CELL THERAPEUTICS INC
Form 10-Q
May 06, 2010
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-Q

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the quarterly period ended: March 31, 2010**

**OR**

**¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from _____ to _____**

**Commission File Number 001-12465**

# CELL THERAPEUTICS, INC.

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

| **Washington** | **91-1533912** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **501 Elliott Avenue West, Suite 400** | |
| **Seattle, Washington** | **98119** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**(206) 282-7100**

**(Registrant s telephone number, including area code)**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

| | |
|---|---|
| Large accelerated filer x | Accelerated filer ¨ |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company ¨ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date:

| **Class** | **Outstanding at May 3, 2010** |
|---|---|
| Common Stock, no par value | 656,297,333 |

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**CELL THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(In thousands, except share amounts)**

| | March 31, 2010 (unaudited) | December 31, 2009 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 41,511 | $ 37,811 |
| Prepaid expenses and other current assets | 5,081 | 4,354 |
| Total current assets | 46,592 | 42,165 |
| Property and equipment, net | 4,034 | 3,430 |
| Goodwill | 17,064 | 17,064 |
| Other assets | 7,841 | 6,936 |
| Total assets | $ 75,531 | $ 69,595 |
| **LIABILITIES AND SHAREHOLDERS DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,143 | $ 7,297 |
| Accrued expenses | 12,679 | 14,807 |
| Current portion of deferred revenue | 80 | 80 |
| Current portion of long-term obligations | 1,219 | 1,312 |
| 4% convertible senior subordinated notes | 40,363 | 40,363 |
| Total current liabilities | 61,484 | 63,859 |
| Deferred revenue, less current portion | 219 | 239 |
| Long-term obligations, less current portion | 1,632 | 1,861 |
| 7.5% convertible senior notes | 10,130 | 10,102 |
| 5.75% convertible senior notes | 11,778 | 11,677 |
| Total liabilities | 85,243 | 87,738 |
| Commitments and contingencies | | |
| Common stock purchase warrants | 450 | 626 |
| Shareholders deficit: | | |
| Common stock, no par value: | | |
| Authorized shares - 800,000,000 | | |
| Issued and outstanding shares - 615,423,905 (unaudited) and 590,282,575 at March 31, 2010 and December 31, 2009, respectively | 1,471,497 | 1,418,931 |
| Accumulated other comprehensive loss | (8,122) | (8,412) |
| Accumulated deficit | (1,473,280) | (1,429,083) |
| Total CTI shareholders deficit | (9,905) | (18,564) |
| Noncontrolling interest | (257) | (205) |
| Total shareholders deficit | (10,162) | (18,769) |

| | | |
|---|---|---|
| Total liabilities and shareholders deficit | $ 75,531 | $ 69,595 |

See accompanying notes.

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**CELL THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(In thousands, except per share amounts)**

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2010** | **2009** |
| Revenues: | | |
| License and contract revenue | $ 20 | $ 20 |
| Total revenues | 20 | 20 |
| Operating expenses, net: | | |
| Research and development | 7,360 | 7,956 |
| Selling, general and administrative | 18,417 | 8,874 |
| Gain on sale of investment in joint venture | | (10,244) |
| Total operating expenses, net | 25,777 | 6,586 |
| Loss from operations | (25,757) | (6,566) |
| Other income (expense): | | |
| Investment and other income, net | 262 | 34 |
| Interest expense | (787) | (1,617) |
| Amortization of debt discount and issuance costs | (215) | (4,851) |
| Foreign exchange gain (loss) | (475) | 41 |
| Make-whole interest expense | | (6,345) |
| Gain on derivative liabilities, net | | 5,622 |
| Equity loss from investment in joint venture | | (1,204) |
| Settlement expense, net | | (170) |
| Other expense, net | (1,215) | (8,490) |
| Net loss before noncontrolling interest | (26,972) | (15,056) |
| Noncontrolling interest | 52 | 89 |
| Net loss attributable to CTI | (26,920) | (14,967) |
| Gain on restructuring of preferred stock | | 2,116 |
| Preferred stock dividends | | (23) |
| Deemed dividends on preferred stock | (17,277) | (250) |
| Net loss attributable to CTI common shareholders | $ (44,197) | $ (13,124) |
| Basic and diluted net loss per common share | $ (0.07) | $ (0.05) |
| Shares used in calculation of basic and diluted net loss per common share | 598,984 | 285,525 |

See accompanying notes.

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**CELL THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2010** | **2009** |
| **Operating activities** | | |
| Net loss | $ (26,920) | $ (14,967) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Non-cash interest expense | 215 | 4,851 |
| Non-cash gain on derivative liabilities | | (5,622) |
| Gain on sale of equity investment in joint venture | | (10,244) |
| Depreciation and amortization | 483 | 580 |
| Equity-based compensation expense | 7,751 | 506 |
| Equity loss from investment in joint venture | | 1,204 |
| Noncontrolling interest | (52) | (89) |
| Other | (120) | 24 |
| Changes in operating assets and liabilities: | | |
| Restricted cash | | 6,640 |
| Accounts receivable, net | | 982 |
| Prepaid expenses and other current assets | (742) | (1,067) |
| Other assets | (1,325) | (36) |
| Accounts payable | (123) | 6,574 |
| Accrued expenses | (2,168) | (8,445) |
| Other liabilities | (188) | (106) |
| Total adjustments | 3,731 | (4,248) |
| Net cash used in operating activities | (23,189) | (19,215) |
| **Investing activities** | | |
| Proceeds received from disposition of Zevalin to joint venture, net | | 6,844 |
| Proceeds received from sale of investment in joint venture, net | | 5,686 |
| Proceeds from maturities of securities available-for-sale | | 600 |
| Proceeds from the sale of property and equipment | 11 | |
| Purchases of property and equipment | (1,118) | |
| Net cash provided by (used in) investing activities | (1,107) | 13,130 |
| **Financing activities** | | |
| Proceeds from issuance of Series 3 preferred stock and warrants, net of issuance costs | 28,108 | |
| Cash paid for repurchase of shares in connection with taxes on restricted stock vesting | (589) | |
| Payment of deemed dividends on conversion of preferred stock | | (3,000) |
| Payment of dividends on preferred stock | | (93) |
| Other | (4) | (115) |
| Net cash provided by (used in) financing activities | 27,515 | (3,208) |

| | | |
|---|---|---|
| Effect of exchange rate changes on cash and cash equivalents | 481 | (31) |
| Net increase (decrease) in cash and cash equivalents | 3,700 | (9,324) |
| Cash and cash equivalents at beginning of period | 37,811 | 10,072 |
| Cash and cash equivalents at end of period | $ 41,511 | $ 748 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid during the period for interest | $ 809 | $ 6,757 |
| Cash paid for taxes | $ | $ |
| **Supplemental disclosure of noncash financing and investing activities** | | |
| Exchange of Series A 3% convertible preferred stock for Series F preferred stock | $ | $ 151 |
| Exchange of Series B 3% convertible preferred stock for Series F preferred stock | $ | $ 1,713 |
| Exchange of Series C 3% convertible preferred stock for Series F preferred stock | $ | $ 3,221 |
| Issuance of Series F preferred stock for Series A, B and C convertible preferred stock | $ | $ 3,931 |
| Conversion of Series B 3% convertible preferred stock to common stock | $ | $ 2,317 |
| Issuance of common stock in exchange for Series A 3% convertible preferred stock | $ | $ 509 |
| Conversion of 10% convertible senior notes due 2011 to common stock | $ | $ 18,000 |
| Conversion of 9% convertible senior notes to common stock | $ | $ 5,250 |
| Conversion of Series 3 preferred stock to common stock | $ 27,761 | $ |

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. Subsequent to the closure of our Bresso, Italy operations in September 2009, our operations are now primarily conducted in the United States. During 2008, we had one approved drug, Zevalin® (ibritumomab tiuxetan), or Zevalin, which we acquired in 2007, generating product sales. We contributed Zevalin to a joint venture, RIT Oncology, LLC, or RIT Oncology, upon its formation in December 2008 and in March 2009 we finalized the sale of our 50% interest in RIT Oncology to the other member, Spectrum Pharmaceuticals, Inc., or Spectrum. All of our current product candidates, including pixantrone, OPAXIO and brostallicin are under development.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration, or FDA, in the United States, by the European Agency for Evaluation of Medicinal Products, or EMEA, in Europe and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, may take many years and involves expenditure of substantial resources.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of March 31, 2010 and for the three months ended March 31, 2010 and 2009 has been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Quarterly Report on 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 our financial position at such date and the operating results and cash flows for such periods. Operating results for the three month period ended March 31, 2010 are not necessarily indicative of the results that may be expected for the entire year.

Certain information and footnote disclosure normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or SEC. These unaudited financial statements and the related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2009 included in our Annual Report on Form 10-K.

The condensed consolidated balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements.

*Principles of Consolidation*

The condensed consolidated financial statements include the accounts of CTI and its wholly-owned subsidiaries, which include CTI Corporate Development, Inc., Systems Medicine LLC, or SM, CTI Commercial LLC and CTI Life Sciences Limited (from the date of formation in March 2009). CTI Life Sciences Limited opened a branch in Italy in December 2009. We also retain ownership of our Company branch, Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe); however, we ceased operations related to this branch in September 2009.

As of March 31, 2010, we also had a 69% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. In accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 810, *Consolidation,* noncontrolling interest in Aequus (previously shown as minority interest) is reported below net loss in *noncontrolling interest* in the condensed consolidated statement of operations and shown as a component of equity in the condensed consolidated balance sheet.

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Additionally, we held a 50% interest in RIT Oncology from the date of its formation in December 2008 to the sale of our interest in March 2009, which we accounted for using the equity method of accounting.

All intercompany transactions and balances are eliminated in consolidation.

*Liquidity*

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve month period following the date of these financial statements. However, we have incurred losses since inception and expect to generate losses for the next few years primarily due to research and development costs for pixantrone, OPAXIO and brostallicin. Our available *cash and cash equivalents* are $41.5 million as of March 31, 2010 and subsequent to period end we raised $20.0 million in gross proceeds from the issuance of 20,000 shares of our Series 4 preferred stock and warrants to purchase up to 20.0 million shares of our common stock in April 2010 (see Note 7, *Subsequent Events*).

If we are successful in exchanging for equity or restructuring our convertible notes due July 1, 2010, we expect our existing cash and cash equivalents, including these proceeds, to fund our presently anticipated operations through the first quarter of 2011. However, if we are not successful in exchanging our convertible notes due July 1, 2010, we expect that our existing cash and cash equivalents, including the cash received from the issuance of our Series 4 preferred stock and warrants, are not sufficient to fund our presently anticipated operations beyond the maturity date of our convertible notes due July 1, 2010. This raises substantial doubt about our ability to continue as a going concern.

We have commenced cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned pixantrone operations as discussed in Note 7, *Subsequent Events*, and we continue to seek additional areas for cost reductions. However, we will need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. We also intend to attempt to utilize the new Qualifying Therapeutic Discovery Project Credit related to life science companies, which may allow the Company to apply for grants in lieu of tax credits for years 2009 and 2010.

We have called a Special Meeting of Shareholders that is scheduled to be held on May 14, 2010 to ask our shareholders to approve proposals, including a proposal to increase our authorized shares of common and preferred stock from 810,000,000 to 1,210,000,000 shares. If our shareholders do not approve this proposal, then we will not be able to issue shares of our common stock or securities convertible for shares of our common stock, and thus, may not be able to raise additional capital. If our shareholders approve this proposal, our Board of Directors would have the option to issue such shares depending on our financial needs and the market opportunities if deemed to be in the best interest of shareholders. However, additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

*Value Added Tax Receivable*

Our European operations were 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 $6.0 million and $6.3 million as of March 31, 2010 and December 31, 2009, respectively, of which $5.6 million and $5.9 million is included in *other assets* and $0.4 million and $0.4 million is included in *prepaid expenses and other current assets* as of March 31, 2010 and December 31, 2009, respectively. This receivable balance relates to our Italian operations and

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typically has a three year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable. On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments including interest and penalties for the years 2003 and 2005 are 0.5 million and 5.5 million, or approximately $0.7 million and $7.4 million as of March 31, 2010, respectively. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. As such, we have not booked an impairment to the carrying amount of our VAT receivable and we intend to vigorously defend ourselves against the assessments and have requested a dismissal on procedural grounds and merits of the case.

*Net Loss Per Share*

Basic net loss per common share is calculated based on the net loss attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted net loss per common share assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and share awards using the treasury stock method. As of March 31, 2010 and 2009, options, warrants, unvested share awards and rights, convertible debt and convertible preferred stock aggregating 40.3 million and 11.4 million common share equivalents, respectively, prior to the application of the treasury stock method for options and warrants, are not included in the calculation of diluted net loss per share as they are anti-dilutive.

*New Accounting Standards*

In February 2010, the FASB issued amended guidance on subsequent events to alleviate potential conflicts between FASB guidance and SEC requirements. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements for the period ended March 31, 2010. The adoption of this guidance did not have a material impact on our financial statements.

*Reclassifications*

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

**2. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Our other comprehensive income or loss includes unrealized gains and losses on our securities available-for-sale and net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries. Total comprehensive loss consisted of the following (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | **2010** | **2009** |
| Net loss before noncontrolling interest | $ (26,972) | $ (15,056) |
| Foreign currency translation gain (loss) | 290 | (208) |
| Net unrealized gain on securities available-for-sale | | 1 |
| Comprehensive loss before noncontrolling interest | (26,682) | (15,263) |
| Noncontrolling interest | 52 | 89 |
| Comprehensive loss attributable to CTI | $ (26,630) | $ (15,174) |

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As of March 31, 2010 and December 31, 2009, cumulative foreign currency translation adjustments accounted entirely for the ending balances of *accumulated other comprehensive loss*.

**3. Restructuring Activities**

*Italian Operations*

In September 2009, we closed our Bresso, Italy operations. These operations were used primarily for pre-clinical research and were underutilized due to our current focused business model on the development of late-stage compounds and their commercialization. We have recorded restructuring charges related to this closure as discussed further below in accordance with ASC 420, *Exit or Disposal Cost Obligations*.

In May 2009, we entered into a severance agreement with the unions representing the employees of our Bresso, Italy operations. Employee separation costs associated with the reduction in force primarily relate to severance payments that we are paying over 42 months, with the majority of these payments made through the first 15 months. In addition, we entered into separate severance or termination agreements with four of our Bresso-based directors and have also completed severance agreements for the remaining two directors, which have been accrued for as of March 31, 2010. For the three months ended March 31, 2010, we did not incur any additional restructuring charges related to the closure of the Bresso operations. We may have additional adjustments to our employee termination benefit expense related to our estimate of amounts due under Italian labor laws. While we cannot predict additional amounts, if any, we do not expect to have material adjustments to this expense.

Our liability for restructuring activities is $1.3 million and is included in *accrued expenses* as of March 31, 2010. The following table summarizes the changes in the liability for restructuring activities during the three months ended March 31, 2010 (in thousands):

| | Employee Termination Costs |
|---|---|
| Balance at December 31, 2009 | $ 1,531 |
| Foreign currency adjustments | (80) |
| Cash payments | (195) |
| Balance at March 31, 2010 | $ 1,256 |

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**4. Preferred Stock**

*Issuance of Series 3 Preferred Stock*

In January 2010, we entered into a securities purchase agreement for the issuance of 30,000 shares of our Series 3 preferred stock, which was convertible into 24.7 million shares of our common stock and warrants to purchase up to 8.6 million shares of our common stock for gross proceeds of $30.0 million. Issuance costs related to this transaction were $2.2 million, including $0.2 million related to the placement agent warrants as discussed below. In January 2010 at the date of closing, all 30,000 shares of our Series 3 preferred stock were converted into 24.7 million shares of our common stock.

Each share of our Series 3 preferred stock was entitled to a liquidation preference equal to the stated value of such share of our Series 3 preferred stock plus any accrued and unpaid dividends. Our Series 3 preferred stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities. It was convertible into our common stock, at the option of the holder, at a conversion price of $1.21375 per share, provided that no holder of Series 3 preferred stock could request a conversion of its shares if such conversion would have resulted in the holder and its affiliates owning 10% or more of our common stock. Our Series 3 preferred stock did not have voting rights except for limited protective provisions and except as otherwise required by law.

The warrants have an exercise price of $1.18 per share of our common stock, are exercisable immediately upon issuance and expire one year and one day after the date of issuance. We estimated the $7.1 million fair value of the warrants using the Black-Scholes pricing model.

Upon conversion of the Series 3 Preferred Stock, we recognized $17.3 million in *deemed dividends on preferred stock* related to the transaction, including $7.1 million resulting from the allocation of net proceeds to the warrants and $10.2 million related to the beneficial conversion feature on the 30,000 shares of our Series 3 preferred stock as the stock was converted immediately.

In connection with this offering, we also issued warrants to purchase 0.2 million shares of our common stock to the placement agent, which were estimated to have a fair value of $0.2 million using the Black-Scholes pricing model. These warrants have an exercise price of $1.517 per share, are exercisable immediately upon issuance and expire one year and one day after the date of issuance.

**5. Stock-Based Compensation Expense**

The following table summarizes stock-based compensation expense for the three months ended March 31, 2010 and 2009, which was allocated as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | **2010** | **2009** |
| Research and development | $ 1,012 | $ 185 |
| Selling, general and administrative | 6,739 | 321 |
| Stock-based compensation expense included in operating expenses | $ 7,751 | $ 506 |

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For the three months ended March 31, 2010 and 2009, we incurred stock-based compensation expense due to the following types of awards (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2010 | 2009 |
| December 2009 performance awards | $ 7,176 | $ |
| Restricted stock | 538 | 433 |
| Options | 37 | 73 |
| Total stock-based compensation expense | $ 7,751 | $ 506 |

**6. Legal Proceedings**

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. and Documedics Acquisition Co., Inc., our former third party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by us in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX. On February 28, 2007, defendant The Lash Group, Inc. removed the case to federal court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims and we filed a timely notice of appeal in the Ninth Circuit Court of Appeals. An appeal hearing was held on August 31, 2009, and on November 18, 2009, the Ninth Circuit Court of Appeals reversed the lower court and held that the False Claims Act did not preclude us from seeking recovery and bringing claims against The Lash Group, Inc. for their alleged violations. On December 1, 2009, the Lash Group, Inc. filed a petition for rehearing with the Ninth Circuit Court of Appeals, which was formally denied on January 6, 2010. The case has been remanded for trial in the District Court. A status conference was held on February 17, 2010, requesting the parties confer on pending motions and to set a trial schedule going forward. Motions opposing our supplemental disclosure of damages and requested leave to amend our complaint to broaden damages claims have been filed. On April 30, 2010 the District Court denied The Lash Group s motion to strike CTI s supplemental damages disclosure, and granted CTI s amended motion for leave to amend the complaint to address damages related to claims already pleaded. A trial schedule has not yet been set. There is no guarantee that we will prevail at trial.

On December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On April 30, 2010, CONSOB notified us that it has begun the preliminary investigation for its decision on these administrative proceedings.

On December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information reported, at CONSOB s request, in the press release disseminated on December 19, 2008 and March 23, 2009. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58.1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules).

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On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments including interest and penalties for the years 2003 and 2005 are 0.5 million and 5.5 million, or approximately $0.7 million and $7.4 million as of March 31, 2010, respectively. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. As such, we have not booked an impairment to the carrying amount of our VAT receivable and we intend to vigorously defend ourselves against the assessments and have requested a dismissal on procedural grounds and merits of the case.

On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan to compel us to source pixantrone from Sicor according to the terms of a supply agreement executed between Sicor and NovusPharma on October 4, 2002. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. A supplemental hearing was held on April 12, 2010 regarding admission of evidence and testimony. The next hearing date is scheduled for November 11, 2010. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On March 12, 2010, a class action complaint was filed in the United States District Court for the Western District of Washington against the Company and certain of its officers and directors, styled *Cyril Sabbagh, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-sv-00414), or the *Sabbagh* action. On March 19, 2010, a substantially similar class action complaint was filed in the same court, styled *Michael Laquidari, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-cv-00480), or the *Laquidari* action. On March 31, 2010, a third substantially similar class action complaint was filed in the same court, styled *William Snyder, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., James A. Bianco, Phillip M. Nudelman, Louis A. Bianco, John H. Bauer, Richard L. Love, Mary O. Mundinger, Jack W. Singer, Frederick W. Telling and Rodman & Renshaw, LLC* (Case No. 2:10-cv-00559), or the *Snyder* action. The complaints allege that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiffs in the *Sabbagh* and *Laquidari* actions seek unspecified damages on behalf of a putative class of purchasers of the Company s securities from May 5, 2009 through February 8, 2010. The plaintiffs in the *Snyder* action seek unspecified damages on behalf of a putative class of purchasers of the Company s securities from May 5, 2009 through March 19, 2010, including purchasers of securities issued pursuant to or traceable to the Company s July 22, 2009, public offering.

On April 1, 2010, a shareholder derivative complaint was filed in the United States District Court for the Western District of Washington, derivatively on behalf of the Company against the members of its Board of Directors, styled *Shackleton v. John A. Bauer, James A. Bianco, Vartan Gregorian, Richard L. Love, Mary O Neil Mundinger, Phillip M. Nudelman, Jack W. Singer, and Frederick W. Telling* (Case No. 2:10-cv-564). On April 5, 2010, and April 13, 2010, substantially similar derivative actions were filed in the same court, styled, respectively, *Marbury v. James A. Bianco, et al.* (Case No. 2:10-cv-00578) and *Cyrek v. John H. Bauer*, *et al.* (Case No. 2:10-cv-00625). The complaints allege that the defendants breached their fiduciary duties to the Company under Washington law by making or failing to prevent the disclosure of certain alleged false and misleading statements. The allegations in the shareholder derivative actions are substantially similar to those in the purported securities class actions.

All of the securities class actions and shareholder derivative lawsuits are pending before Judge Marsha J. Pechman in the Western District of Washington. Additional purported securities class actions and shareholder derivative lawsuits containing substantially similar allegations could be filed in the near future. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

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.

**7. Subsequent Events**

On March 30, 2010, we entered into a securities purchase agreement, pursuant to which we agreed to issue in a registered offering an aggregate of 20,000 shares of our Series 4 preferred stock, no par value per share, initially convertible into 40.0 million shares of our common stock and warrants to purchase up to 20.0 million shares of our common stock for gross proceeds of $20.0 million. The warrants have an exercise price of $0.6029 per share of our common stock, exercisable six months and one day after the date of issuance and expire four years and one day after the date of issuance.

The transaction closed on April 6, 2010, and all 20,000 shares of the Series 4 preferred stock were converted into 40.0 million shares of our common stock upon closing.

Each share of Series 4 preferred stock is entitled to a liquidation preference equal to the stated value plus any accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 4 preferred stock is not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities. The Series 4 preferred stock is convertible into common stock, at the option of the holder, at an initial conversion price of $0.50 per share, subject to a 4.99% blocker provision. A holder of Series 4 preferred stock may elect to increase the blocker provision to 9.99% by providing 61 days prior notice. The Series 4 preferred stock has no voting rights except for limited protective provisions and except as is otherwise required by law.

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On April 12, 2010, we conducted an immediate reduction in force of 36 employees due to an implementation of a cost reduction plan. We estimate that the costs to be recorded for severance-related expenses resulting from the reduction in force will be approximately $0.4 million for the employees subject to the immediate reduction in force. We expect the estimated costs will be paid within 30 days after termination of the affected employees. These costs are associated with the severance benefits to be provided by the Company to each terminated employee.

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

*This Quarterly Report on Form 10-Q, including the following discussion contains forward-looking statements, which involve risks and uncertainties and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item I of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on 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 Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, particularly in Factors Affecting Our Operating Results and Financial Condition, that could cause actual results, levels of activity, performance or achievement to differ significantly from those projected. Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We will not update any of the forward-looking statements after the date of this Quarterly Report on 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 Quarterly Report on 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 currently focusing our efforts on pixantrone, OPAXIO , brostallicin and novel bisplatinum analogues. As of March 31, 2010, we had incurred aggregate net losses of approximately $1.5 billion since inception. Unless we execute a partnership agreement for pixantrone with terms adequate to cover our operating expenses, we expect to generate losses from operations for the next few years.

*Pixantrone*

We are developing pixantrone, a novel aza-anthracenedione, for the treatment of non-Hodgkin s lymphoma, or NHL, and various other hematologic malignancies, and solid tumors. Pixantrone was studied in our EXTEND, or PIX301, clinical trial, which was a phase III single-agent trial of pixantrone for patients with relapsed refractory aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In November 2008, we announced that this trial achieved the primary efficacy endpoint. Based on the outcome of the EXTEND trial and on the basis of pre-New Drug Application, or NDA, communication we received from the Food and Drug Administration, or FDA, relating to this phase III trial, we began a rolling NDA submission to the FDA in April 2009. We completed the submission in June 2009.

The FDA completed its inspection of the facility at NerPharMa (a pharmaceutical manufacturing company belonging to Nerviano Medical Sciences Srl, in Nerviano, Italy), which manufactures our drug, pixantrone, and found the site in compliance and acceptable for continued manufacturing of the drug product in early March 2010.

On March 22, 2010, the FDA s Oncologic Drugs Advisory Committee, or ODAC, panel voted unanimously that the clinical trial data was not adequate to support approval of pixantrone for this patient population. In early April 2010, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone and

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recommended that we design and conduct an additional trial to demonstrate the safety and effectiveness of pixantrone. Based on the FDA s March 22, 2010 ODAC presentation, which provided ODAC and us with alternative options to consider to make investigational drugs available to patients if drugs need to be studied further prior to approval, we have decided to pursue an expanded access program for pixantrone while we conduct an additional study in aggressive NHL. Our plan is to request a meeting with the FDA on both the design of the follow-on study as well as expanded access program for patients in the United States who are not participating in our clinical trial.

The results of the EXTEND trial showed that patients randomized to treatment with pixantrone achieved a significantly higher rate of confirmed and unconfirmed complete remissions compared to patients treated with standard chemotherapy, had a significantly increased overall response rate and experienced a statistically significant improvement in median progression free survival. Pixantrone was safely administered at the proposed dose and schedule in the PIX301 clinical trial in heavily pre-treated patients. The most common (incidence greater than or equal to 10%) grade 3/4 adverse events reported for pixantrone-treated subjects across studies were neutropenia and leukopenia. Use of growth factor support was minimal. Other common adverse events (any grade) included infection, anemia, leukopenia, thrombocytopenia, asthenia, pyrexia and cough. Overall, the incidence of grade 3 or greater cardiac adverse events was 7% (5 patients) on the pixantrone arm and 2% (1 patient) on the comparator arm. There were an equal number of deaths due to an adverse event in both the pixantrone and comparator arm.

We also conducted the RAPID, or PIX203, phase II clinical trial study (CHOP-R vs. CPOP-R) in which pixantrone is substituted for doxorubicin in the CHOP-R regimen compared to the standard CHOP-R regimen in patients with aggressive NHL. An interim analysis of the RAPID trial, reported in July 2007, showed that to date, a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). Patients on the pixantrone arm of the study had clinically significant less left ventricular ejection fraction (LVEF) drops, infections, and thrombocytopenia (a reduction in platelets in the blood), as well as significant reduction in febrile neutropenia. In early 2008, we closed enrollment on the RAPID trial because we had adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. The preliminary analysis of LVEF by Multigated Acquisition Scan, or MUGA, suggests that the patients in the pixantrone regimen (CPOP-R) experienced a lower incidence of >20% LVEF decline (2% vs. 13%) than patients in the doxorubicin control arm (CHOP-R). In addition, the preliminary analysis also suggests that grade 3/4 reductions in LVEF or symptomatic Congestive Heart Failure, or CHF, were lower in the pixantrone arm (CPOP-R) with no patients (0%) developing CHF in the pixantrone arm (CPOP-R) compared to 5% of the patients in the control arm (CHOP-R). Further the preliminary analysis suggests that grade 3/4 reductions in LVEF were also more frequent in the doxorubicin containing control arm (CHOP-R) at 10% compared to 2% in the pixantrone (CPOP-R) regimen. We expect to report results from the RAPID trial in the second half of 2010.

In line with our company values, we have already made pixantrone available on a compassionate use basis in Europe. In May 2009, we entered into an agreement with IDIS, Limited, or IDIS, to manage pixantrone as an investigational drug on a named-patient basis in Europe. Pixantrone is made available through IDIS to healthcare professionals for the treatment of individual patients with relapsing aggressive non-Hodgkin s lymphoma.

In July 2009, we were notified by the EMEA that pixantrone is eligible to be submitted for a Marketing Authorization Application, or MAA, through the EMEA s centralized procedure. The centralized review process provides for a single coordinated review for approval of pharmaceutical products that is conducted by the EMEA on behalf of all European Union, or EU, member states. The EMEA also designated pixantrone as a New Active Substance, or NAS; if approved, compounds designated as an NAS receive a 10-year market exclusivity period in EU member states. In September 2009, we applied to the EMEA for orphan drug designation for pixantrone, which was granted in December 2009. In September 2009, we also submitted a Pediatric Investigation Plan, or PIP, to the EMEA as part of the required filing process for approval of pixantrone for treating relapsed, refractory aggressive NHL in Europe. In April 2010, the EMEA recommended that we submit an updated PIP for pixantrone following discussions with us about the preclinical and clinical pixantrone data, including EXTEND, and the desire to explore the potential benefits pixantrone may offer to children with hematologic cancer. The initial PIP was withdrawn and we expect to submit a revised PIP to the EMEA by the end of the second quarter of 2010. We anticipate the formal MAA filing for pixantrone for the treatment of relapsed or refractory aggressive NHL in the second half of 2010.

*OPAXIO*

We are currently focusing our development of OPAXIO (paclitaxel poliglumex), which we have previously referred to as XYOTAX, as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study, the GOG0212 trial, is under the control of the Gynecologic Oncology Group, or GOG, and is expected to enroll 1,100 patients with more than 650 patients enrolled to date. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival and based on current enrollment and study duration, the interim analysis could be conducted as early as 2011. If successful, the Company could utilize those results to form the basis of its New Drug Application for OPAXIO.

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In June 2009, we announced that, in a study released from Brown University at the 2009 American Society for Clinical Oncology Annual Meeting, patients with cancer of the lower esophagus had evidence of a high pathological complete response rate when given OPAXIO in addition to cisplatin and full-course radiotherapy. In this phase II clinical trial study, preliminary data suggests that OPAXIO may provide enhanced radiation sensitization as compared to standard therapy. We plan to meet with the FDA in 2010 to explore a potential phase III registration study utilizing OPAXIO as a radiation sensitizer in the treatment of esophageal cancer.

In March 2008, we submitted an MAA to the EMEA for first-line treatment of patients with advanced non-small cell lung cancer, or NSCLC, who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the EMEA s Scientific Advice Working Party, or SAWP; the EMEA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMEA of our decision to withdraw the MAA and we refocused our resources on the approval of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

We continue to monitor the use of OPAXIO in women with premenopausal levels of estrogen, regardless of age, who have advanced NSCLC with normal or poor performance status. We believe the lack of safe and effective treatment for women with advanced first-line NSCLC, who have premenopausal estrogen levels, represents an unmet medical need. Based on a pooled analysis of STELLAR 3 and 4 phase III trials for treatment of first-line NSCLC PS2 patients, we believe that there is a demonstrated statistically significant survival advantage among women receiving OPAXIO when compared to women or men receiving standard chemotherapy. A survival advantage for women over men also was demonstrated in a first-line phase II clinical trial of OPAXIO and carboplatin, known as the PGT202 trial, supporting the potential benefit observed in the STELLAR 3 and 4 trials. In September 2007, we initiated our PGT307 trial which focuses exclusively on NSCLC in women with premenopausal estrogen levels, the subset of patients where OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. Due to limited resources, we have suspended enrollment in this study.

*Brostallicin*

We are developing brostallicin through our wholly-owned subsidiary, Systems Medicine LLC, or SM, which holds worldwide rights to use, develop, import and export brostallicin. Brostallicin is a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity and a favorable safety profile in clinical trials in which more than 230 patients have been treated to date. SM uses a genomic-based platform to guide the development of brostallicin. We expect to use that platform to guide the development of our licensed oncology products in the future. We also have a strategic affiliation with the Translational Genomics Research Institute, or TGen, and have the ability to use TGen s extensive genomic platform and high throughput capabilities to target a cancer drug s context-of-vulnerability, which is intended to guide clinical trials toward patient populations where the highest likelihood of success should be observed, thereby potentially lowering risk and shortening time to market.

The North Central Cancer Treatment Group, or NCCTG, plans to initiate a phase II study of brostallicin in combination with cisplatin in patients with metastatic triple-negative breast cancer, or mTNBC, in mid 2010. mTNBC is defined by tumors lacking expression of estrogen, progesterone receptors and without over-expression of HER2. Women with mTNBC have very limited effective treatments and based on the novel mechanism of action of brostallicin and the recognized activity of cisplatin in this disease, the combination of the two agents will be explored by the NCCTG. In addition to standard clinical efficacy measures, biological endpoints will also be evaluated to assist in understanding the specific activity brostallicin in this disease.

A phase II study of brostallicin in relapsed/refractory soft tissue sarcoma met its predefined activity and safety hurdles and resulted in a first-line phase II clinical trial study that is currently being conducted by the European Organization for Research and Treatment of Cancer, or EORTC. Planned enrollment for this study was completed in August 2008 and the EORTC conducted final data analysis in 2009. The EORTC trial demonstrated, in this hard to treat patient group, a modest level of clinical activity with an acceptable level of toxicity. No further development is

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planned in this indication. A multi-arm phase I combination study with brostallicin and other agents, including Avastin (bevacizumab), was completed in the first quarter of 2009. Brostallicin also has demonstrated synergy with new targeted agents as well as established treatments in preclinical trials.

*Research and Preclinical Development*

Platinates constitute an important class of cornerstone chemotherapy agents used to treat a wide variety of cancers. There are three currently commercially available platinates (cisplatin, carboplatin, and oxaliplatin) which are first-line agents in ovarian cancer, lung cancer, testicular cancer, and colorectal cancer and are also used in a broad variety of other diseases. We are developing new analogues of the dinuclear-platinum complex CT-3610 that is more potent than any of the commercially available platinates. These bisplatinates have a different mechanism of action than the commercially available platinum compounds and are substantially more active on many preclinical models including those with resistance to monoplatinates. We have initiated an Investigational New Drug application, or IND, enabling activities for bisplatinates.

**Critical Accounting Policies and 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 condensed 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. As described in Item 7, *Management s Discussion and Analysis of Consolidated Financial Condition and Results of Operations,* of our Annual Report on Form 10-K for the year ended December 31, 2009, we consider our policies for license and contract revenue, impairment of long-lived assets, valuation of goodwill, derivatives embedded in certain debt or equity securities, restructuring charges and stock-based compensation expense to be the most critical in the preparation of the condensed consolidated financial statements because they involve the most difficult, subjective, or complex judgments about the effect of matters that are inherently uncertain. There have been no material changes to our application of critical accounting policies and significant judgments and estimates since December 31, 2009.

**RESULTS OF OPERATIONS**

**Three months ended March 31, 2010 and 2009**

***License and contract revenue***. License and contract revenue for the three months ended March 31, 2010 and 2009 represents recognition of deferred revenue from the sale of Lisofylline material to DiaKine.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2010** | **2009** |
| Compounds under development: | | |
| Pixantrone | $ 2,172 | $ 940 |
| OPAXIO | 735 | 1,307 |
| Brostallicin | 68 | 351 |
| Zevalin | | 938 |
| Operating expenses | 4,120 | 4,189 |
| Discovery research | 265 | 231 |
| Total research and development expenses | $ 7,360 | $ 7,956 |

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 pixantrone, OPAXIO and brostallicin are approximately $57.2 million, $221.3 million and $9.2 million, respectively. Costs for pixantrone prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, or CTI (Europe), in January 2004 are excluded from this amount. Costs for brostallicin prior to our acquisition of SM in July 2007 are also excluded from this amount.

Research and development expenses decreased to approximately $7.4 million for the three months ended March 31, 2010, from approximately $8.0 million for the three months ended March 31, 2009. Pixantrone costs increased primarily due to an increase in clinical development and regulatory activity mainly related to an increase in consulting and advisory costs associated with preparation for the ODAC panel meeting and potential product launch. In addition, manufacturing activity for pixantrone also increased due to preparation for potential product launch. These increases were partially offset by a decrease in clinical development activity associated with the continuing wind-down of the RAPID and EXTEND trials. Costs for our OPAXIO program decreased primarily due to a decrease in costs associated with the GOG0212 study related to a change in estimated timeline for interim analysis and data transfer. In addition, costs associated with regulatory activity decreased primarily due to the EMEA filing fee, which was incurred in March 2009. Costs for brostallicin decreased primarily due to a decrease in clinical development activities related to phase I and phase II studies. Zevalin costs decreased primarily due to the contribution of the product to RIT Oncology, the joint venture we formed with Spectrum on December 15, 2008 which assumed all related Zevalin expenses subsequent to that date. Our operating expenses decreased primarily due to a reduction in personnel and overhead costs associated with the closure of our Bresso, Italy operations, partially offset by an increase in stock-based compensation costs associated with restricted stock awards. Discovery research increased due to an increase in activities related to the development of bisplatinates, partially offset by decreases related to the closure of our Bresso, Italy operations.

Our lead drug candidates, pixantrone, OPAXIO and brostallicin, are currently in clinical trials. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. Regulatory agencies, including the FDA and EMEA, regulate many 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

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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. We have drug candidates that 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 and we will be able to generate revenues only if:

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

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

***Selling, general and administrative expenses.*** Selling, general and administrative expenses increased to approximately $18.4 million for the three months ended March 31, 2010, from approximately $8.9 million for the three months ended March 31, 2009. This is primarily due to a $6.4 million increase in non-cash stock-based compensation expense mainly related to performance rights granted in December 2009. We also had a $3.5 million increase in sales and marketing costs associated with supporting activities for pixantrone in preparation for potential commercial development.

***Gain on sale of investment in joint venture.*** During the three months ended March 31, 2009, we recorded a $10.2 million one-time gain on the sale of our 50% interest in RIT Oncology. This amount was based on the difference between $16.5 million in gross proceeds and the approximately $4.6 million book value of our investment in RIT Oncology at the time of sale, net of approximately $1.6 million in transaction costs.

***Interest expense***. Interest expense decreased to approximately $0.8 million for the three months ended March 31, 2010 from approximately $1.6 million for the three months ended March 31, 2009. This decrease is primarily due to the exchanges of $42.3 million principal balance of our 5.75%, 6.75% and 7.5% convertible senior notes and $14.8 million of our 4% convertible senior subordinated notes in 2009.

***Amortization of debt discount and issuance costs***. Amortization of debt discount and issuance costs decreased to approximately $0.2 million for the three months ended March 31, 2010 from approximately $4.9 million for the three months ended March 31, 2009. During the three months ended March 31, 2009, conversions of $5.3 million and $18.0 million of our 9% and 10% convertible senior notes, respectively, resulted in accelerated amortization of debt discount and issuance costs of $4.4 million. In addition, amortization of debt discount and issuance costs decreased by $0.3 million due to the accelerated amortization of debt discount and issuance costs on our 5.75%, 6.75% and 7.5% convertible senior notes and 4% convertible senior subordinated notes as a result of exchanges and conversions in 2009 reducing the remaining cost basis and discount amount to be amortized over the remaining term of the notes.

***Foreign exchange gain (loss).*** The foreign exchange loss for the three months ended March 31, 2010 and the foreign exchange gain for the three months ended March 31, 2009 is due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

***Make-whole interest expense.*** Make-whole interest expense for the three months ended March 31, 2009 is related to $5.4 million in payments made upon the conversion of $18.0 million of our 10% convertible senior notes and $0.9 million in payments made upon the conversion of $5.3 million of our 9% convertible senior notes.

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***Gain on derivative liabilities, net.*** The gain on derivative liabilities of $5.6 million for the three months ended March 31, 2009 is primarily due to a gain of $4.4 million resulting from the change in the estimated fair value of the derivative liabilities related to the embedded conversion option on our 10% convertible senior notes. In addition, there was also a gain of $1.3 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant that was issued in connection with the issuance of our 13.5% convertible senior notes and Series E preferred stock financing in April 2008.

***Equity loss from investment in joint venture.*** The loss for the three months ended March 31, 2009 relates to our 50% interest in RIT Oncology, prior to the sale of this interest in March 2009, which we accounted for using the equity method of accounting.

***Settlement expense.*** Settlement expense of $0.2 million for the three months ended March 31, 2009 relates to payments made to RHP Master Fund, Ltd, or RHP, for the release of all claims against us in connection with our alleged breach of contract related to RHP s Series A preferred stock.

**LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2010, we had approximately $41.5 million in cash and cash equivalents.

Net cash used in operating activities increased to approximately $23.2 million during the three months ended March 31, 2010, compared to approximately $19.2 million for the same period during 2009 primarily due to an increase in *selling, general and administrative* expense, excluding the allocation of non-cash stock based compensation expense to these activities as well as an increase in *prepaid expenses and other current assets* for the three months ended March 31, 2010 as compared to an increase in these amounts during the comparable period in 2009.

Net cash used in investing activities of approximately $1.1 million for the three months ended March 31, 2010 was primarily due to purchases of property and equipment. Net cash provided by investing activities of approximately $13.1 million for the three months ended March 31, 2009 was primarily due to $6.8 million in net proceeds from Spectrum in January 2009 related to the initial formation of RIT Oncology in December 2008. We also received $5.7 million in net proceeds from Spectrum in March 2009 related to the sale of our 50% interest in RIT Oncology.

Net cash provided by financing activities of approximately $27.5 million for the three months ended March 31, 2010 was primarily due to $28.1 million in net proceeds received from the issuance of 30,000 shares of our Series 3 preferred stock and warrants to purchase approximately 8.6 million shares of our common stock in January 2010. Net cash used in financing activities of approximately $3.2 million for the three months ended March 31, 2009 was primarily due to a $3.0 million deemed dividend payment in connection with our settlement with Tang Capital Partners LP for full release of all claims against us in connection with our alleged breach of contract related to Tang s Series B preferred stock. This amount was accrued as of December 31, 2008 and paid in January 2009.

We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred net losses since inception and expect to generate losses from operations for the next few years primarily due to research and development costs for pixantrone, OPAXIO and brostallicin. Subsequent to period end, we raised $20.0 million in gross proceeds from the issuance of 20,000 shares of our Series 4 preferred stock and warrants to purchase up to 20.0 million shares of our common stock in April 2010.

If we are successful in exchanging for equity or restructuring our convertible notes due July 1, 2010, we expect our existing cash and cash equivalents, including these proceeds, to fund our presently anticipated operations through the first quarter of 2011. However, if we are not successful in exchanging our convertible notes due July 1, 2010, we expect that our existing cash and cash equivalents, including the cash received from the issuance of our Series 4 preferred stock and warrants are not sufficient to fund our presently anticipated operations beyond the due date of the notes due July 1, 2010. This raises substantial doubt about our ability to continue as a going concern.

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We have commenced cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned pixantrone operations and we continue to seek additional areas for cost reductions. We estimate our average net cash used in operating activities to be approximately $4.4 million per month starting in the second quarter of 2010 and plan to reduce the Company s projected net cash operating expenses to a forecasted $60 million in 2010. However, we will need to raise additional funds and are currently exploring alternative sources of financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources. We also intend to attempt to utilize the new Qualifying Therapeutic Discovery Project Credit related to life science companies, which may allow the Company to apply for grants in lieu of tax credits for the years 2009 and 2010.

We have called a Special Meeting of Shareholders that is scheduled to be held on May 14, 2010 to ask shareholders to approve proposals, including a proposal to increase our authorized shares of common and preferred stock from 810,000,000 to 1,210,000,000 shares. If our shareholders do not approve this proposal, then we will not be able to issue common stock or securities convertible or exercisable for common stock, and thus, may not be able to raise additional capital. If our shareholders approve this proposal, our Board of Directors would have the option to issue such shares depending on our financial needs and the market opportunities, if deemed to be in the best interest of the shareholders. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

Our future capital requirements will depend on many factors, including:

- results of our clinical trials;
- regulatory approval of our products;
- success in acquiring or divesting products, technologies or businesses;
- progress in and scope of our research and development activities;
- finding appropriate partners for the development and commercialization of our products if they are approved for marketing; 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.

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The following table includes information relating to our contractual obligations as of March 31, 2010 (in thousands):

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **1 Year** | **2-3 Years** | **4-5 Years** | **After 5 Years** |
| 7.5% Convertible senior notes (1) | $ 10,250 | $ | $ 10,250 | $ | $ |
| 5.75% Convertible senior notes (2) | 10,913 | | 10,913 | | |
| 4.0% Convertible senior subordinated notes (3) | 40,363 | 40,363 | | | |
| Interest on convertible notes | 2,312 | 1,803 | 509 | | |
| Operating leases: | | | | | |
| Facilities | 10,612 | 4,420 | 5,981 | 211 | |
| Long-term obligations (4) | 2,077 | 864 | 1,187 | 26 | |
| | $ 76,527 | $ 47,450 | $ 28,840 | $ 237 | $ |

(1) The 7.5% convertible senior notes are convertible into shares of our common stock at a conversion rate of 11.96298 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $83.59 per share.
(2) The 5.75% convertible senior notes are convertible into shares of our common stock at a conversion rate of 33.33333 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $30.00 per share.
(3) The 4.0% convertible senior subordinated notes are convertible into shares of our common stock at a conversion rate of 1.85185 shares of our common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $540.00 per share.
(4) Long-term obligations do not include $0.7 million related to excess facilities charges.

*Additional Milestone Activities*

We have an amended agreement with PG-TXL Company L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL s polymer technology. We may be required to pay up to $14.4 million in additional milestone payments under this agreement. The timing of the remaining milestone payments under the amended agreement is based on trial commencements and completions, as well as regulatory and marketing approval with the FDA, EMEA or equivalent in another major market country.

We have an agreement with the Gynecologic Oncology Group, or GOG, related to the GOG0212 trial which the GOG is conducting. As of March 31, 2010, we recorded a $1.6 million payment due to the GOG based on the 650 patient enrollment milestone achieved in the first quarter of 2010. This amount is included in *accounts payable*. Under this agreement we are required to pay up to $3.5 million in additional milestone payments related to the trial of which $1.7 million may become due in the first quarter of 2011 based on current planned patient enrollment.

Under a license agreement entered into for brostallicin, we may be required to pay up to $80.0 million in milestone payments, based on the achievement of certain product development results. Due to the early stage of development that brostallicin is in, we are not able to determine whether the clinical trials will be successful and therefore cannot make a determination that the milestone payments are reasonably likely to occur at this time.

Pursuant to an acquisition agreement entered into with Cephalon, Inc., or Cephalon, in June 2005, we may receive up to $100.0 million in payments upon achievement by Cephalon of specified sales and development milestones related to TRISENOX. However, the achievement of any such milestones is uncertain at this time.

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Under our agreement with Novartis Pharmaceutical Company Ltd., or Novartis, if Novartis elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option to develop and commercialize pixantrone and we are able to negotiate a definitive agreement with Novartis, we may receive up to $374.0 million in registration and sales related milestone payments. Novartis is under no obligation to make such election or exercise such right and may never do so. Additionally, even if Novartis exercises such rights, any milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals, which we may never receive.

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

*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. As of March 31, 2010, our foreign currency transactions are minimal and changes to the exchange rate between the U.S. dollar and foreign currencies would have an immaterial affect on our earnings. 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. As of March 31, 2010, we had a net euro asset balance excluding intercompany payables and receivables in our European branches. If the euro were to weaken 20% against the dollar, our net asset balance would decrease by approximately $0.8 million as of this date.

**Item 4. Controls and Procedures**

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and EVP of Finance have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

**Recent Legal Proceedings**

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. and Documedics Acquisition Co., Inc., our former third party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by us in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX. On February 28, 2007, defendant The Lash Group, Inc. removed the case to federal court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims and we filed a timely notice of appeal in the Ninth Circuit Court of Appeals. An appeal hearing was held on August 31, 2009, and on November 18, 2009, the Ninth Circuit Court of Appeals reversed the lower court and held that the False Claims Act did not preclude us from seeking recovery and bringing claims against The Lash Group, Inc. for their alleged violations. On December 1, 2009, the Lash Group, Inc. filed a petition for rehearing with the Ninth Circuit Court of Appeals, which was formally denied on January 6, 2010. The case has been remanded for trial in the District Court. A status conference was held on February 17, 2010, requesting the parties confer on pending motions and to set a trial schedule going forward. Motions opposing our supplemental disclosure of damages and requested leave to amend our complaint to broaden damages claims have been filed. On April 30, 2010 the District Court denied The Lash Group s motion to strike CTI s supplemental damages disclosure, and granted CTI s amended motion for leave to amend the complaint to address damages related to claims already pleaded. A trial schedule has not yet been set. There is no guarantee that we will prevail at trial.

On December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On April 30, 2010, CONSOB notified us that it has begun the preliminary investigation for its decision on these administrative proceedings.

On December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information reported, at CONSOB s request, in the press release disseminated on December 19, 2008 and March 23, 2009. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58.1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules).

On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments including interest and penalties for the years 2003 and 2005 are 0.5 million and 5.5 million, or approximately $0.7 million and $7.4 million as of March 31, 2010, respectively. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. As such, we have not booked an impairment to the carrying amount of our VAT receivable and we intend to vigorously defend ourselves against the assessments and have requested a dismissal on procedural grounds and merits of the case.

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On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan to compel us to source pixantrone from Sicor according to the terms of a supply agreement executed between Sicor and NovusPharma on October 4, 2002. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. A supplemental hearing was held on April 12, 2010 regarding admission of evidence and testimony. The next hearing date is scheduled for November 11, 2010. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On March 12, 2010, a class action complaint was filed in the United States District Court for the Western District of Washington against the Company and certain of its officers and directors, styled *Cyril Sabbagh, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-sv-00414), or the *Sabbagh* action. On March 19, 2010, a substantially similar class action complaint was filed in the same court, styled *Michael Laquidari, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-cv-00480), or the *Laquidari* action. On March 31, 2010, a third substantially similar class action complaint was filed in the same court, styled *William Snyder, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., James A. Bianco, Phillip M. Nudelman, Louis A. Bianco, John H. Bauer, Richard L. Love, Mary O. Mundinger, Jack W. Singer, Frederick W. Telling and Rodman & Renshaw, LLC* (Case No. 2:10-cv-00559), or the *Snyder* action. The complaints allege that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiffs in the *Sabbagh* and *Laquidari* actions seek unspecified damages on behalf of a putative class of purchasers of the Company s securities from May 5, 2009 through February 8, 2010. The plaintiffs in the *Snyder* action seek unspecified damages on behalf of a putative class of purchasers of the Company s securities from May 5, 2009 through March 19, 2010, including purchasers of securities issued pursuant to or traceable to the Company s July 22, 2009, public offering.

On April 1, 2010, a shareholder derivative complaint was filed in the United States District Court for the Western District of Washington, derivatively on behalf of the Company against the members of its Board of Directors, styled *Shackleton v. John A. Bauer, James A. Bianco, Vartan Gregorian, Richard L. Love, Mary O Neil Mundinger, Phillip M. Nudelman, Jack W. Singer, and Frederick W. Telling* (Case No. 2:10-cv-564). On April 5, 2010, and April 13, 2010, substantially similar derivative actions were filed in the same court, styled, respectively, *Marbury v. James A. Bianco, et al.* (Case No. 2:10-cv-00578) and *Cyrek v. John H. Bauer, et al.* (Case No. 2:10-cv-00625). The complaints allege that the defendants breached their fiduciary duties to the Company under Washington law by making or failing to prevent the disclosure of certain alleged false and misleading statements. The allegations in the shareholder derivative actions are substantially similar to those in the purported securities class actions.

All of the securities class actions and shareholder derivative lawsuits are pending before Judge Marsha J. Pechman in the Western District of Washington. Additional purported securities class actions and shareholder derivative lawsuits containing substantially similar allegations could be filed in the near future. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

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**

***This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The occurrence of any of the following risks described below and elsewhere in this document, including the risk that our actual results may differ materially from those anticipated in these forward-looking statements, could materially adversely affect our business, financial condition, operating results or prospects and the trading price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, operating results and prospects and the trading price of our securities.***

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

*We need to raise additional funds and expect that we will need to continue to raise funds in the future, and additional funds may not be available on acceptable terms, or at all; failure to raise significant additional funds may cause us to cease development of our products and operations.*

We have substantial operating expenses associated with the development of our product candidates, and as of March 31, 2010, we had cash and cash equivalents of $41.5 million.

As of March 31, 2010, our total current liabilities were $61.5 million, including $40.4 million related to our 4% convertible senior subordinated notes which are due in July 2010. The aggregate long-term principal balance of our outstanding 7.5% and 5.75% convertible senior notes as of March 31, 2010 was $21.2 million.

If we are successful in exchanging for equity or restructuring our 4% convertible senior subordinated notes due in July 2010, we expect that our existing cash and cash equivalents as well as proceeds received from our offerings to date will provide sufficient working capital to fund our presently anticipated operations through the first quarter of 2011. However, if we are not successful, we do not expect that we are able to fund our presently anticipated operations beyond the due date of the notes in July 2010. We would therefore need to raise additional capital. Raising additional capital may require that we issue additional shares of our currently authorized common stock. At a special meeting of shareholders which has been adjourned to May 14, 2010, we are asking our shareholders to

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approve an amendment to our amended and restated articles of incorporation to increase the total number of authorized shares of our stock from 810,000,000 shares to 1,210,000,000 shares and to increase the total number of our authorized shares of common stock from 800,000,000 to 1,200,000,000 shares of common stock. We may not obtain sufficient votes from our shareholders for this amendment, which may limit our ability to raise additional funds through the issuance of additional shares. We may not be able to raise such capital or if we can, it may not be on favorable terms. There can be no assurance that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations, including our debt service obligations.

*Additional funds may not be available on acceptable terms, or at all; if we fail to raise significant additional funds, we may be forced to cease development of our products and operations.*

We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. However, additional funding may not be available on favorable terms or at all and we are subject to certain regulatory and contractual limitations on our financing activities, which may limit our ability to raise additional funding. 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 pixantrone, OPAXIO and brostallicin, and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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, such as our transfer of Zevalin assets to RIT Oncology and our subsequent sale of our 50% interest in RIT Oncology. In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the United States, which may increase our costs and adversely affect our ability to obtain financing. To the extent that we raise additional capital through the sale of equity securities, or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us.

*If our shareholders do not approve an increase in our authorized shares, we may not be able to raise additional funds through equity offerings.*

Our shareholders have been asked to vote on a proposal to amend our amended and restated articles of incorporation, or our articles of incorporation, to increase the number of authorized shares of common stock at a special meeting of shareholders, which has been adjourned to May 14, 2010. Even though a quorum requirement has been reduced to one-third of the shares entitled to vote being present or represented at a meeting of our shareholders, the proposed amendment to our articles of incorporation requires an approval of a majority of the shares entitled to vote on the proposal. There is a risk that we may not get shareholder approval to increase the number of authorized shares of common stock. Because of the number of shares reserved for issuance under various convertible securities, warrants, derivative securities and otherwise, we do not have enough shares authorized at present to effect an equity financing of any substantial amount. If we do not receive shareholder approval for the proposed increase in authorized shares, our ability to raise capital through equity financings will be adversely affected.

*We may need to implement a reduction in expenses across our operations.*

We need substantial additional capital to fund our current operations. If we are unable to secure additional financing on acceptable terms in the near future, we may need to implement additional cost reduction initiatives, such as further reductions in the cost of our workforce and the discontinuation of a number of business initiatives to further reduce our rate of cash utilization and extend our existing cash balances. We believe that these additional cost reduction initiatives, if undertaken, could provide us with additional time to continue our pursuit of additional funding sources and also strategic alternatives. In the event that we are unable to obtain financing on acceptable terms and reduce our expenses, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects.

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During 2009, we finalized the closure our Italian operations that we used primarily for pre-clinical research. These operations were underutilized due to our current business model that is focused on the development of late-stage compounds and their commercialization. In connection with this closure, we entered into a severance agreement with the unions representing the employees of our Italian operations related to a reduction in force of our Italian employees. On April 12, 2010, we conducted an immediate reduction in force of 36 employees due to an implementation of a cost reduction plan. We expect the reduction in force and elimination of previously planned increase in commercial personnel along with a reduction in planned operating expenses to result in savings of approximately $16 million in 2010.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of March 31, 2010, we had an accumulated deficit of $1.5 billion. We are pursuing regulatory approval for pixantrone, OPAXIO and brostallicin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. We may never become profitable, even if we are able to commercialize products currently in development or otherwise.

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

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. Unless we raise substantial additional capital and reduce our operating expenses, we may not be able to pay all of our operating expenses or repay our debt or the interest, liquidated damages or other payments that may become due with respect to our debt.

*We may be unable to use our net operating losses.*

We have substantial tax loss carryforwards for U.S. federal income tax purposes. As a result of prior changes in the stock ownership of the Company, our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Moreover, future changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

*We have received audit reports with a going concern disclosure on our consolidated financial statements.*

As we may need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their reports on our December 31, 2009, 2008 and 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our common stock and we may have a more difficult time obtaining necessary financing.

*Our common stock is listed on the NASDAQ Capital Market and the Mercato Telematico Azionario stock market in Italy, or the MTA, and we may not be able to maintain those listings or trading on these exchanges may be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.*

Effective with the opening of trading on January 8, 2009, the U.S. listing of our common stock was transferred to the NASDAQ Capital Market, subject to meeting a minimum market value of listed securities of $35 million. The NASDAQ Stock Market LLC s, or NASDAQ, Listing Qualifications Panel, or the Panel, approved this transfer after our market capitalization did not comply with the minimum market capitalization required for companies listed on the NASDAQ Global Market, and we presented a plan to the Panel for regaining compliance with the NASDAQ Marketplace Rules. On January 23, 2009, we received an Additional Staff Determination Letter from the NASDAQ that stated that the NASDAQ staff had concluded that we had violated Marketplace Rule 4350(i)(1)(C) (now Marketplace Rule 5635), which requires shareholder approval in connection with an acquisition if the issuance or potential issuance is greater than 20% of the pre-acquisition shares outstanding, and that we had at times not

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complied with Marketplace Rule 4310(c)(17) regarding submission of a Listing of Additional Shares form. On February 18, 2009, we updated the Panel on our plan for regaining compliance and requested an extension of the deadline to regain compliance with the minimum market capitalization requirement for the NASDAQ Capital Market. On March 6, 2009, we were notified by the NASDAQ that the Panel had determined to continue the listing of our common stock on the NASDAQ Capital Market, subject to the condition that, on or before April 6, 2009, we demonstrate compliance with all applicable standards for continued listing on the NASDAQ Capital Market, including the $35 million minimum market capitalization requirement. In addition, the Panel issued a public reprimand for our prior failures to comply with the shareholder approval requirements and late filing of Listing of Additional Shares forms. On April 2, 2009, we were notified by the NASDAQ that we had complied with the Panel s decision dated March 6, 2009, and, accordingly, the Panel had determined to continue the listing of our common stock on the NASDAQ Capital Market.

NASDAQ reinstated the $1.00 minimum bid price requirement on August 3, 2009 and there can be no assurances that our stock price will be $1.00 or above. At our special meeting of shareholders held on March 24, 2009, the proposal to allow the Board, in its discretion, to effect a reverse stock split of our common stock was not approved by the shareholders. At any time our stock price is below $1.00, we may not be able to effect a reverse stock split to increase our stock price if we are unable to obtain shareholder approval of a reverse stock split in the future. On May 3, 2010, we received notice from NASDAQ indicating that for the last 30 consecutive business days the closing bid price of our common stock was below the minimum $1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2). This notification has no immediate effect on the listing of or the ability to trade our common stock on The NASDAQ Capital Market. In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have been provided a grace period of 180 calendar days, or until November 1, 2010, to regain compliance. We will achieve compliance if the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days before November 1, 2010. If we are unable to attain compliance with the minimum bid price we may be delisted. In addition, if we fail to maintain the minimum value of listed securities, we may be delisted. The level of trading activity of our common stock may decline if it is no longer listed on the NASDAQ Capital Market. Furthermore, our failure to maintain a listing on the NASDAQ Capital Market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, if our common stock ceases to be listed for trading on the NASDAQ Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to sell shares of our common stock.

In the event our common stock is delisted from NASDAQ, we currently expect that our common stock would be eligible to be listed on the OTC Bulletin Board or Pink Sheets. We do not know what impact delisting from NASDAQ may have on our listing with the Borsa Italiana.

Although we continue to be listed on the NASDAQ Capital Market, trading in our common stock may be halted or suspended due to market conditions or if NASDAQ, CONSOB or the Borsa Italiana determines that trading in our common stock is inadvisable. Trading in our common stock was halted by the Borsa Italiana on February 10, 2009, and, as a consequence, trading in our common stock was halted by NASDAQ. After we provided CONSOB with additional information and clarification on our business operations and financial condition, as requested, and published a press release containing such information in Italy, CONSOB and NASDAQ lifted the trading halt on our stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA and resumed trading prior to opening of the MTA the next day after we filed a press release regarding the explanatory paragraph in our auditor s reports on our December 31, 2008 and 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. As a consequence, NASDAQ also halted trading in our common stock on March 23, 2009, but re-initiated trading later that day. Although we file press releases with CONSOB at the end of each month regarding our business and financial condition, CONSOB may make additional inquiries about our business and financial conditions at any time, and there can be no guarantee that CONSOB or NASDAQ will not halt trading in our shares again in the future.

If our common stock ceases to be listed for trading on the NASDAQ Capital Market, the MTA, or both for any reason or if trading in our stock is halted or suspended on the NASDAQ Capital Market, the MTA or both, such events may harm the trading price of our securities, increase the volatility of the trading price of our securities and make it more difficult for investors to buy or sell shares of our common stock. Moreover, if our common stock

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ceases to be listed for trading on the NASDAQ Capital Market or if trading in our stock is halted or suspended on the NASDAQ Capital Market, we may become subject to certain obligations. In addition, if we are not listed on the NASDAQ Capital Market and/or if our public float falls below $75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations may have a material adverse effect on our ability to raise the capital we need.

*The global financial crisis may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.*

The ongoing credit crisis and related turmoil in the global financial system has had and may continue to have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve or continue to worsen. In particular, our ability to access the capital markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so, which could have an adverse effect on our ability to meet our current and future funding requirements and on our flexibility to react to changing economic and business conditions.

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

Our common stock is traded on the MTA and we are required to also comply with the rules and regulations of CONSOB, which is the public authority responsible for regulating the Italian securities market, and the Borsa Italiana, which ensures the development of the managed market in Italy. Collectively these entities regulate companies listed on Italy s public markets. Conducting our operations in a manner that complies with all of the 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 of the applicable regulatory regimes. In addition, the Borsa Italiana and CONSOB have made several requests for information asking us to provide additional clarifications about our business operations and financial condition, and we have complied with such requests and have met with CONSOB on several occasions to answer questions. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

In addition, under Italian law, we must publish a listing prospectus that has been approved by CONSOB prior to issuing common stock that exceeds, in any twelve-month period, 10% of the number of shares of our common stock outstanding at the beginning of that period. We have attempted to publish a listing prospectus in Italy to cover our general offerings for the past two years, beginning in April 2007. After working with CONSOB to meet its requirements to publish that listing prospectus for the remainder of 2007, we were finally able to publish a listing prospectus in January 2008; however, that listing prospectus was limited to shares to be issued to Société Générale under the Step-Up Equity Financing Agreement we entered into with Société Générale in 2006, which has since terminated. After meeting with CONSOB in 2008 to further discuss its requirements for a more general listing prospectus, we filed a new listing prospectus on December 31, 2008, which was rejected by CONSOB on January 16, 2009. On January 28, 2009, we filed a registration document (i.e., one of the three documents that, according to European Regulation No. 809/2004 and together with the securities note and the summary, constitute a listing prospectus, which can be separately filed, examined and eventually approved by CONSOB).

On July 2, 2009, after several requests of supplements, clarifications and submissions of new drafts of our registration document, CONSOB informed us that the relevant administrative procedure for CONSOB s authorization to publish the registration document had expired since CONSOB alleged that we had not amended the text of the registration document to provide certain information CONSOB had requested. On July 23, 2009, we filed a new draft of the registration document and on September 24, 2009, CONSOB approved publication of such registration document. On September 29, 2009, we published the registration document in Italy and we may use it to register our securities on the Italian stock market.

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The registration document will be effective for twelve months from the date of its publication (i.e., twelve months from September 29, 2009). Within such twelve-month period, we will also have to obtain CONSOB s clearance over the relevant securities note and summary, which together with the registration document, will constitute a listing prospectus. A listing prospectus allows us to issue common stock and have it admitted to listing on the Italian MTA over the aforesaid threshold of 10% of the number of shares of our common stock outstanding at the beginning of any twelve-month period. We have already reached this 10% threshold limit through issuances of shares of our common stock over the past twelve months. Pending CONSOB s clearance of the securities note and the summary, we are required to raise money using alternative forms of securities. For example, we may need to use convertible preferred stock and convertible debt in lieu of our common stock because convertible preferred stock and convertible debt, subject to the provisions of European Directive No. 71/2003 and according to the interpretations of the Committee of European Securities Regulators (CESR), are not subject to the 10% limitation imposed by European Union and Italian law.

Moreover, on December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd., or Midsummer, on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58/1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On April 30, 2010, CONSOB notified us that it has begun the preliminary investigation for its decision on these administrative proceedings.

On December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information reported, at CONSOB s request, in the press release disseminated on December 19, 2008 and March 23, 2009. The sanctions established by the Section 193, paragraph 1 of the Italian Legislative Decree no. 58.1998 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, applicable to each one of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules).

*Our assets and liabilities that remain in our Italian branch make us subject to increased risk regarding currency exchange rate fluctuations.*

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. As long as we continue to have assets and liabilities held in our Italian branch, the carrying value of these 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.

*We may owe additional amounts for value added taxes related to our operations in Europe.*

Our European operations are subject to Value Added Tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is $6.0 million and $6.3 million as of March 31, 2010 and December 31, 2009. On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments including interest and penalties for the years 2003 and 2005 are 0.5 million and 5.5 million, or approximately $0.7 million and $7.4 million

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as of March 31, 2010, respectively. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed and we intend to vigorously defend ourselves against the assessments and have requested a dismissal on procedural grounds and merits of the case. However, if we are unable to defend ourselves against the year 2003 and 2005 assessments and if we receive an assessment for subsequent years, it may harm our results of operations and financial condition.

*Our financial condition may be adversely affected if third parties default in the performance of contractual obligations.*

Because we do not currently have any marketed products producing revenue, our business is dependent on the performance by third parties of their responsibilities under contractual relationships and if third parties default on their performance of their contractual obligations, we could suffer significant financial losses and operational problems, which could in turn adversely affect our financial performance, cash flows or results of operations and may jeopardize our ability to maintain our operations.

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

We have entered into a License and Co-Development agreement related to OPAXIO and pixantrone with Novartis pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize pixantrone. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to pixantrone and we are able to reach a definitive agreement or Novartis elects to participate in the development and commercialization of OPAXIO. Novartis is under no obligation to make such election and enter into a definitive license agreement 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. In the event Novartis does not elect to participate in the development of OPAXIO or pixantrone, we may not be able to find another suitable partner for the commercialization and development of those products, which may have an adverse effect on our ability to bring those drugs to market. In addition, we would need to obtain a release from Novartis prior to entering into any agreement to develop and commercialize pixantrone or OPAXIO with a third party. As announced on April 9, 2010, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone. The FDA cited as its primary reason for the action its concerns previously raised at the Oncologic Drugs Advisory Committee, or ODAC, meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of pixantrone. Based on the FDA s ODAC presentation, which provided ODAC and us with alternative options to consider to make investigational drugs available to patients if drugs need to be studied further prior to approval, we have decided to pursue expanded access program for pixantrone while we conduct an additional study in aggressive NHL. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels to generate royalty or milestone payments even if Novartis elects to exercise its option with regard to pixantrone and enter into a definitive license agreement or to participate in the development and commercialization of OPAXIO. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time upon written notice to us.

*We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.*

Obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

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At the ODAC meeting on March 22, 2010, the ODAC panel did not recommend approval of our New Drug Application, or NDA, for pixantrone. Subsequently, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010 and recommended that we conduct an additional clinical trial to demonstrate the safety and effectiveness of pixantrone. Based on the FDA s ODAC presentation, which provided ODAC and us with alternative options to consider to make investigational drugs available to patients if drugs need to be studied further prior to approval, we have decided to pursue expanded access program for pixantrone while we conducts an additional study in aggressive NHL. We expect that we will need at least an additional clinical trial to obtain FDA approval of our NDA for pixantrone and we do not know what this trial will cost. We may also need more than one additional clinical trial or we may need to take additional steps to obtain regulatory approval of pixantrone. The expense to design and conduct clinical trials are substantial and any additional clinical trials or actions we may need to pursue to obtain approval of our NDA for pixantrone may negatively affect our business, financial condition and results of operations.

*We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO given that our three STELLAR phase III clinical trials for the treatment of non-small cell lung cancer did not meet their primary endpoints and we withdrew our Marketing Authorization Application, or MAA, from the EMEA for first-line treatment of patients with advanced non-small lung cancer, or NSCLC, to refocus our resources on approval of OPAXIO for other indications.*

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

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

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA for OPAXIO in Europe on March 4, 2008 based on results of the STELLAR trials. In April 2009, the MAA was accepted for review by the EMEA; however, in September 2009, we notified the EMEA of our decision to withdraw the MAA and refocus our resources on the approval of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer.

*We are subject to extensive government regulation.*

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

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. On April 13, 2009, we began submission of a rolling NDA to the FDA for pixantrone to treat relapsed aggressive NHL. We completed the submission in June 2009 and as announced on April 9, 2010, we received a Complete Response Letter from the FDA regarding our NDA for pixantrone. The FDA cited as its primary reason for the action its concerns previously raised at the

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Oncologic Drugs Advisory Committee, or ODAC, meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of pixantrone. Based on the FDA s ODAC presentation, which provided ODAC and us with alternative options to consider to make investigational drugs available to patients if drugs need to be studied further prior to approval, we have decided to pursue expanded access program for pixantrone while we conduct an additional study in aggressive NHL.

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. In addition, data obtained from preclinical and clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business, financial condition and results of operations will be adversely affected.

In the event that we receive marketing approval for any of our product candidates, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. 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 us or our employees from participation in federal and state health care programs. Although we have policies prohibiting violations of relevant regulations and statutes, unauthorized actions of our employees or consultants, or unfavorable interpretations of such regulations or statutes may result in third parties or regulatory agencies bringing legal proceedings or enforcement actions against us. Because we will likely need to develop a new sales force for any future marketed products, we may have a greater risk of such violations from lack of adequate training or experience. The expense to retain and pay legal counsel and consultants to defend against any such proceedings would be substantial, and together with the diversion of management s time and attention to assist in any such defense, may negatively affect our business, financial condition and results of operations.

In addition, both before and after approval, our contract manufacturers and our products are subject to numerous regulatory requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA and other regulatory authorities periodically inspect manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort to maintain compliance. Failure to comply with FDA, EMEA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of $10.6 million and entered into a settlement agreement with the United States Attorney s Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct.

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

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

Because pixantrone is intended to provide less toxic treatments to patients who have failed standard chemotherapy treatment, if we are successful in bringing pixantrone 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.

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

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

Many of our competitors, particularly the multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial resources and substantially larger 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 current or future 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 continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. In the United States, given the comprehensive health care reform legislation that the President signed into law on March 23, 2010, under the Patient Protection and Affordable Care Act (HR 3590), or the PPACA, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of healthcare services and products and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals 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.

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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.

*If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.*

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations ( HMOs ). Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

*Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market.*

The successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market for several reasons, including:

- clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;
- preclinical tests may show the product to be toxic or lack efficacy in animal models;
- failure to receive the necessary U.S. and international regulatory approvals or a delay in receiving such approvals;
- difficulties in formulating the product, scaling the manufacturing process, or getting approval for manufacturing;
- manufacturing costs, pricing, reimbursement issues or other factors may make the product uneconomical to commercialize;
- other companies or people have or may have proprietary rights to a product candidate, such as patent rights, and will not let the product candidate be sold on reasonable terms, or at all; or
- the product candidate is not cost effective in light of existing therapeutics.

Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. In addition, any significant problem in the production of our products, such as the inability of a supplier to provide raw materials or supplies used to manufacture our products; equipment obsolescence, malfunctions or failures; product quality or contamination problems; or changes in regulatory requirements or standards that require modifications to our manufacturing process could delay, limit or prevent regulatory approval which could have a material adverse effect on our business, financial condition and results or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for our products.

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

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

*If there is an adverse outcome in the securities class actions and shareholder derivative litigation that have been filed against us, our business may be harmed.*

We and certain of our officers and directors are named as defendants in purported securities class action and shareholder derivative lawsuits filed in the United States District Court for the Western District of Washington. The securities class action lawsuits are brought on behalf of a putative class of purchasers of our securities from May 5, 2009 through March 19, 2010, and seek unspecified damages. As is typical in this type of litigation, additional purported securities class action and shareholder derivative lawsuits containing substantially similar allegations could be filed in the near future. We expect that all of the actions will be consolidated into one consolidated securities class action and one consolidated derivative action. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits. In the event of an adverse outcome, our business could be materially harmed.

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

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

- obtain patent protection for our products or processes both in the United States and other countries;
- protect trade secrets; and
- prevent others from infringing on our proprietary rights.

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

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

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

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

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

Our articles of incorporation require that a quorum, consisting of one-third of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our articles of incorporation, such as an amendment to increase our authorized capital stock, require the approval of a majority of our outstanding shares. A substantial majority of our common shares are held by Italian institutions and, under Italian laws and regulations, it is difficult to communicate with the beneficial holders of those shares to obtain votes. In 2006, when a quorum required a majority of the outstanding shares of our voting stock be represented in person or by proxy, we scheduled two annual meetings of shareholders, but were unable to obtain quorum at either meeting. Following that failure to obtain quorum, we contacted certain depository banks in Italy where significant numbers of shares of our common stock were held and asked them to cooperate by making a book-entry transfer of their share positions at Monte Titoli to their U.S. correspondent bank, who would then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks contacted agreed to make the share transfer pursuant to these arrangements as of the record date of the meeting, subject to the relevant beneficial owner taking no action to direct the voting of such shares. Under Rule 452 of the New York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as the uncontested election of directors, an amendment to our articles of incorporation to increase authorized shares that are to be used for general corporate purposes, and the ratification of our auditors. As a result of this custody transfer, we were able to hold special meetings of the shareholders in April 2007, January 2008 and March 2009 and annual meetings of the shareholders in September 2007, June 2008 and October 2009. At the meeting in June 2008, our shareholders approved a proposal to reduce our quorum requirement from a majority of outstanding voting shares to one-third of outstanding voting shares. However, obtaining a quorum at future meetings even at the lower threshold and obtaining necessary shareholder approvals will depend in part upon the willingness of the Italian depository banks to continue participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to participate in custody transfer arrangements in the future. We are continuing to explore other alternatives to achieve quorum for and shareholder representation at our meetings; however, we cannot be certain that we will find an alternate method if we are unable to continue to use the custody transfer arrangements. As a result, we may be unable to obtain a quorum at future annual or special meetings of shareholders or obtain shareholder approval of proposals when needed.

If we are unable to obtain a quorum at our shareholder meetings and thus fail to get shareholder approval of corporate actions, such failure could have a materially adverse effect on us. Even if we obtain quorum, we may not obtain enough votes to approve matters to be resolved upon at the shareholders meeting. In addition, brokers may

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only vote on those matters for which broker discretionary voting is allowed under Rule 452 of the New York Stock Exchange, and we may not be able to obtain the required number of votes to approve certain proposals (i.e., such as a proposal to increase the number of authorized shares) that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, including the proposal submitted to our shareholders to be determined at the special meeting of shareholders that has been adjourned to May 14, 2010 to increase the number of authorized shares of our common stock, such failure could have a material adverse effect on us. For example, a proposal to approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting.

*We could fail in financing efforts or be delisted from NASDAQ if we fail to receive shareholder approval when needed.*

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

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

We may not be able to continue to purchase the materials necessary to produce OPAXIO, including paclitaxel, in adequate volume and quality. Paclitaxel is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. Paclitaxel is available and we have purchased it from several sources. We purchase the raw materials paclitaxel and polyglutamic acid from single sources. 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 qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

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

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

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by United States and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers and contract service providers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Failure to comply with FDA, EMEA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

In addition, one of our other products under development, OPAXIO, has a complex manufacturing process and supply chain, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredients and drug products for pixantrone and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both pixantrone and brostallicin are to be manufactured and distributed by

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different single vendors. We are currently disputing our right to cancel the exclusive manufacturing contract between us and the former manufacturer of pixantrone. We assert multiple grounds for terminating this exclusive manufacturing agreement, which the former manufacturer disputes. The former manufacturer has asserted that we do not have the right to terminate the manufacturing contracts and has filed a lawsuit in the Court of Milan to compel us to source pixantrone from that manufacturer. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. The next hearing date is scheduled for November 11, 2010.

*If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.*

We divested our commercial product, TRISENOX, in July 2005 and fully divested our commercial product, Zevalin, in March 2009. Currently, we do not have a marketed product, and unless we are able to develop one of our product candidates, such as pixantrone, into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixantrone, OPAXIO and brostallicin are currently in clinical trials; these clinical trials may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, 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 these and any additional product candidates. Even if our trials are viewed as successful, we may not get regulatory approval. 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 in-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. All of our product candidates in clinical development are in-licensed from a third-party, including pixantrone, OPAXIO and brostallicin.

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

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

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors. For example:

- 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 require significantly more time, resources or expertise than originally expected to be necessary;

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- clinical testing may not show potential products to be safe and efficacious and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;

- clinical testing may show that potential products are not appropriate for the specific indication for which they are being tested;

- 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;

- 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; and

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

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

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

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

- collaborative arrangements may not be on terms favorable to us;

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

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

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

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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 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 will not develop into commercial products.

*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 the product use in our clinical trials for our product candidates, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will not provide adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of 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 the regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

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

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

*The unfavorable outcome of litigation and other claims against us could have a material adverse impact on our financial condition and results of operations.*

We are subject to a variety of claims and lawsuits from time to time, some of which arise in the ordinary course of our business. Adverse outcomes in some or all of such pending cases may result in significant monetary damages

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or injunctive relief against us. While we currently believe that resolution of these matters, individually or in the aggregate, will not have a material adverse impact on our financial position, results of operations or trading price of our securities, the ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future. It is possible that our financial condition and results of operations could be materially adversely affected in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable.

*Our financial condition and results of operations could be adversely affected by public health issues, wars and other military action, as well as terrorist attacks and threats and government responses thereto, especially if any such actions were directed at us or our facilities or customers.*

Public health issues, terrorist attacks in the United States and elsewhere, government responses thereto, and military actions in Iraq, Afghanistan and elsewhere, may disrupt our operations or those of our customers and suppliers and may affect the availability of materials needed to manufacture our products or the means to transport those materials to manufacturing facilities and finished products to customers. In June 2009, the World Health Organization declared an H1N1 influenza, or swine flu, pandemic, and such pandemic could cause damage or disruption to international commerce by creating economic and political uncertainties that may have a strong negative impact on the global economy, us, and our customers or suppliers. Should the severity of the H1N1 influenza pandemic increase or other public health issues arise, we could be negatively impacted by the need for more stringent employee travel restrictions, additional limitations in the availability of freight services, governmental actions limiting the movement of products between various regions and disruptions in the operations of our customers or suppliers. The long-term effects of the H1N1 pandemic, the terrorist attacks, and the ongoing war on terrorism on our business and on the global economy remain unknown. In addition, any of these events could increase volatility in the United States and world financial markets which may depress the price of our common stock and may limit the capital resources available to us or our customers or suppliers, which could result in decreased orders from customers, less favorable financing terms from suppliers, and scarcity or increased costs of materials and components of our products. Additionally, terrorist attacks directly upon us may significantly disrupt our ability to conduct our business. Any of these occurrences could have a significant impact on our operating results, revenues and costs and may result in increased volatility of the trading price of our securities.

*Higher health care costs could adversely affect our business.*

We will be impacted by the recent passage of the PPACA. Under the PPACA, we may be required to amend our health care plans to, among other things, provide affordable coverage, as defined in the PPACA, to all employees, or otherwise be subject to a payment per employee based on the affordability criteria in the Act: cover adult children of our employees to age 26; delete lifetime limits; and delete pre-existing condition limitations. Many of these requirements will be phased in over a period of time. Additionally, some states and localities have passed state and local laws mandating the provision of certain levels of health benefits by some employers. Increased health care costs could have a material adverse effect on our business, financial condition and results of operations.

**Risks Related To the Securities Markets**

*The market price for shares of our common stock 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 May 3, 2010, our stock price has ranged from a low of $0.12 to a high of $2.23. 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;

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our issuance of additional debt, equity or other securities, which we need to pursue in 2010 to generate additional funds to cover our current debt and operating expenses;

our quarterly operating results;

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts recommendations;

short selling;

changes in health care policies and practices;

halting or suspension of trading in our common stock by NASDAQ, CONSOB or the Borsa Italiana;

economic and other external factors; and

general market conditions.

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

*Anti-takeover provisions in our charter documents, in our Shareholder Rights Agreement, or Rights Agreement, 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 second amended and restated bylaws, or our bylaws, may have the effect of deterring or delaying attempts by our shareholders to remove or replace management, to commence proxy contests, or to effect changes in control. These provisions include:

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

elimination of cumulative voting in the election of directors;

procedures for advance notification of shareholder nominations and proposals;

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

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

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Pursuant to our Rights Agreement, an acquisition of 20% or more of our common stock could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20% shareholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. The existence of our Rights Agreement could have the effect of delaying, deferring or preventing a third party from making an acquisition proposal for us and may inhibit a change in control that some, or a majority, of our stockholders might believe to be in their best interest or that could give our stockholders the opportunity to realize a premium over the then-prevailing market prices for their shares.

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 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. (Removed and Reserved)**

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

(a) Exhibits

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| 3.1 | Registrant s Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008). |
| 3.2 | Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on February 9, 2009). |
| 3.3 | Registrant s Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on March 27, 2009). |
| 3.4 | Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 13, 2009). |
| 3.5 | Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on August 21, 2009). |
| 3.6 | Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on December 28, 2009). |
| 3.7 | Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on January 19, 2010). |

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| 3.8 | Registrant s Articles of Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on April 5, 2010). |
| 3.9 | Registrant s Second Amended and Restated Bylaws (incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on February 22, 2010). |
| 4.1 | Form of Common Stock Purchase Warrant, dated January 19, 2010 (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on January 19, 2010). |
| 4.2 | Form of Series 4 Preferred Stock Certificate (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 5, 2010). |
| 4.3 | Form of Common Stock Purchase Warrant, dated April 6, 2010 (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 5, 2010). |
| 10.1 | Form of Securities Purchase Agreement (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on January 19, 2010). |
| 10.2 | Form of Securities Purchase Agreement (incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on April 5, 2010). |
| 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: May 6, 2010

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

Dated: May 6, 2010

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