

CELL THERAPEUTICS INC  
Form 10-Q/A  
February 06, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-Q/A**

**(Amendment No. 1)**

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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: September 30, 2006

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)

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

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501 Elliott Avenue West, Suite 400

Seattle, Washington  
(Address of principal executive offices)

(206) 282-7100

98119  
(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 October 31, 2006 |
|----------------------------|---------------------------------|
| Common Stock, no par value | 144,652,751                     |

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*Explanatory Note:*

Cell Therapeutics, Inc., or CTI, is filing this Amendment No. 1 on Form 10-Q/A to its Form 10-Q for the quarter ended September 30, 2006, to reflect the restatement of its previously issued financial statements to correct inadvertent errors in accounting for accounts payable and accrued expenses in our Italian subsidiary, Cell Therapeutics Europe, S.r.l., or CTI (Europe).

The information contained in this Amendment, including the financial statements and the notes hereto, amends only Items 1, 2 and 4 of Part I and Item 1A of Part 2 of our originally filed Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and no other items in our originally filed Form 10-Q are amended hereby. In accordance with Rule 12b-15 of the Securities and Exchange Act of 1934, the complete text of those items in which amended language appears is set forth herein, including those portions of the text that have not been amended from that set forth in the original Form 10-Q. Except for the aforementioned adjustments, this Form 10-Q/A does not materially modify or update other disclosures in the original Form 10-Q, including the nature and character of such disclosure to reflect events occurring after November 9, 2006, the filing date of the original Form 10-Q. Accordingly this Form 10-Q/A should be read in conjunction with our filings made with the Securities and Exchange Commission. Currently dated certifications from the our Chief Executive Officer and Chief Financial Officer have been included as exhibits to this amendment.

*Impact on Management's Assessment of Internal Control over Financial Reporting:* In connection with the restatement, we reevaluated our disclosure controls and procedures in CTI (Europe). We concluded that our failure to correctly account for accounts payable and accrued expenses constituted a material weakness in our internal control over financial reporting. As a result of this material weakness, we concluded that our disclosure controls and procedures in relation thereto were not effective as of September 30, 2006.

*Remediation of Material Weakness:* In an effort to remediate the material weakness described above, we are currently implementing enhanced procedures that are designed to ensure that we will properly record accounts payable and accrued expenses in CTI (Europe). These enhanced procedures will provide for additional managerial oversight of accounts payable and accrued expense balances.

**Table of Contents****CELL THERAPEUTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share amounts)**

|  | September 30,<br>2006<br>(unaudited) | December 31,<br>2005 |
|--|--------------------------------------|----------------------|
|  | (restated)                           |                      |
| <b>ASSETS</b>  |                                      |                      |
| Current assets:  |                                      |                      |
| Cash and cash equivalents  | \$ 16,128                            | \$ 50,022            |
| Restricted cash  | 57                                   | 25,596               |
| Securities available-for-sale  | 51,329                               | 18,858               |
| Interest receivable  | 645                                  | 187                  |
| Accounts receivable, net   | 339                                  | 2,306                |
| Prepaid expenses and other current assets  | 11,062                               | 10,107               |
| <b>Total current assets</b>  | <b>79,560</b>                        | <b>107,076</b>       |
| Property and equipment, net  | 9,013                                | 12,278               |
| Goodwill   | 17,064                               | 17,064               |
| Other intangibles, net   | 1,799                                | 2,239                |
| Other assets   | 13,550                               | 16,783               |
| <b>Total assets</b>  | <b>\$ 120,986</b>                    | <b>\$ 155,440</b>    |
| <b>LIABILITIES AND SHAREHOLDERS DEFICIT</b>  |                                      |                      |
| Current liabilities:   |                                      |                      |
| Accounts payable   | \$ 4,800                             | \$ 3,370             |
| Accrued expenses   | 22,201                               | 17,558               |
| Current portion of deferred revenue  | 80                                   | 80                   |
| Current portion of long-term obligations   | 2,701                                | 2,880                |
| Current portion of convertible senior notes  |                                      | 6,900                |
| <b>Total current liabilities</b>   | <b>29,782</b>                        | <b>30,788</b>        |
| Deferred revenue, less current portion   | 498                                  | 558                  |
| Long-term obligations, less current portion  | 5,242                                | 7,326                |
| 7.5% convertible senior notes  | 50,409                               |                      |
| 6.75% convertible senior notes   | 6,954                                | 72,146               |
| Convertible senior subordinated notes  | 82,557                               | 122,079              |
| Convertible subordinated notes   | 28,490                               | 29,640               |
| Commitments and contingencies  |                                      |                      |
| Shareholders' deficit:   |                                      |                      |
| Preferred stock, no par value:   |                                      |                      |
| Authorized shares - 10,000,000   |                                      |                      |
| Series C, 100,000 shares designated, none issued or outstanding  |                                      |                      |
| Common stock, no par value:  |                                      |                      |
| Authorized shares - 200,000,000  |                                      |                      |
| Issued and outstanding shares - 137,073,731 (unaudited) and 73,421,721 at September 30, 2006 and December 31, 2005, respectively | 843,600                              | 721,544              |
| Deferred stock-based compensation  |                                      | (1,669)              |
| Accumulated other comprehensive loss   | (1,038)                              | (1,683)              |

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|   |            |            |
|---|------------|------------|
| Accumulated deficit                         | (925,508)  | (825,289)  |
| Total shareholders' deficit                 | (82,946)   | (107,097)  |
| Total liabilities and shareholders' deficit | \$ 120,986 | \$ 155,440 |

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<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|--|---|-------------|--|-------------|
|  | <b>2006</b>                                 | <b>2005</b> | <b>2006</b>                                | <b>2005</b> |
|  | <b>(restated)</b>                           |             | <b>(restated)</b>                          |             |
| <b>Revenues:</b>   |   |             |  |             |
| Product sales  | \$  | \$ 1,190    | \$   | \$ 14,599   |
| License and contract revenue                                       | 20  | 101         | 60   | 300         |
| Total revenues   | 20  | 1,291       | 60   | 14,899      |
| <b>Operating expenses:</b>   |   |             |  |             |
| Cost of product sold   |   | 60          |  | 518         |
| Research and development   | 14,443                                      | 13,340      | 45,370                                     | 55,582      |
| Selling, general and administrative                                | 9,032                                       | 12,500      | 27,452                                     | 49,475      |
| Amortization of purchased intangibles                              | 200   | 236         | 588  | 731         |
| Restructuring charges and related asset impairments                | 25  | 5,077       | 367  | 7,049       |
| Gain on divestiture of TRISENOX                                    |   | (30,500)    |  | (30,500)    |
| Total operating expenses   | 23,700                                      | 713         | 73,777                                     | 82,855      |
| Income (loss) from operations                                      | (23,680)                                    | 578         | (73,717)                                   | (67,956)    |
| <b>Other income (expense):</b>                                     |   |             |  |             |
| Investment and other income  | 607   | 414         | 1,843                                      | 1,326       |
| Interest expense   | (3,552)                                     | (2,955)     | (16,888)                                   | (10,842)    |
| Foreign exchange gain (loss)                                       | (115)                                       | (104)       | 997  | 98          |
| Make-whole interest expense  | (213)                                       |             | (24,753)                                   |             |
| Gain (loss) on derivative liabilities                              | (879)                                       |             | 5,204                                      |             |
| Gain on exchange of convertible notes                              |   |             | 7,978                                      |             |
| Settlement expense   |   |             | (883)                                      |             |
| Loss on extinguishment of royalty obligation                       |   | (6,437)     |  | (6,437)     |
| Other expense, net   | (4,152)                                     | (9,082)     | (26,502)                                   | (15,855)    |
| Net loss   | \$ (27,832)                                 | \$ (8,504)  | \$ (100,219)                               | \$ (83,811) |
| Basic and diluted net loss per share                               | \$ (0.25)                                   | \$ (0.13)   | \$ (0.98)                                  | \$ (1.32)   |
| Shares used in calculation of basic and diluted net loss per share | 111,560                                     | 63,515      | 102,132                                    | 63,385      |

See accompanying notes.

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

|   | <b>Nine Months Ended<br/>September 30,</b> |             |
|---|--|-------------|
|   | <b>2006</b>                                | <b>2005</b> |
|   | <b>(restated)</b>                          |             |
| <b>Operating activities</b>   |  |             |
| Net loss  | \$ (100,219)                               | \$ (83,811) |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |             |
| Depreciation and amortization   | 4,850                                      | 7,426       |
| Equity-based compensation expense   | 3,579                                      | 2,516       |
| Loss on disposition of property and equipment                               | 91   | 83          |
| Amortization of investment premium  | 85   | 271         |
| Non-cash gain on exchange of convertible notes                              | (7,978)                                    |             |
| Non-cash gain on derivative liabilities                                     | (5,204)                                    |             |
| Non-cash interest expense   | 10,445                                     | 719         |
| Asset impairments   |  | 2,563       |
| Gain on divestiture of TRISENOX   |  | (30,500)    |
| Loss on extinguishment of royalty obligation                                |  | 6,437       |
| Non-cash rent (benefit) expense   | (11)                                       | 135         |
| Loss on sale of investment securities                                       |  | 14          |
| Changes in operating assets and liabilities:                                |  |             |
| Restricted cash   | 877  |             |
| Interest receivable   | (458)                                      | 48          |
| Accounts receivable, net  | 1,532                                      | (1,855)     |
| Inventory   |  | 4           |
| Prepaid expenses and other current assets                                   | 3,182                                      | 1,443       |
| Other assets  | 103  | (1,029)     |
| Accounts payable  | (2,767)                                    | (3,433)     |
| Accrued expenses  | 2,189                                      | (8,703)     |
| Deferred revenue  | (60)                                       | 1,568       |
| Excess facilities obligations   | (1,913)                                    | 4,675       |
| Other long-term obligations   | (416)                                      | 3,740       |
| Total adjustments   | 8,126                                      | (13,878)    |
| Net cash used in operating activities                                       | (92,093)                                   | (97,689)    |
| <b>Investing activities</b>   |  |             |
| Net proceeds from divestiture of TRISENOX                                   |  | 67,061      |
| Purchases of securities available-for-sale                                  | (57,635)                                   | (26,922)    |
| Proceeds from maturities of securities available-for-sale                   | 25,113                                     | 13,494      |
| Proceeds from sales of securities available-for-sale                        |  | 15,815      |
| Purchases of property and equipment   | (472)                                      | (1,946)     |
| Proceeds from sale of property and equipment                                | 511  |             |
| Net cash provided by (used in) investing activities                         | (32,483)                                   | 67,502      |



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**Financing activities**

|  |          |          |
|--|----------|----------|
| Sale of common stock, net of offering costs  | 37,903   |          |
| 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   |          |
| Mandatory redemptions of 6.75% convertible senior notes  | (2,655)  |          |
| Repayment of royalty obligation  |          | (39,388) |
| Proceeds from common stock options exercised and stock sold via the employee stock purchase plan | 17       | 218      |
| Repayment of long-term obligations   | (122)    | (1,074)  |
| Net cash provided by (used in) financing activities  | 91,032   | (40,244) |
| Effect of exchange rate changes on cash and cash equivalents                                     | (350)    | (1,917)  |
| Net decrease in cash and cash equivalents  | (33,894) | (72,348) |
| Cash and cash equivalents at beginning of period   | 50,022   | 105,033  |

|  |           |           |
|--|-----------|-----------|
| Cash and cash equivalents at end of period | \$ 16,128 | \$ 32,685 |
|--|-----------|-----------|

**Supplemental disclosure of cash flow information**

|  |           |          |
|--|-----------|----------|
| Cash paid during the period for interest | \$ 29,281 | \$ 7,714 |
| Cash paid for taxes                      | \$        | \$       |

**Supplemental disclosure of noncash financing and investing activities**

|   |           |    |
|---|-----------|----|
| Conversion of 6.75% convertible senior notes to common stock  | \$ 69,345 | \$ |
| Conversion of 7.5% convertible senior notes to common stock   | \$ 15,902 | \$ |
| 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. Our Italian operations commenced on January 1, 2004, the effective date of our merger with Novuspharma S.p.A., or Novuspharma, an Italian biopharmaceutical company focused on cancer therapeutics.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of September 30, 2006 and for the three and nine months ended September 30, 2006 and 2005 has been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the Company's financial position at such date and the operating results and cash flows for such periods. Operating results for the three and nine month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for the entire year. These financial statements and the related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2005 included in our Form 10-K/A.

The balance sheet at December 31, 2005 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.

*Liquidity*

Cash and cash equivalents, restricted cash, securities available-for-sale and interest receivable are approximately \$68.2 million as of September 30, 2006, approximately \$3.0 million of which was used to repurchase shares of our common stock and warrants exercisable for our common stock in October 2006 (see Note 7, *Common Stock Offering*). In addition we received \$15.0 million of cash from an offering of our common stock in October 2006 (see Note 6, *Agreements with Novartis International Pharmaceutical Ltd.*) We expect that this amount will not be sufficient to fund our operations for the next 12 months. Accordingly, we will need to raise additional funds and are currently exploring alternative sources of equity or debt financing. Additional funding may not be available on favorable terms or at all. If we are unable to raise additional capital in the near term, we have developed a plan to further curtail operations significantly, by delaying, modifying, or canceling selected aspects of research and development programs related to XYOTAX, pixantrone and other products we may be developing. The plan contains reductions in operating expenditures related to certain research and development and general and administrative activities including compensation and benefits, corporate costs and clinical trial costs, which are designed to allow the company to continue to operate on a going concern basis.

*Product Sales*

Because we sold our only commercial product, TRISENOX, to Cephalon on July 18, 2005, there have been no product sales subsequent to this date. Prior to this, we recognized revenue from product sales when there was persuasive evidence that an arrangement existed, title had passed and delivery had occurred, the price was fixed and determinable, and collectability was reasonably assured. Product sales were generally recorded upon shipment net of

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an allowance for returns and discounts. Customers were able to return damaged or expired inventory for up to one year after the expiration date. Estimated returns were based on historical returns and sales patterns. If we were unable to reasonably estimate returns related to a particular customer or market, we deferred revenue recognition until return rights had expired. There was no allowance for returns, discount and bad debts at September 30, 2006 or December 31, 2005 as all trade receivables were sold in connection with the divestiture of TRISENOX to Cephalon.

### *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 an 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 \$9.8 million and \$8.9 million as of September 30, 2006 and December 31, 2005, respectively, of which \$9.2 million and \$8.3 million is included in *other assets* as of September 30, 2006 and December 31, 2005, respectively and \$0.6 million is included in *prepaid expenses and other current assets* as of both dates. 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 September 30, 2006 and 2005, options, warrants, unvested share awards and rights and convertible debt aggregating 48,338,717 and 23,390,105, 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, and our 7.5% convertible senior notes, or 7.5% notes, contain certain features providing for payments in cash or common stock to be made in the event of certain conversions or repurchases of the debt. In the event of any conversion of our 6.75% notes to common stock, the feature calls for make-whole payments equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion. Our 7.5% notes include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. This 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.

These make-whole features represent embedded derivatives which are required to be accounted for separately from the related debt securities. The fair value of the derivative for the 6.75% notes is calculated based on a discounted cash flow model. The fair value of the derivative related to the 7.5% notes 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. Changes in the estimated fair value of the liabilities are included in *gain (loss) 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 52, Foreign Currency Translation.

### *Recently Issued Accounting Pronouncements*

In September 2006, the Financial Accounting Standards Board, or 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 September 2006, the SEC staff issued Staff Accounting Bulletin, or SAB, No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB 108 is effective for fiscal years ending after November 15, 2006. We will initially apply the provisions of SAB 108 in connection with the preparation of our annual financial statements for the year ending December 31, 2006. We have evaluated the potential impact that SAB 108 may have on our financial statements and do not believe the impact of the application of this guidance will be material.

In September 2006, the FASB issued SFAS No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans*, or SFAS 158. This Statement requires companies to recognize in their statement of financial position an asset for a plan's overfunded status or a liability for a plan's underfunded status and to measure a plan's assets and its obligations that determine its funded status as of the end of the company's fiscal year. Additionally, SFAS 158 requires companies to recognize changes in the funded status of a defined benefit postretirement plan in the year that the changes occur and those changes will be reported in comprehensive income. The provisions of SFAS 158 are effective as of the end of fiscal year 2006 and we are currently in the process of quantifying the impact to the financial statements.

## **2. Restatement**

In the fourth quarter of 2006, we discovered the following errors in CTI (Europe):

A \$1.0 million accounts payable balance to Micromet AG, or Micromet, which had been recorded by CTI (Europe) prior to its acquisition by the Company in January 2004. In May 2006, we settled a dispute with Micromet whereby we paid Micromet \$1.9 million to settle all outstanding claims between the two companies. Accordingly, the outstanding payable balance should have been reversed with a corresponding offset to settlement expense at the time we recorded the settlement charge in the first quarter of 2006.

In March 2006, CT (Europe) received a \$251,000 payment from a clinical trial vendor. The payment represented a settlement of prior amounts paid to the vendor for which the company claimed it had not received services. The Company made the claim in December 2005 and at December 31, 2005 the claim represented a gain contingency and was not recorded due to significant uncertainty around receipt of payment. Upon receipt of payment in March 2006 the payment was inadvertently recorded as accounts payable rather than a reduction of research and development expense.

In the second and third quarters of 2006 CTI (Europe) inadvertently continued to record accruals for clinical trial activities that had been transferred to CTI Seattle in the first quarter of 2006. These accruals amounted to approximately \$912,000 as of September 30, 2006.

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The following tables summarize the effect of the restatement adjustments on the financial statements as of and for the three and nine months ended September 30, 2006.

|                                      | September 30, 2006<br>(in thousands) |             |           |
|--------------------------------------|--------------------------------------|-------------|-----------|
|                                      | As Filed                             | Adjustments | Restated  |
| Accounts payable                     | \$ 6,087                             | \$ (1,287)  | \$ 4,800  |
| Accrued expenses                     | 23,113                               | (912)       | 22,201    |
| Total current liabilities            | 31,981                               | (2,199)     | 29,782    |
| Accumulated other comprehensive loss | (1,055)                              | 17          | (1,038)   |
| Accumulated deficit                  | (927,690)                            | 2,182       | (925,508) |
| Total shareholders' deficit          | (85,145)                             | 2,199       | (82,946)  |

|                          | Three Months Ended September 30, 2006<br>(in thousands) |             |           |
|--------------------------|---|-------------|-----------|
|                          | As Filed  | Adjustments | Restated  |
| Research and development | \$ 14,809   | \$ (366)    | \$ 14,443 |
| Total operating expenses | 24,066  | (366)       | 23,700    |
| Loss from operations     | (24,046)  | 366         | (23,680)  |
| Net loss                 | (28,198)  | 366         | (27,832)  |

|                                      | Nine Months Ended September 30, 2006<br>(in thousands, except per share data) |             |           |
|--------------------------------------|---|-------------|-----------|
|                                      | As Filed  | Adjustments | Restated  |
| Research and development             | \$ 46,516   | \$ (1,146)  | \$ 45,370 |
| Total operating expenses             | 74,923  | (1,146)     | 73,777    |
| Loss from operations                 | (74,863)  | 1,146       | (73,717)  |
| Settlement expense                   | (1,919)   | 1,036       | (883)     |
| Other expense, net                   | (27,538)  | 1,036       | (26,502)  |
| Net loss                             | (102,401)   | 2,182       | (100,219) |
| Basic and diluted net loss per share | \$ (1.00)   | \$ 0.02     | \$ (0.98) |

The adjustments to the balance sheet and income statement as of and for the three and nine months ended September 30, 2006 had no impact on total cash flows from operating, investing and financing activities.

### 3. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. SFAS 130, *Reporting Comprehensive Income*, provides for unrealized gains and losses on our securities available-for-sale and our former interest rate swap agreement which was designated as a cash flow hedge, to be included in other comprehensive loss. Also included are net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries. Total comprehensive loss was \$27.8 million and \$8.4 million for the three month periods ended September 30, 2006 and 2005, respectively. Total comprehensive loss was \$99.6 million and \$87.1 million for the nine month periods ended September 30, 2006 and 2005, respectively.

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

|   | September 30,      | December 31, |
|---|--------------------|--------------|
|   | 2006<br>(restated) | 2005         |
| Foreign currency translation adjustment                     | \$ (1,052)         | \$ (1,663)   |
| Net unrealized gain (loss) on securities available-for-sale | 14                 | (20)         |
| Accumulated other comprehensive loss                        | \$ (1,038)         | \$ (1,683)   |

### 4. Stock-Based Compensation Expense

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On January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment (Revised 2004)*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan, or employee stock purchases, based on estimated fair values. SFAS 123(R) supersedes our

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previous accounting under Accounting Principles Board Opinion, or APB, No. 25, Accounting for Stock Issued to Employees, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin, or SAB, No. 107 relating to SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

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. Our Condensed Consolidated Financial Statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our Condensed Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the three months ended September 30, 2006 was \$1.1 million, which consisted of \$0.6 million of stock-based compensation expense related to employee stock options and employee stock purchases and \$0.5 million of stock-based compensation expense related to share awards. Stock-based compensation expense recognized for the nine months ended September 30, 2006 was \$3.6 million, which consisted of \$2.2 million related to employee stock options and employee stock purchases and \$1.4 million related to share awards. Stock-based compensation expense recognized for share awards was \$0.9 million and \$2.6 million during the three and nine months ended September 30, 2005, respectively. There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized during the three and nine months ended September 30, 2005.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Condensed Consolidated Statement of Operations. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under SFAS 123, *Accounting for Stock-Based Compensation*. Under the intrinsic value method, no employee stock-based compensation expense related to stock options had been recognized in our Condensed Consolidated Statement of Operations because the exercise price of our stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in our Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2006 included 1) compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and 2) compensation expense for the share-based payment awards granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). We use the straight-line single-option method to recognize the value of stock-based compensation expense for all share-based payment awards granted after January 1, 2006. Expense is recognized using the graded-vesting multiple-option method for options granted prior to January 1, 2006. As stock-based compensation expense recognized in the Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

The following table summarizes stock-based compensation expense related to employee stock options, employee stock purchases, and share awards under SFAS 123(R) for the three and nine months ended September 30, 2006, which was allocated as follows (in thousands):

|   | Three Months Ended<br>September 30,<br>2006 | Nine Months Ended<br>September 30,<br>2006 |
|---|---|--|
| Research and development  | \$ 314                                      | \$ 1,393                                   |
| Selling, general and administrative                             | 763   | 2,186                                      |
| Stock-based compensation expense included in operating expenses | \$ 1,077                                    | \$ 3,579                                   |



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Stock-based compensation had a \$1.1 million and \$3.6 million effect on our net loss and a \$(0.01) and \$(0.04) effect on basic and diluted net loss per share for the three and nine month periods ending September 30, 2006, respectively. There was no effect on cash flows from operations or financing activities for the periods presented. The weighted average fair value of employee stock options granted in the three months ended September 30, 2006 and 2005 was \$0.89 and \$1.57, respectively. The weighted average fair value of employee stock options granted in the nine months ended September 30, 2006 and 2005 was \$0.89 and \$3.34, respectively.

SFAS 123(R) requires the disclosure of pro-forma information for periods prior to the adoption. The following table illustrates the effect on net loss and net loss per share for the three and nine months ended September 30, 2005 if we had recognized compensation expense for all share-based payments to employees based on their fair values (in thousands, except per share amounts):

|   | Three Months Ended |         | Nine Months Ended  |          |
|---|--------------------|---------|--------------------|----------|
|   | September 30, 2005 |         | September 30, 2005 |          |
| Net loss, as reported   | \$                 | (8,504) | \$                 | (83,811) |
| Add: Stock-based employee compensation included in reported net loss (share awards)                             |                    | 872     |                    | 2,563    |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards |                    | (1,300) |                    | (5,430)  |
| Pro forma net loss  | \$                 | (8,932) | \$                 | (86,678) |
| Basic and diluted net loss per share:   |                    |         |                    |          |
| As reported   | \$                 | (0.13)  | \$                 | (1.32)   |
| Pro forma   | \$                 | (0.14)  | \$                 | (1.37)   |

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

|                          | Three Months Ended |                    | Nine Months Ended  |                    |
|--------------------------|--------------------|--------------------|--------------------|--------------------|
|                          | September 30, 2006 | September 30, 2005 | September 30, 2006 | September 30, 2005 |
| Risk-free interest rates | 4.7%               | 4.0%               | 4.9%               | 4.0%               |
| Expected dividend yield  | None               | None               | None               | None               |
| Expected life (in years) | 2.7                | 3.6                | 2.8                | 3.6                |
| Volatility               | 74%                | 96%                | 74%                | 96%                |

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

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

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Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and EITF 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is periodically remeasured as the underlying options vest.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets.

*Stock Option Plans*

During 2003, shareholders approved the 2003 Equity Incentive Plan, or 2003 Plan, which replaced the 1994 Equity Incentive Plan, or 1994 Plan. The 1994 Plan has since been terminated, except with respect to outstanding awards previously granted thereunder. The 2003 Plan provides for (a) the grant of nonqualified and/or incentive stock options, stock appreciation rights and share awards, (b) annual, automatic, non-discretionary grants of non-qualified stock options and share awards to non-employee members of our board of directors and (c) the award of stock-based performance bonuses. There are 6,443,289 shares authorized under the 2003 Plan including the authorization for issuance of an additional 5,000,000 shares of common stock as set forth in an August 2004 amendment to the 2003 Plan approved by our shareholders at our 2004 Annual Meeting of Shareholders and 293,289 shares which had been reserved but not granted under the 1994 Plan.

The Novospharma S.p.A. Stock Option Plan, or 2004 Plan, authorized 350,000 shares and provides for the grant of nonqualified and/or incentive stock options and share awards to employees, consultants and directors in Italy.

The Plans are administered by the Compensation Committee of the Board of Directors which has the discretion to determine which employees, consultants and directors shall be granted options. The options are typically exercisable ratably over a four-year period commencing one year from the date of grant, and expire not more than 10 years from the date of grant. As of September 30, 2006, approximately 558,000 shares of common stock were available for future grants.

The following table summarizes stock option activity for all of stock option plans during the nine months ended September 30, 2006:

|  | Options   | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term | Aggregate<br>Intrinsic<br>Value<br>(Thousands) |
|--|-----------|--|---|--|
| Outstanding December 31, 2005                    | 6,115,000 | \$ 10.95                                 |   |  |
| Granted  | 905,000   | \$ 1.75                                  |   |  |
| Exercised  |           | \$                                       |   |  |
| Forfeited  | (363,000) | \$ 4.35                                  |   |  |
| Expired  | (395,000) | \$ 13.45                                 |   |  |
| Outstanding September 30, 2006                   | 6,262,000 | \$ 9.85                                  | 7.1   | \$ 76  |
| Vested or expected to vest at September 30, 2006 | 5,956,826 | \$ 10.17                                 | 7.0   | \$ 74  |
| Exercisable at September 30, 2006                | 4,462,784 | \$ 12.40                                 | 6.4   | \$ 48  |

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A summary of the status of nonvested share awards as of September 30, 2006 and changes during the period then ended, is presented below:

|                                 | Nonvested<br>Shares | Weighted<br>Average<br>Grant Date<br>Fair Value<br>Per Share |
|---------------------------------|---------------------|--|
| Nonvested at December 31, 2005  | 1,608,000           | \$ 4.92  |
| Granted                         | 76,000              | \$ 1.76  |
| Vested                          | (518,000)           | \$ 3.56  |
| Forfeited                       | (134,000)           | \$ 2.79  |
| Nonvested at September 30, 2006 | 1,032,000           | \$ 5.65  |

The total fair value of share awards vested during the nine months ended September 30, 2006 was \$884,000.

As of September 30, 2006, the total remaining unrecognized compensation cost related to unvested stock options and share awards amounted to \$1.8 million, which will be amortized over the weighted-average remaining requisite service period of 1.2 years. This amount does not include unrecognized compensation cost related to 525,000 shares of contingent share awards granted during 2005.

**5. Convertible Senior Notes***6.75% Convertible Senior Notes*

As of September 30, 2006, \$72.3 million of our 6.75% notes due 2010 had been converted into 27.5 million shares of common stock, resulting in cumulative make-whole interest payments of \$24.1 million which was paid in cash. In addition, certain holders of the notes exercised their right to redeem up to 30% aggregate principal of their notes, and on April 30, 2006, we redeemed approximately \$2.7 million in aggregate principal of these notes. Subsequent to this date the mandatory redemption right expired and the remaining cash which we held in escrow to fund the potential redemptions was returned to us. As of September 30, 2006, we had \$7.0 million principal amount of 6.75% notes outstanding.

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 \$0.1 million and \$4.0 million for the three and nine months ended September 30, 2006, respectively, primarily in connection with the note conversions. The estimated fair value of the derivative liability was \$0.3 million at September 30, 2006 and was recorded in *6.75% convertible senior notes*. The change in the estimated fair value for the three and nine months ended September 30, 2006 was a gain of \$0.1 million and \$4.1 million, respectively, and is recorded in *gain (loss) on derivative liabilities*.

*7.5% Convertible Senior Notes*

In April 2006, we issued approximately \$66.3 million aggregate principal amount of our 7.5% notes, approximately \$33.2 million of which was issued in a registered offering for cash with net proceeds of approximately \$31.2 million, after deducting expenses and the initial purchaser's discounts and commissions. Approximately \$33.2 million was issued in a private exchange for approximately \$39.5 million aggregate principal amount of our 5.75% convertible senior subordinated notes and approximately \$1.2 million aggregate principal amount of our 5.75% convertible subordinated notes. We recognized a net gain of \$8.0 million on the early extinguishment and exchange of these notes which is based on the carrying value of the exchanged notes less the fair value of the new notes, net of issuance costs of \$0.4 million and accrued interest of \$0.9 million attributable to the exchanged notes. We recorded issuance costs related to 7.5% notes of approximately \$2.0 million which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the five-year life of the notes.

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As of September 30, 2006, a total of \$15.9 million of our 7.5% notes had been converted into 7.6 million shares of common stock and we had \$50.4 million principal amount of 7.5% notes outstanding. In connection with the conversion of \$7.4 million of these notes in May 2006, we made a discretionary interest make-whole payment of approximately \$1.7 million as a one-time concession which is included in *make-whole interest expense* for the nine months ended September 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. The resulting discount to the notes is being accreted over the life of the notes as additional interest expense using the effective interest method. Accordingly, we recorded interest expense of \$0.6 million and \$1.1 million for the three and nine months ended September 30, 2006, respectively, primarily in connection with the note conversions. The estimated fair value of the derivative liability will be adjusted quarterly for changes in the estimated market value. The change in the estimated fair value for the three and nine months ended September 30, 2006 was a loss of \$0.9 million and a gain of \$1.1 million, respectively, and was included in *gain (loss) on derivative liabilities*. At September 30, 2006, the fair value of the derivative was \$2.6 million and was recorded in *7.5% convertible senior notes*.

**6. Restructuring Activities**

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

The following table summarizes the changes in the liability for restructuring activities during nine months ended September 30, 2006 (in thousands):

|                               | <b>Excess Facilities<br/>Charges</b> | <b>Employee<br/>Separation Costs</b> |
|-------------------------------|--------------------------------------|--------------------------------------|
| Balance at December 31, 2005  | \$ 6,334                             | \$ 1,925                             |
| Adjustments                   | 441                                  | (71)                                 |
| Payments                      | (2,354)                              | (1,824)                              |
| Balance at September 30, 2006 | \$ 4,421                             | \$ 30                                |

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Charges for excess facilities relate to our lease obligation for excess laboratory and office space in the U.S. that we have vacated as a result of the restructuring plan. Pursuant to SFAS 146, we recorded restructuring charges in 2005 when we ceased using this space. The liability is calculated as the present value of total lease commitments, net of estimated sublease income. The additional charges for excess facilities for the nine months ended September 30, 2006 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. The adjustments to our employee separation costs are due to changes in estimates of amounts due to employees as well as adjustments due to foreign currency fluctuations. We will 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 September 30, 2006, approximately \$2.5 million of the liability for restructuring activities is included in *current portion of long-term obligations* and approximately \$2.0 million is included in *other long-term obligations, less current portion*.

### **7. Agreements with Novartis International Pharmaceutical Ltd.**

#### *Co-Development Agreement*

In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis International Pharmaceutical Ltd. or Novartis, for the development and commercialization of XYOTAX. Total product registration and sales milestones due from Novartis for XYOTAX under the agreement could reach up to \$270 million. The agreement also provides Novartis with an option to develop and commercialize pixantrone based on agreed terms. If Novartis exercises its option on pixantrone under certain conditions, Novartis would pay CTI a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on pixantrone worldwide net sales as well as reimbursement for certain expenses.

#### *Securities Purchase Agreement*

In connection with the licensing agreement, we also entered into a securities purchase agreement with Novartis, under which we agreed to sell and Novartis agreed to purchase an aggregate of 8,670,520 shares of our common stock for a total purchase price of \$15 million.

In October 2006, both the co-development and securities purchase agreements became effective upon the receipt of antitrust regulatory clearance, and accordingly, we closed the sale of the shares of common stock to Novartis.

#### *Registration Rights Agreement*

In connection with the sale of our common stock, we entered into a registration rights agreement with Novartis, under which we agreed to prepare, file and have declared effective a shelf registration statement with the Securities and Exchange Commission, or SEC, covering the resale of this common stock. The shelf registration statement must be declared effective on or prior to the fifteenth day following the date we receive notice that the registration statement will not be reviewed by the SEC or the ninetieth day following the filing date in the event that it is reviewed by the SEC. If we fail to timely have the shelf registration declared effective, we may be required to make a default payment to the investor.

### **8. Common Stock Offering**

In September 2006, we received \$40 million in gross proceeds from an offering of 23,121,394 shares of our common stock. These shares were sold under an existing shelf offering filed in April 2006 at an offering price of \$1.73 per share. We also issued to the purchasing investors warrants to purchase an additional 5,780,352 shares at \$1.73 per share if exercised within 90 days. We incurred approximately \$2.1 million in expenses related to this offering.

In October 2006, we were notified by the Nasdaq Stock Market, or Nasdaq, that this offering did not comply with the shareholder approval requirements set forth in Nasdaq Marketplace Rule 4350(i)(1)(D). This rule requires

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shareholder approval for transactions other than public offerings that exceed 20% of the outstanding shares at a price less than market value. In response to this notification, we repurchased 1,094,000 shares of common stock and 5,660,352 warrants for an aggregate price of \$3,024,691 thereby reducing the number of shares below the 20% threshold. Nasdaq has confirmed that the Company has regained compliance with Nasdaq Marketplace Rule 4350(i)(1)(D) and the matter is now closed.

Because this non-compliance occurred upon the issuance of stock under this agreement, it existed as of September 30, 2006 and we recorded a liability of approximately \$3.0 million related to the repurchase of the shares and warrants. This amount is included in *accrued liabilities* as well as a reduction to *common stock* as of September 30, 2006. The 1,094,000 shares are included in our issued and outstanding shares as of September 30, 2006.

### **9. Equity Financing Agreement**

On June 21, 2006, we entered into a Step-Up Equity Financing Agreement with Société Générale. Subject to certain conditions, the agreement allows us to issue to Société Générale shares of our common stock in a series of tranches over a period of 24 months. Under the agreement, we can initially issue up to 45 million worth of our common stock based on a pre-determined formula and have the right to increase the total amount of all issuances to up to 60 million worth of our common stock. Any issuance of our common stock pursuant to this agreement is at our election and we are not required to issue any common stock.

Société Générale's obligation to purchase shares upon request by CTI is subject to certain conditions. Under an amendment to this agreement, if such conditions are not satisfied by December 15, 2006, the agreement will terminate as of this date. As of September 30, 2006, there have not been any shares of common stock issued under this agreement.

Upon effectiveness of the agreement we will be required to pay a fee of 800,000. In addition, on each settlement of a share issuance, we must pay a subscriber fee equal to 3.5% of the selling price as well as 2.0% of the aggregate selling amount raised during each fiscal quarter.

### **10. Prepaid Supply Agreement**

In September 2001, we entered into a purchase agreement with Natural Pharmaceuticals, Inc., or NPI, to purchase \$6.0 million of paclitaxel, a starting material for XYOTAX, which was to be delivered by NPI over several years. This material was intended to be used primarily for research and development activities. We paid for the entire purchase upon execution of the agreement in 2001 and recorded the amount as a prepaid asset. As we had adequate supply of paclitaxel on hand to support our validation campaigns and clinical activities, we amended our supply agreement with NPI in October 2005 to reduce the amount of material we would receive and we were refunded \$0.8 million of our prepayment. In addition, the amended agreement grants NPI the exclusive right to purchase up to 5 kilograms of our paclitaxel supply at our original cost through September 1, 2006. We are currently in the process of renewing this contract to extend the term for an additional year. In January 2006, CTI and NPI amended the agreement to allow NPI the right to sell some or all of the paclitaxel supply to its customers and replace the material within 60 days with newer material having a longer expiration date.

As of September 30, 2006 and December 31, 2005, we had paclitaxel supply of \$1.7 million and \$2.3 million, respectively, which is included in *prepaid expenses and other current assets*. The amount as of September 30, 2006 includes approximately \$0.4 million in supply due from NPI. These costs have been capitalized since there is a ready market for this active pharmaceutical ingredient.

### **11. Legal Proceedings**

On February 10, 2004, Micromet AG, or Micromet, a Munich, Germany-based company, filed complaints against us in the federal district court for the Western District in the State of Washington, asserting that Cell Therapeutics Europe S.r.l., or CTI-Europe, formerly known as Novuspharma S.p.A., had purportedly breached a contract with Micromet for the development of MT-201, a fully human antibody targeting the EP-CAM molecule.

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The claims alleged that CTI-Europe failed to pay for certain milestones and development expenses owed under the contract. On February 23, 2004, we answered the complaint, denying the substance of the allegations and filed counterclaims for breach of contract and for rescission of the contract based on Micromet's misrepresentations and failures to disclose material information including preclinical trial tests which were determined to be invalid. On May 3, 2006, we entered into a settlement and release with Micromet regarding this lawsuit pursuant to which we paid Micromet approximately \$1.9 million in cash and the lawsuit was dismissed with prejudice.

On May 9, 2005, Terence Fernandes, a shareholder of CTI, filed a complaint in the Superior Court of the State of Washington, King County on behalf of CTI against members of CTI's board of directors. The shareholder derivative action alleged breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment since June 7, 2004. On December 7, 2005, plaintiff filed an amended complaint and defendants filed a motion to dismiss on February 6, 2006, to which plaintiffs responded on March 10, 2006. Defendants filed a reply brief on April 10, 2006. On June 22, 2006 the Court granted CTI's motion to dismiss this lawsuit with leave to the plaintiffs to amend. On July 31, 2006, after the period of time for the plaintiffs to amend the complaint had tolled, the defendants filed a motion to dismiss this lawsuit with prejudice for the failure of the plaintiffs to amend the complaint. On August 23, 2006, the Court entered a dismissal of this lawsuit with prejudice.

In October 2004, we announced that the United States Attorney's Office, or USAO, for the Western District of Washington had initiated an investigation into certain of our business practices relating to TRISENOX. USAO's investigation relates to our promotional practices relating to TRISENOX; our reporting of revenue relating to TRISENOX sales; and statements made by our representatives, and our expert third party reimbursement consultant, relating to the eligibility of TRISENOX for Medicare reimbursement when the drug was used to treat certain off-label indications. USAO has issued subpoenas to third parties relating to its investigation. We are fully cooperating with USAO (through the provision of documents and periodic meetings) and have not received a subpoena relating to the matter. We cannot predict whether USAO will bring formal criminal enforcement proceedings (and USAO has not indicated that it will). Claims associated with the above-referenced as well as related conduct have been filed against us under seal on behalf of the government by a private party in a qui tam action. Based on information currently available to us, we believe that the USAO may recommend to the Department of Justice that the government intervene in the qui tam action, as is its right, and assume the conduct of this lawsuit. We believe that regardless of whether the government or the private party pursues this lawsuit that one of the primary claims that might be pursued would be that we violated the Federal False Claims Act by receiving reimbursement from Medicare for improper off-label use of TRISENOX or otherwise ineligible sales of TRISENOX over the period ranging from October 2000 until TRISENOX's disposition to Cephalon in July of 2005. During this period we utilized a third party reimbursement expert. We believe that we have meritorious defenses to these claims. It is unclear to us under this theory what sales or portions thereof would be in question. Accordingly, we cannot provide an estimate of a possible loss or range of loss in connection with this investigation or lawsuit and therefore, we have not recorded a reserve for this matter as of September 30, 2006. Under the False Claims Act, damages can be trebled and separate fines imposed for each violation, if the government or the private party plaintiff were to prevail in this lawsuit it is likely that such an adverse judgment would have a material adverse effect on our financial position, liquidity and results of operations.

In addition to the litigation discussed above, we are from time to time, subject to legal proceedings and claims arising in the ordinary course of business, some of which may be covered in whole or in part by insurance.

**Table of Contents****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/A, 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 of 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 an additional study, known as the PIONEER, or PGT305, study, for XYOTAX as first-line monotherapy in PS2 women with NSCLC. In February 2006, the U.S. Food and Drug Administration, or FDA, confirmed that XYOTAX qualifies for fast track designation for the treatment of PS2 women with first-line advanced NSCLC. In November 2006, we temporarily 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. We plan to change the PIONEER study during the temporary suspension to focus on the primary efficacy endpoint of survival in women with normal estrogen levels. Whether we change the study through an amendment to the current PIONEER protocol or by submission of a new study protocol, we expect that the change to this pivotal trial will push back the interim analysis of the trial by at least six months to the first half of 2008. If the pivotal trial meets its revised pre-specified interim endpoint, we plan to submit a new drug application, or NDA, for XYOTAX for women with advanced NSCLC who are PS2 based on the interim results of the trial with the results of the STELLAR 3 and 4 trials to support the filing. We plan to submit the NDA as soon as practicable following such interim results and would request a priority (six month) review based on the fast track designation, instead of the standard (ten month) review as previously planned. We may be unable to submit an NDA as discussed if the pivotal trial does not meet its revised pre-specified interim endpoint. Based on discussions with Scientific Advice Working Party, or SAWP, of the European Medicines Agency, or EMEA, we plan to submit a marketing authorization application, or MAA, in Europe based on a non-inferior survival and improved side effect profile. 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.

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 study, was



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performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study will continue. Another interim analysis of the study will be performed on approximately 100 patients and is targeted for mid-year 2007.

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.

In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of XYOTAX. Total product registration and sales milestones for XYOTAX under the agreement could reach as much as \$270 million. We will not receive any product registration or sales milestone payments under the licensing agreement unless Novartis elects to participate in the development and commercialization of XYOTAX and we receive the necessary regulatory approvals. There is no guarantee that Novartis will make any such election or that we will receive such regulatory approvals. The licensing agreement also provides Novartis with an option to develop and commercialize pixantrone based on certain agreed terms. There is no guarantee that Novartis will exercise this option.

As of September 30, 2006, we had incurred aggregate net losses of approximately \$925.5 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.

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.

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

### *Valuation of Goodwill*

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

### *Derivatives Embedded in Certain Debt Securities*

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

Our 6.75% convertible senior notes, or 6.75% notes, and our 7.5% convertible senior notes, or 7.5% notes, contain certain features providing for payments in cash or common stock to be made in the event of certain conversions or repurchases of the debt. In the event of any conversion of our 6.75% notes to common stock, the feature calls for make-whole payments equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion. Our 7.5% notes include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. This 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.

These make-whole features represent embedded derivatives which are required to be accounted for separately from the related debt securities. The fair value of the derivative for the 6.75% notes is calculated based on a discounted cash flow model. The fair value of the derivative related to the 7.5% notes 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. Changes in the estimated fair value of the liabilities are included in *gain (loss) on derivative liabilities* and will be required until the relevant feature expires or all of the relevant notes are converted or repurchased.

### *Restructuring Charges*

We have recorded charges in connection with our restructuring activities, including estimates pertaining to employee separation costs, the related abandonment of excess facilities and impairment of fixed assets, and certain contract termination costs. Restructuring charges are recorded in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The recognition of restructuring charges requires management to make certain judgments regarding the nature, timing and amount associated with the planned restructuring activities. At the end of each reporting period, we evaluate the appropriateness of the remaining accrued balances.

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### *Stock-Based Compensation Expense*

On January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment (Revised 2004)*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. SFAS 123(R) supersedes our previous accounting under Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees*, for periods beginning in fiscal 2005. In March 2005, the Securities and Exchange Commission issued SAB 107 relating to SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

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. Our Condensed Consolidated Financial Statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our Condensed Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

As a result of adopting SFAS 123(R), our net loss was \$3.6 million higher and our basic and diluted net loss per share was \$0.04 higher than if we had continued to account for share-based compensation under APB No. 25 for the nine months ended September 30, 2006.

As of September 30, 2006, the total remaining unrecognized compensation cost related to unvested stock options and share awards amounted to \$1.8 million, which will be amortized over the weighted-average remaining requisite service period of 1.2 years. This amount does not include unrecognized compensation cost related to 525,000 shares of contingent share awards granted during 2005.

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

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

## **RESULTS OF OPERATIONS**

### **Three months ended September 30, 2006 and 2005.**

**Product sales.** TRISENOX was, prior to its divestiture to Cephalon in July 2005, our commercial product approved by the FDA, EMEA, and the Japanese Ministry of Health to treat patients with relapsed or refractory acute promyelocytic leukemia. As a result of the divestiture, there were no product sales for the three months ended September 30, 2006. We recorded net product sales of approximately \$1.2 million for TRISENOX for the three months ended September 30, 2005.

**License and contract revenue.** In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd., or Chugai, for the development and commercialization of XYOTAX. This agreement granted an exclusive license to Chugai to develop and commercialize XYOTAX in several Asian markets. Upon

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execution of the Chugai agreement, we received a \$3.0 million initial payment, which we recorded as deferred revenue and which was being recognized as revenue over the estimated development period of approximately seven years on a straight-line basis. As of December 31, 2005, we recognized the remaining deferred revenue related to this initial payment in anticipation of the termination of our agreement with Chugai which occurred in March 2006.

License and contract revenue for the three months ended September 30, 2006 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine. For the three month period ended September 30, 2005, we recognized approximately \$0.1 million of license and contract revenue primarily relating to the amortization of the initial payments from Chugai.

**Cost of product sold.** There was no cost of product sold for the three months ended September 30, 2006 due to the divestiture of TRISENOX to Cephalon on July 18, 2005. The cost of product sold during the three months ended September 30, 2005 was approximately \$0.1 million. Cost of product sold consisted primarily of manufacturing costs, royalties paid on product sales, and allowances for excess inventory that may expire and become unsaleable.

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

|  | Three Months Ended    |                  |
|--|-----------------------|------------------|
|  | September 30,<br>2006 | 2005             |
| Compounds under development:                   |                       |                  |
| XYOTAX   | \$ 6,412              | \$ 2,626         |
| Pixantrone                                     | 1,986                 | 1,940            |
| Other compounds                                | 239                   | 407              |
| Operating expenses                             | 5,508                 | 7,161            |
| Discovery research                             | 298                   | 1,206            |
| <b>Total research and development expenses</b> | <b>\$ 14,443</b>      | <b>\$ 13,340</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, TRISENOX and pixantrone are approximately \$185.7 million, \$29.1 million and \$20.7 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 \$14.4 million for the three months ended September 30, 2006, from approximately \$13.3 million for the three months ended September 30, 2005. Costs for our XYOTAX program increased primarily due to costs associated with our PIONEER trial which was initiated in the fourth quarter of 2005. Pixantrone costs increased due to costs associated with our EXTEND trial which was also initiated in the fourth quarter of 2005 and had increased enrollment throughout 2006 offset by a decrease in our phase I and II clinical trials due to the winding down of these trials. Operating expenses decreased primarily due to a reduction in our headcount resulting from our restructuring activities in 2005. Discovery research expenses decreased primarily as a result of decreased personnel and other costs due to a reduction in programs.

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



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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;

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. Based on recent developments with the PIONEER trial, we are targeting submission of an NDA for XYOTAX in the second half of 2008, depending on the duration of the review cycle, timing, and assuming positive results of the interim analysis of the pivotal trial, with a U.S. XYOTAX approval targeted in the first half of 2009 and launch shortly thereafter. Approval in the EU would be targeted approximately 15 months following the submission of an MAA, which is planned for the first half of 2007 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 \$9.0 million for the three months ended September 30, 2006, from approximately \$12.5 million for the three months ended September 30, 2005. This decrease is primarily attributed to a \$2.3 million decrease in our sales and marketing expenses related to reduced commercialization efforts and headcount associated with the divestiture of TRISENOX to Cephalon on July 18, 2005 and a \$1.2 million decrease in operating expenses primarily related to decreased compensation and benefits, occupancy and other expenses resulting from a reduction in headcount. In addition, corporate development expenses decreased by \$0.3 million primarily due to a decrease of \$1.1 million in aircraft operating costs resulting from the termination of our aircraft operating lease in the fourth quarter of 2005 offset by an increase in compensation and benefits of approximately \$0.8 million mainly due to executive bonus and severance expense. There was also a \$0.3 million increase in stock-based compensation expense primarily related to the implementation of SFAS 123(R). Corporate development expenses include certain legal expenses, business development and corporate communication activities, and costs related to operating our aircraft.

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We expect selling, general and administrative expenses to continue to decrease in 2006 as compared to 2005 due to the divestiture of TRISENOX to Cephalon as well as the termination of our aircraft lease in 2005. In the event that we are able to move forward with the commercialization of XYOTAX, our sales and marketing expenses would then increase.

**Amortization of purchased intangibles.** Amortization for the three months ended September 30, 2006 decreased slightly as compared to the three months ended September 30, 2005, due to a write-down of our assembled workforce asset in December 2005.

**Restructuring charges and related asset impairments.** In 2005, we announced plans to reduce our workforce through selected layoffs of employees as part of our cost savings initiative in an effort to reduce costs and conserve capital in anticipation of an NDA filing and potential launch of XYOTAX. In conjunction with our workforce reduction, we vacated a portion of our laboratory and office facilities. Restructuring activities and asset impairments for the three months ended September 30, 2006 primarily relate to adjustments related to our excess facilities for a change in our estimate of the timing and amount of cash flows and adjustments for the passage of time as well as changes in the estimates of separation costs due to employees. For the three months ended September 30, 2005, we recorded approximately \$5.1 million in restructuring and related asset impairment charges including a \$4.7 million charge related to excess facilities costs, approximately \$0.3 million in write-downs related to asset impairments and \$0.1 million for a reduction in workforce.

**Gain on divestiture of TRISENOX.** The gain of \$30.5 million for three months ended September 30, 2005 related to the portion of the gain recognized on the divestiture of TRISENOX and certain proteasome assets to Cephalon. We provided transition services to Cephalon related to TRISENOX and proteasome assets for a period of approximately six months subsequent to the date of closing.

**Investment and other income.** Investment and other income for the three months ended September 30, 2006 and 2005 was approximately \$0.6 million and \$0.4 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 three months ended September 30, 2006 compared to the three months ended September 30, 2005.

**Interest expense.** Interest expense increased to approximately \$3.6 million for the three months ended September 30, 2006 from approximately \$3.0 million for the three months ended September 30, 2005. This increase is due to \$0.7 million in accretion of the debt discount on our 6.75% and 7.5% notes, interest expense of \$1.0 million related to these notes and \$0.3 million increase in the amortization of debt issuance costs primarily associated with conversions of these notes. These increases were partially offset by a decrease of \$1.1 million in interest expense on our 4.0% senior subordinated and 5.75% subordinated and senior subordinated notes due to the retirement and exchange of a portion of these notes in the fourth quarter of 2005 and first half of 2006 and a decrease of \$0.3 million in interest charges related to our royalty financing agreement entered into with PharmaBio in December 2004 and terminated in July 2005 when we divested TRISENOX.

**Foreign exchange gain (loss).** The foreign exchange loss for the three months ended September 30, 2006 and 2005 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 \$0.2 million is related to payments made upon the conversion of \$0.7 million of our 6.75% notes during the three months ended September 30, 2006.

**Gain (loss) on derivative liabilities.** The loss on the derivative liabilities of \$0.9 million for the three months ended September 30, 2006 represents the change in the estimated fair value of our derivative liabilities related to the interest make-whole provisions on our 6.75% and 7.5% notes. During this period we recorded a gain of approximately \$0.1 million and a loss of approximately \$0.9 million related to the derivative liability for our 6.75% and 7.5% notes, respectively.

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**Loss on extinguishment of royalty obligation.** The loss on extinguishment of royalty obligation for the three months ended September 30, 2005 relates to the repayment of our royalty obligation to PharmaBio as a result of the divestiture of TRISENOX. The loss of \$6.4 million was calculated based on the excess of our termination payment of \$39.4 million over the amount of the accreted royalty obligation and the unused portion of the prepaid service commitment at the time of extinguishment of \$28.9 million and \$4.1 million, respectively.

**Nine months ended September 30, 2006 and 2005.**

**Product sales.** As a result of the divestiture of TRISENOX to Cephalon, there were no product sales for the nine months ended September 30, 2006. We recorded net product sales of approximately \$14.6 million for TRISENOX for the nine months ended September 30, 2005.

**License and contract revenue.** License and contract revenue for the nine months ended September 30, 2006 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine. For the nine months ended September 30, 2005, we recognized approximately \$0.3 million of license and contract revenue primarily relating to the amortization of the initial payments from Chugai.

**Cost of product sold.** There was no cost of product sold for the nine months ended September 30, 2006 due to the divestiture of TRISENOX to Cephalon on July 18, 2005. The cost of product sold during the nine months ended September 30, 2005 was approximately \$0.5 million. Cost of product sold consisted primarily of manufacturing costs, royalties paid on product sales, and allowances for excess inventory that may expire and become unsaleable.

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

|   | Nine Months Ended     |           |
|---|-----------------------|-----------|
|   | September 30,<br>2006 | 2005      |
| Compounds under development:            |                       |           |
| XYOTAX                                  | \$ 17,996             | \$ 14,695 |
| Pixantrone                              | 7,277                 | 5,104     |
| TRISENOX                                |                       | 3,543     |
| Other compounds                         | 794                   | 1,523     |
| Operating expenses                      | 18,217                | 25,116    |
| Discovery research                      | 1,086                 | 5,601     |
| Total research and development expenses | \$ 45,370             | \$ 55,582 |

Research and development expenses decreased to approximately \$45.4 million for the nine months ended September 30, 2006, from approximately \$55.6 million for the nine months ended September 30, 2005. Costs for our XYOTAX program increased primarily due to an increase in clinical activity related to the initiation of the PIONEER trial in the fourth quarter of 2005 offset in part by a \$1.7 million write-down of our paclitaxel supply to its estimated fair value in the second quarter of 2005. Pixantrone costs increased due to an increase in clinical trial expenses, attributable to increased patient enrollment and sites for our phase II and III clinical trials. TRISENOX costs decreased due to the divestiture of TRISENOX to Cephalon. Costs for other compounds decreased due to slower new patient enrollment in our CT-2106 trials in 2006 as compared to 2005. Operating costs decreased primarily due to a reduction in our headcount resulting from our restructuring activities in 2005. Discovery research costs decreased primarily as a result of decreased personnel and other costs due to a reduction in programs.

**Selling, general and administrative expenses.** Selling, general and administrative expenses decreased to approximately \$27.5 million for the nine months ended September 30, 2006, from approximately \$49.5 million for the nine months ended September 30, 2005. This decrease is primarily attributed to a \$15.6 million decrease in our sales and marketing expenses related to reduced commercialization efforts and headcount associated with the divestiture of TRISENOX to Cephalon in the third quarter of 2005 and a \$4.2 million decrease in operating expenses primarily related to decreased compensation and benefits, occupancy and other expenses resulting from a reduction in headcount. In addition, corporate development expenses decreased by \$3.0 million primarily due to a decrease in





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aircraft operating costs of \$3.7 million resulting from the termination of our aircraft operating lease in the fourth quarter of 2005, offset by an increase in compensation and benefits of approximately \$0.8 million mainly due to executive bonus and severance expense. There was also a \$0.8 million increase in stock-based compensation expense primarily related to the implementation of SFAS 123(R).

**Amortization of purchased intangibles.** Amortization for the nine months ended September 30, 2006 decreased to approximately \$0.6 million from approximately \$0.7 million for the nine months ended September 30, 2005, due to a write-down of our assembled workforce asset in December 2005.

**Restructuring charges and related asset impairments.** Restructuring activities and asset impairments for the nine months ended September 30, 2006 primarily relate to adjustments related to our excess facilities due to a change in our estimate of the timing and amount of cash flows and adjustments due to the passage of time as well as changes in the estimates of separation costs due to employees. Restructuring activities and asset impairments for the nine months ended September 30, 2005 of approximately \$7.0 million included \$4.7 million related to excess facilities charges, \$1.5 million due to a significant reduction in workforce in the U.S. and \$0.8 million in write-downs of tangible assets, primarily lab equipment in the U.S., that will cease to be used as we consolidate our research operations with CTI (Europe).

**Gain on divestiture of TRISENOX.** The gain of \$30.5 million for nine months ended September 30, 2005 related to the portion of the gain recognized on the divestiture of TRISENOX and certain proteasome assets to Cephalon. We provided transition services to Cephalon related to TRISENOX and proteasome assets for a period of approximately six months subsequent to the date of closing.

**Investment and other income.** Investment and other income for the nine months ended September 30, 2006 and 2005 was approximately \$1.8 million and \$1.3 million, respectively. This increase is due to a higher average securities available-for-sale balance as well as higher prevailing interest rates on our investments during the nine months ended September 30, 2006 compared to the nine months ended September 30, 2005.

**Interest expense.** Interest expense increased to approximately \$16.9 million for the nine months ended September 30, 2006 from approximately \$10.8 million for the nine months ended September 30, 2005. This increase is due to \$5.1 million in accretion of the debt discount on our 6.75% and 7.5% notes, an increase in the amortization of debt issuance costs of \$4.6 million primarily associated with conversions of these notes, and interest expense of \$1.6 million related to our 7.5% notes. These increases were offset by a decrease of \$2.8 million in interest charges related to our royalty financing agreement entered into with PharmaBio in December 2004 and terminated in July 2005 in when we divested TRISENOX and a decrease of \$2.4 million in interest expense for our convertible notes due to the retirement, exchange or conversion of a portion of these notes in the fourth quarter of 2005 and first half of 2006.

**Foreign exchange gain (loss).** The foreign exchange gain for the nine months ended September 30, 2006 and 2005 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 \$24.8 million is related to payments of \$23.1 million made upon the conversion of \$69.3 million of our 6.75% notes and \$1.7 million made upon conversion of \$7.4 million of our 7.5% notes during the nine months ended September 30, 2006.

**Gain (loss) on derivative liabilities.** The gain on the derivative liabilities of \$5.2 million for the nine months ended September 30, 2006 represents the change in the estimated fair value of our derivative liabilities related to the interest make-whole provisions on our 6.75% and 7.5% notes of \$4.1 million and \$1.1 million, respectively.

**Gain on exchange of convertible notes.** We recorded a gain of \$8.0 million during the nine months ended September 30, 2006 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 in the second quarter of 2006. The gain is net of accrued interest of \$0.9 million and issuance costs of \$0.4 million attributable to the exchanged notes.

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**Settlement expense.** Settlement expense for the nine months ended September 30, 2006 relates to the amount paid under the settlement of our dispute with Micromet AG in May 2006 and is net of payables previously due to Micromet.

**Loss on extinguishment of royalty obligation.** The loss on extinguishment of royalty obligation for the nine months ended September 30, 2005 relates to the repayment of our royalty obligation to PharmaBio as a result of the divestiture of TRISENOX.

## **LIQUIDITY AND CAPITAL RESOURCES**

As of September 30, 2006, we had approximately \$68.2 million in cash and cash equivalents, restricted cash, securities available-for-sale and interest receivable, approximately \$3.0 million of which was used to repurchase shares of our common stock and warrants exercisable for our common stock in October 2006. In addition we received \$15.0 million of cash from an offering of our common stock in October 2006.

Net cash used in operating activities decreased to approximately \$92.1 million during the nine months ended September 30, 2006, compared to approximately \$97.7 million for the same period during 2005 primarily due to an increase in our net loss, offset by a non cash gain on the divestiture of TRISENOX to Cephalon during the nine months ended September 30, 2005. For the nine months ended September 30, 2006, our net loss included \$24.8 million in make-whole interest payments related to conversions of our 6.75% and 7.5% notes.

Net cash used in investing activities totaled approximately \$32.5 million during the nine months ended September 30, 2006, compared to net cash provided by investing activities of approximately \$67.5 million for the same period during 2005. The net cash used in investing activities during the nine months ended September 30, 2006 was primarily due to purchases of securities available-for-sale offset by proceeds from maturities of securities available-for-sale. The net cash provided by investing activities during the nine months ended September 30, 2005 was primarily due to proceeds from the divestiture of TRISENOX and proceeds from sales and maturities of securities available-for-sale, offset in part by purchases of securities available-for-sale.

Net cash provided by financing activities totaled approximately \$91.0 million during the nine months ended September 30, 2006, compared to net cash used in financing activities of approximately \$40.2 million for the same period during 2005. The net cash provided by financing activities for the nine months ended September 30, 2006 was primarily due to net proceeds of \$37.9 million received from the sale of approximately 23.1 million shares of our common stock in September 2006, \$31.2 million received from the issuance of our 7.5% notes as well as \$24.7 million in restricted cash related to the issuance of our 6.75% notes that was released from escrow upon conversion of a portion of these notes. The net cash used in financing activities during the nine months ended September 30, 2005 was primarily due to the repayment of \$39.4 million for our royalty obligation with PharmaBio.

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.

The financial statements have been prepared on a basis of a going concern which contemplates realization of assets and satisfaction of liabilities in the normal course of business. We expect that our existing cash, cash equivalents, securities available-for-sale and interest receivable will not be sufficient to fund our operations for the next 12 months. Accordingly, we will need to raise additional funds and are currently exploring alternative sources of equity or debt financing. Additional funding may not be available on favorable terms or at all. If we are unable to raise additional capital in the near term, we have developed a plan to further curtail operations significantly, by delaying, modifying, or canceling selected aspects for research and development programs related to XYOTAX, pixantrone and other products we may be developing. The plan contains reductions in operating expenditures related to certain research and development and general and administrative activities including compensation and benefits, corporate costs and clinical trial costs, which are designed to allow the company to continue to operate on a going concern basis.

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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;

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

competitive market developments.

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

The following table includes information relating to our contractual obligations as of September 30, 2006 (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)               | \$ 50,410              | \$        | \$        | \$ 50,410  | \$            |
| 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 (6)               | 32,996                 | 9,673     | 15,195    | 8,128      |               |
| Operating leases:                               |                        |           |           |            |               |
| Facilities                                      | 35,089                 | 8,077     | 11,637    | 10,649     | 4,726         |
| Long term obligations (7)                       | 2,602                  | 238       | 814       | 989        | 561           |
|   | \$ 239,144             | \$ 17,988 | \$ 83,543 | \$ 132,326 | \$ 5,287      |

- (1) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 478.519 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$2.09 per share.
- (2) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 380.37 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$2.63 per share.
- (3) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 100 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$10.00 per share.

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- (4) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 74.0741 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$13.50 per share.
- (5) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of 29.4118 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$34.00 per share.
- (6) As of September 30, 2006, we have made \$25.8 million in cumulative make-whole interest payments related to the early conversions of \$72.3 million of our 6.75% convertible senior notes and \$7.4 million of our 7.5% convertible senior notes.
- (7) Long-term obligations does not include \$4.4 million related to excess facilities charges and \$0.9 million recorded as a long-term obligation for benefits owed to our Italian employees pursuant to Italian Law. The timing of the payments related to this obligation is unknown as the benefit is paid upon an employees 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.

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

We are exposed to market risk related to changes in interest rates that could adversely affect the value of our investments. We maintain a short-term investment portfolio consisting of interest bearing securities with an average maturity of less than one year. These securities are classified as available-for-sale. These securities are interest bearing and thus subject to interest rate risk and will fall in value if market interest rates increase. Since we generally hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected significantly by a sudden change in market interest rates related to our securities portfolio. The fair value of our securities available-for-sale at September 30, 2006 and December 31, 2005 was \$51.3 million and \$18.9 million, respectively. For each one percent change in interest rates, the fair value of our securities available-for-sale would change by approximately \$260,000 and \$63,000 as of September 30, 2006 and December 31, 2005, 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, restricted cash, cash equivalents and interest receivable (foreign funds). Based on the balance of foreign funds at September 30, 2006 of \$2.7 million, an assumed 5%, 10% and 20% negative currency exchange movement would result in fair value declines of \$0.1 million, \$0.3 million and \$0.5 million.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in its Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as our controls are designed to do, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Previously, our management, under the supervision and with the participation of the Company's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), had evaluated the effectiveness of our disclosure controls and procedures as defined in SEC Rule 13a-15(e) as of the end of the period covered by this report. Management had concluded that our disclosure controls and procedures were effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act is communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. However, in connection with the filing of this Amendment No. 1 to our quarterly report on Form 10-Q, our management, under the supervision and with the participation of the Company's CEO and CFO, reevaluated the effectiveness of our disclosure controls and procedures as of September 30, 2006, and concluded that due to the material weakness described below, we did not have effective disclosure controls and procedures relative to accounts payable and accrued expense balances as of September 30, 2006.

*Description of Material Weakness*

A material weakness is a control deficiency, or 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 at September 30, 2006, we had a material weakness relative to the effectiveness of our internal control over financial reporting. Specifically, we did not maintain effective

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controls over the accuracy, presentation and disclosure of accounts payable and accrued expenses in conformity with generally accepted accounting principles, including, maintaining effective controls to ensure that these balances were accurate in CTI (Europe).

### *Remediation of Material Weakness*

In an effort to remediate the material weakness described above, we are currently implementing enhanced procedures that are designed to help ensure that we will accurately record accounts payable and accrued expense balances in CTI (Europe). These enhanced procedures will provide for additional managerial oversight of accounts payable and accrued expense balances.

### (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.

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**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

On May 9, 2005, Terence Fernandes, a shareholder of CTI, filed a complaint in the Superior Court of the State of Washington, King County on behalf of CTI against members of CTI's board of directors. The shareholder derivative action alleged breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment since June 7, 2004. On December 7, 2005, plaintiff filed an amended complaint and defendants filed a motion to dismiss on February 6, 2006, to which plaintiffs responded on March 10, 2006. Defendants filed a reply brief on April 10, 2006. On June 22, 2006 the Court granted CTI's motion to dismiss this lawsuit with leave to the plaintiffs to amend. On July 31, 2006, after the period of time for the plaintiffs to amend the complaint had tolled, defendants filed a motion to dismiss this lawsuit with prejudice for the failure of the plaintiffs to amend the complaint. On August 23, 2006, the Court entered a dismissal of this lawsuit with prejudice.

In October 2004, we announced that the United States Attorney's Office, or USAO, for the Western District of Washington had initiated an investigation into certain of our business practices relating to TRISENOX. USAO's investigation relates to our promotional practices relating to TRISENOX; our reporting of revenue relating to TRISENOX sales; and statements made by our representatives, and our expert third party reimbursement consultant, relating to the eligibility of TRISENOX for Medicare reimbursement when the drug was used to treat certain off-label indications. USAO has issued subpoenas to third parties relating to its investigation. We are fully cooperating with USAO (through the provision of documents and periodic meetings) and have not received a subpoena relating to the matter. We cannot predict whether USAO will bring formal criminal enforcement proceedings (and USAO has not indicated that it will). Claims associated with the above-referenced as well as related conduct have been filed against us under seal on behalf of the government by a private party in a qui tam action. Based on information currently available to us, we believe that the USAO may recommend to the Department of Justice that the government intervene in the qui tam action, as is its right, and assume the conduct of this lawsuit. We believe that regardless of whether the government or the private party pursues this lawsuit that one of the primary claims that might be pursued would be that we violated the Federal False Claims Act by receiving reimbursement from Medicare for improper off-label use of TRISENOX or otherwise ineligible sales of TRISENOX over the period ranging from October 2000 until TRISENOX's disposition to Cephalon in July of 2005. During this period we utilized a third party reimbursement expert. We believe that we have meritorious defenses to these claims. It is unclear to us under this theory what sales or portions thereof would be in question. Accordingly, we cannot provide an estimate of a possible loss or range of loss in connection with this investigation or lawsuit and therefore, we have not recorded a reserve for this matter as of September 30, 2006. Under the False Claims Act, damages can be trebled and separate fines imposed for each violation, if the government or the private party plaintiff were to prevail in this lawsuit it is likely that such an adverse judgment would have a material adverse effect on our financial position, liquidity and results of operations.

In addition to the litigation discussed above, we are from time to time, subject to legal proceedings and claims arising in the ordinary course of business, some of which may be covered in whole or in part by insurance.

**Item 1A. Risk Factors**

**Factors Affecting Our Operating Results and Financial Condition**

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of September 30, 2006, we had an accumulated deficit of approximately \$925.5 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.



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*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.

*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 expect that our existing cash and cash equivalents, securities available for sale and interest receivable will not be sufficient to fund our operations for the next 12 months. Accordingly, 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. In particular, we will need to raise additional funds to complete the phase III clinical trials for XYOTAX and pixantrone.

If our plans or assumptions change or are inaccurate, it will affect the amount of additional funds we will need to raise. 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. 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 be unable to obtain a quorum for our 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 held on June 23, 2006. We have rescheduled our annual meeting to be held at The Borsa Italiana, Palazzo Mezzanote, Piazza degli Affari, 6 Milano, Italy on Thursday, November 30, 2006, at 2:00 p.m. Central European Time (CET), or 5:00 a.m. (PST). If we are unable to obtain a quorum at this rescheduled meeting, we may be unable to take corporate actions which require the prior approval of our shareholders, including but not limited to actions such as increasing the authorized number of shares of our common stock, increasing the number of incentive options available for issuance, mergers and other matters. The failure to obtain the prior approval of our shareholders for any of these corporate actions could have a material adverse effect on the Company.

*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. Société Générale would then resell such shares on the Italian stock market. One of the conditions that must be satisfied before we may issue shares pursuant to this agreement is that we are reasonably satisfied that any offering under the Step-Up Equity Financing Agreement will be able to comply with the registration notice requirements of the Milan Stock Exchange in a manner customary for offerings on the Milan Stock Exchange. We have not yet determined that an offering under the Step-Up Equity Financing Agreement will be able to comply with such registration notice requirements, and there is no guarantee that we will be able to comply

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with such requirements. 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 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.

*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 November 2006, we temporarily suspended enrollment in the PIONEER clinical trial and plan to amend the study during this suspension to focus on the primary efficacy endpoint of survival in women with normal estrogen levels. We may not receive positive interim results from the amended trial, which would preclude our planned submission of an NDA based on such interim 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.

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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 largely 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 intended to make physicians aware of off-label uses of TRISENOX, without engaging in off-label promotion, could nevertheless 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 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 October 2004, we announced that the United States Attorney's Office, or USAO, for the Western District of Washington had initiated an investigation into certain of our business practices relating to TRISENOX. USAO's investigation relates to our promotional practices relating to TRISENOX; our reporting of revenue relating to TRISENOX sales; and statements made by our representatives, and our expert third party reimbursement consultant, relating to the eligibility of TRISENOX for Medicare reimbursement when the drug was used to treat certain off-label indications. USAO has issued subpoenas to third parties relating to its investigation. We are fully cooperating with USAO (through the provision of documents and periodic meetings) and have not received a subpoena relating to the matter. We cannot predict whether USAO will bring formal criminal enforcement proceedings (and USAO has not indicated that it will). Claims associated with the above-referenced as well as related conduct have been filed against us under seal on behalf of the government by a private party in a qui tam action. Based on information currently available to us, we believe that the USAO may recommend to the Department of Justice that the government intervene in the qui tam action, as is its right, and assume the conduct of this lawsuit. We believe that regardless of whether the government or the private party pursues this lawsuit that one of the primary claims that might be pursued would be that we violated the Federal False Claims Act by receiving reimbursement from Medicare for improper off-label use of TRISENOX or otherwise ineligible sales of TRISENOX over the period ranging from October 2000 until TRISENOX's disposition to Cephalon in July of 2005. During this period we utilized a third party reimbursement expert. We believe that we have meritorious defenses to these claims. It is unclear to us under this theory what sales or portions thereof would be in question. Accordingly, we cannot provide an estimate of a possible loss or range of loss in connection with this investigation or lawsuit. Under the False Claims Act, damages can be trebled and separate fines imposed for each violation, if the government or the private party plaintiff were to prevail in this lawsuit it is likely that such an adverse judgment would have a material adverse effect on our financial position, liquidity and results of operations.

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 industry 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 market 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.



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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.

*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.

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*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.

*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.

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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<sup>®</sup>, one of the world's best selling cancer drugs, linked to polyglutamate. We may not receive a patent for all of our polymer-drug conjugates and we may be challenged by the holder of a patent covering the underlying drug and/or methods for its use or manufacture.

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

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

*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.



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*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 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;

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.



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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.

*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;

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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 required to comply with the regulatory structure of Italy because our stock is traded on the Nuovo Mercato, 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.

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

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

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

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

tariffs, customs, duties and other trade barriers; and

capital controls, terrorism and other political risks.

We are also subject to the following operational challenges, among others, as a result of 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;

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

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

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

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

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

Our business exposes us to potential product liability risks inherent in the testing, manufacturing 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.

*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.

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### **Risks Related To The Securities Markets**

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve month period ended September 30, 2006, our stock price ranged from a low of \$1.12 to a high of \$2.83. 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;

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.



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*Anti-takeover provisions in our charter documents, our shareholder rights plan, 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;

the ability of our board of directors to issue up to 10,000,000 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; and

a shareholder rights plan.

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

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

## **Item 6. Exhibits**

(a) Exhibits

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: February 5, 2007

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

Dated: February 5, 2007

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