financial reporting and we have 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.*

A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. We identified that as of December 31, 2006 we had the following material weaknesses relative to the effectiveness of our internal control over financial reporting:

We did not maintain an effective review and approval process in CTI (Europe) to ensure the accuracy of accounts payable and accrued expenses for certain activities shared by headquarters and CTI (Europe) in conformity with generally accepted accounting principles.

We did not maintain effective internal controls related to the financial reporting process to detect errors that are not identified by the process level controls in CTI (Europe).

During the first six months of 2007, to remedy the material weaknesses in our internal control over financial reporting, we implemented enhanced review and approval procedures that are designed to help ensure we accurately record accounts payable and accrued expense balances in CTI (Europe), and trained personnel in key finance positions in CTI (Europe) regarding the enhanced procedures and appropriate levels of oversight and review.

The existence of a material weakness is an indication that there is more than a remote likelihood that a material misstatement of our financial statements will not be prevented or detected in the current or any future period. If we fail to maintain an effective system of internal controls, we may not be able to report our financial results accurately, which may cause investors to lose confidence in our reported financial information and have an adverse effect on the trading price of our common stock.

*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 XYOTAX and pixantrone with Novartis International Pharmaceutical Ltd., or Novartis, pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of XYOTAX 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 XYOTAX 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.

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

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 XYOTAX in non-small cell lung cancer. All three trials did not achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. Our success depends in large part on obtaining regulatory approval of XYOTAX.

In December 2006, we closed the PIONEER clinical trial and in early 2007, we submitted two new protocols for clinical trials, PGT306 and PGT307, to focus on the primary efficacy endpoint of survival in women with pre-menopausal estrogen levels. We may not receive positive results from the PGT306 or PGT307 trials, which would preclude our planned submission of an NDA based on such results with the results of the STELLAR 3 and 4 trials to support the filing.

Based on discussions with the EMEA Scientific Advice Working Party, we plan to submit an MAA in Europe based on results of the STELLAR trials, specifically the STELLAR 4 trial, however a successful regulatory outcome from the EMEA is not assured as the EMEA's final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the clinical data that will be presented in the MAA.

*We are subject to extensive government regulation.*

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

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current 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 fashion, our business and financial condition may be adversely affected.

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

We believe that while we owned TRISENOX, which was divested to Cephalon, Inc. in July 2005, it was prescribed by physicians for uses not approved by the FDA. Although physicians may lawfully prescribe pharmaceutical products, such as TRISENOX, for such off-label uses, promotion by us of such off-label uses is unlawful. Some of our practices could have been construed as off-label promotion, and it is likely that some instances of off-label promotion occurred in the past. Although we have, and during the relevant time period had, policies and procedures in place designed to assure ongoing compliance with FDA requirements regarding off-label promotion, some non-compliant actions may nevertheless have occurred. In April 2007, we entered into a settlement agreement with the United States Attorney's Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior business practices relating to TRISENOX. Pursuant to that settlement agreement, we made a single payment of \$10.6 million to the USAO, which included a settlement amount of \$10.5 million plus interest accrued on that amount since the date of reaching an agreement in principle, in return for a

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release of all government claims in connection with a qui tam action brought by a private party plaintiff and related matters. In addition, we have agreed to provide notice to the Office of the Inspector General of the Department of Health and Human Services, or the OIG-HHS, prior to manufacturing, marketing, selling or distributing any product reimbursed by government programs or upon acquiring any product or any company that manufactures, markets, sells or distributes a product reimbursed by government programs. We have further agreed to enter into a corporate integrity agreement with the OIG-HHS in the event we intend to manufacture, market, sell or distribute any product reimbursed by government programs prior to April 16, 2012. This settlement does not address separate claims brought against the Company by the private party plaintiff in such matters, which generally relate to attorney's fees and employment related claims.

Additionally, 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 our employees from participation in federal and state healthcare programs. Although we have policies prohibiting violations of relevant regulations and statutes, unauthorized actions of our employees or consultants (including unlawful off-label promotion), or unfavorable interpretations of such regulations or statutes may result in third-parties or regulatory agencies bringing legal proceedings or enforcement actions against us.

*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:

If we are successful in bringing XYOTAX to market, we will face direct competition from oncology-focused multinational corporations. XYOTAX 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., which markets paclitaxel; Aventis, which markets docetaxel; Genentech and OSI Pharmaceuticals, which markets Tarceva; Genentech, which markets Avastin; Lilly, which markets Alimta; and American Pharmaceutical Partners, which markets Abraxane. In addition, several companies such as NeoPharm Inc., Sonus Pharmaceuticals and Telik, Inc. are also developing products which could compete with XYOTAX.

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.

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.

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

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

challenging the prices charged for health care products and services,

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

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

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

denying coverage altogether.

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

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

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

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. All of our compounds currently are in research or development, and none have been submitted for 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.

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*If any of our license agreements for intellectual property underlying XYOTAX, pixantrone 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 from The University of Vermont, Hoffman La Roche and others, including the intellectual property relating to pixantrone. We have also in-licensed the intellectual property relating to our drug delivery technology that uses polymers that are linked to drugs, known as polymer-drug conjugates, including XYOTAX and CT-2106. 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, XYOTAX is paclitaxel, the active ingredient in Taxol®, one of the world's best selling cancer drugs, linked to polyglutamate. We may not receive a patent for all of our polymer-drug conjugates and we may be challenged by the holder of a patent covering the underlying drug and/or methods for its use or manufacture.

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

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.

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*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 attorney's 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 XYOTAX 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 XYOTAX, 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 sufficient control over the manufacture of our products.*

We do not currently have internal analytical laboratory or manufacturing facilities to allow the testing or production 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 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, XYOTAX, 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 ingredient and finished product for pixantrone are both manufactured by a single vendor. If the CT-2106 trials are successful and we need to manufacture additional materials for new clinical trials, we will need to identify and qualify vendors to manufacture such materials and we may not be able to do so in a timely manner, if at all.

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

We divested our sole commercial product, TRISENOX, in July 2005. XYOTAX, pixantrone and CT-2106 are currently in clinical trials and may not be successful. For example, our STELLAR phase III clinical trials for XYOTAX for the treatment of non-small cell lung cancer failed to meet their primary endpoints. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. We will need to commit significant time and resources to develop this and additional product candidates. Our product candidates will be successful only if:

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

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

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

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

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

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Substantially all of our product candidates in clinical development are in-licensed from a third party, including XYOTAX, pixantrone and CT-2106.

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.

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

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

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.

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*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 XYOTAX 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.

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

collaborative arrangements may not be on terms favorable to us;

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

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

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

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

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

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

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

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

We base several of our product candidates upon novel technologies that we are using to develop drugs for the treatment of cancer. These technologies have not been proven. Furthermore, preclinical results in animal studies may not predict outcomes in human clinical trials. Our product candidates may not be proven safe or effective. If these technologies do not work, our drug candidates may not develop into commercial products.

*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;

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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 our merger with Novuspharma and 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.

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

We currently plan to further expand our product portfolio through acquisitions of other complementary businesses or technologies or marketed products. For example, in July 2007, we acquired Systems Medicine Inc., 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. We are currently in discussions to acquire a marketed product. Mergers and acquisitions are inherently risky, and we cannot assure you that we will be able to complete these acquisitions or that our acquisitions will be successful. The successful execution of our acquisition strategy will depend 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. Acquisitions involve numerous risks, including the following:

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

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 stockholders may be diluted.

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

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering product use in our clinical trials, 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 any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

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

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



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

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

*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 June 30, 2007, our stock price, as adjusted to reflect the one-for-four reverse stock split, ranged from a low of \$2.85 to a high of \$10.12. 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;

the issuance of additional debt, equity or other securities;

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;

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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, James Bianco and Max Link 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.

*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 5. Other Information**

On July 17, 2007, at a meeting of the Compensation Committee of our Board of Directors, or the Committee, the Committee discussed the mid-year corporate performance of our senior executive officers. In particular, the Committee discussed the achievement of significant mid-year corporate goals under the leadership of our senior management. In recognition of such achievements, on July 17, 2007, the Committee approved the payment of mid-year cash bonuses to our senior executive officers. Our named executive officers received the following mid-year bonus payments in conjunction with payments made to employees under a company-wide bonus plan in which payments are distributed semi-annually: James A. Bianco, M.D., \$130,000, Louis A Bianco, \$39,600, Dan Eramian, \$37,800, Jack W. Singer, M.D., \$40,800 and Scott Stromatt, M.D., \$42,000.



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**Item 6. Exhibits**

(a) Exhibits

15 Letter Regarding Unaudited Interim Financial Information

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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**SIGNATURES**

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

**CELL THERAPEUTICS, INC.**  
(Registrant)

Dated: August 9, 2007

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

Dated: August 9, 2007

By: /s/ Louis A. Bianco  
Louis A. Bianco  
Executive Vice President,  
Finance and Administration  
(Principal Financial Officer,  
Chief Accounting Officer)